AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

VA OUTREACH TO VETERANS AT RISK FOR HEPATITIS C INFECTION

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTH CONGRESS

FIRST SESSION

JUNE 9, 1999

Serial No. 106–30

Printed for the use of the Committee on Government Reform

Available via the World Wide Web: http://www.house.gov/reform

U.S. GOVERNMENT PRINTING OFFICE
59–652 CC WASHINGTON : 1999

COMMITTEE ON GOVERNMENT REFORM

DAN BURTON, Indiana, *Chairman*

BENJAMIN A. GILMAN, New York
CONSTANCE A. MORELLA, Maryland
CHRISTOPHER SHAYS, Connecticut
ILEANA ROS-LEHTINEN, Florida
JOHN M. MCHUGH, New York
STEPHEN HORN, California
JOHN L. MICA, Florida
THOMAS M. DAVIS, Virginia
DAVID M. MCINTOSH, Indiana
MARK E. SOUDER, Indiana
JOE SCARBOROUGH, Florida
STEVEN C. LATOURETTE, Ohio
MARSHALL "MARK" SANFORD, South Carolina
BOB BARR, Georgia
DAN MILLER, Florida
ASA HUTCHINSON, Arkansas
LEE TERRY, Nebraska
JUDY BIGGERT, Illinois
GREG WALDEN, Oregon
DOUG OSE, California
PAUL RYAN, Wisconsin
JOHN T. DOOLITTLE, California
HELEN CHENOWETH, Idaho

HENRY A. WAXMAN, California
TOM LANTOS, California
ROBERT E. WISE, JR., West Virginia
MAJOR R. OWENS, New York
EDOLPHUS TOWNS, New York
PAUL E. KANJORSKI, Pennsylvania
PATSY T. MINK, Hawaii
CAROLYN B. MALONEY, New York
ELEANOR HOLMES NORTON, Washington, DC
CHAKA FATTAH, Pennsylvania
ELIJAH E. CUMMINGS, Maryland
DENNIS J. KUCINICH, Ohio
ROD R. BLAGOJEVICH, Illinois
DANNY K. DAVIS, Illinois
JOHN F. TIERNEY, Massachusetts
JIM TURNER, Texas
THOMAS H. ALLEN, Maine
HAROLD E. FORD, JR., Tennessee
JANICE D. SCHAKOWSKY, Illinois

BERNARD SANDERS, Vermont (Independent)

KEVIN BINGER, *Staff Director*
DANIEL R. MOLL, *Deputy Staff Director*
DAVID A. KASS, *Deputy Counsel and Parliamentarian*
CARLA J. MARTIN, *Chief Clerk*
PHIL SCHILIRO, *Minority Staff Director*

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS

CHRISTOPHER SHAYS, Connecticut, *Chairman*

MARK E. SOUDER, Indiana
ILEANA ROS-LEHTINEN, Florida
JOHN M. MCHUGH, New York
JOHN L. MICA, Florida
DAVID M. MCINTOSH, Indiana
MARSHALL "MARK" SANFORD, South Carolina
LEE TERRY, Nebraska
JUDY BIGGERT, Illinois
HELEN CHENOWETH, Idaho

ROD R. BLAGOJEVICH, Illinois
TOM LANTOS, California
ROBERT E. WISE, JR., West Virginia
JOHN F. TIERNEY, Massachusetts
THOMAS H. ALLEN, Maine
EDOLPHUS TOWNS, New York
BERNARD SANDERS, Vermont (Independent)
JANICE D. SCHAKOWSKY, Illinois

EX OFFICIO

DAN BURTON, Indiana
HENRY A. WAXMAN, California

LAWRENCE J. HALLORAN, *Staff Director and Counsel*
MARCIA SAYER, *Professional Staff Member*
ROBERT NEWMAN, *Professional Staff Member*
JASON CHUNG, *Clerk*
DAVID RAPALLO, *Minority Counsel*

CONTENTS

Page

Hearing held on June 9, 1999 1

Statement of:

Baker, Terry, Vietnam Veterans of America and president of Veterans Aiming Towards Awareness; George C. Duggins, president, Vietnam Veterans of America, accompanied by Rick Weidman, director of Government Relations, Vietnam Veterans of America; Dr. Adrian DiBisceglie, professor, Department of Internal Medicine, St. Louis University, and medical director of the American Liver Foundation; and Dr. Alan Brownstein, president, American Liver Foundation 26

Garthwaite, Dr. Thomas L., Veterans Administration, Deputy Under Secretary for Health, accompanied by Dr. Tom Holohan, Chief Patient Care Services Officer; Dr. Toni Mitchell, MBA, chief consultant Acute Care, Strategic Health Care Group; James J. Farsetta, director, VISN Region III; and Dr. Simberkoff, chief of staff, New York Harbor Health Care System 3

Letters, statements, etc., submitted for the record by:

Baker, Terry, Vietnam Veterans of America and president of Veterans Aiming Towards Awareness, prepared statement of 30

Brownstein, Dr. Alan, president, American Liver Foundation, prepared statement of 57

DiBisceglie, Dr. Adrian, professor, Department of Internal Medicine, St. Louis University, and medical director of the American Liver Foundation, prepared statement of 46

Duggins, George C., president, Vietnam Veterans of America, prepared statement of 39

Garthwaite, Dr. Thomas L., Veterans Administration, Deputy Under Secretary for Health, prepared statement of 5

Snyder, Hon. Vic, a Representative in Congress from the State of Arkansas, prepared statement of 17

VA OUTREACH TO VETERANS AT RISK FOR HEPATITIS C INFECTION

WEDNESDAY, JUNE 9, 1999

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS, AND INTERNATIONAL RELATIONS,
COMMITTEE ON GOVERNMENT REFORM,
Washington, DC.

The subcommittee met, pursuant to notice, at 10 a.m., in room 2203, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Present: Representatives Shays, Biggert, Towns, Schakowsky, and Sanders.

Also present: Representative Snyder.

Staff present: Lawrence J. Halloran, staff director and counsel; J. Vincent Chase, chief investigator; Robert Newman and Marcia Sayer, professional staff members; Jason Chung, clerk; David Rapallo, minority counsel; and Jean Gosa, minority staff assistant.

Mr. SHAYS. Let me call this hearing to order. Last year the House adopted our committee's call for a more aggressive, coordinated public health response to the silent epidemic of hepatitis C, HCV, infection. We recommended steps to inform, test and offer treatment to the 4 million Americans affected by the lingering viral liver disease. Among those steps, we urged the Department of Veterans Affairs [VA], to determine the prevalence of HCV among VA patients and reach out to those at risk.

Why ask the already burdened VA health system to take a lead in a national public health effort? Because recent studies confirm 8 to 10 percent of all veterans suffer from HCV, four to five times the rate of infection in the general population. At one recent VA screening, more than a third of the veterans tested positive for HCV antibodies, with almost two-thirds of those having served in the Vietnam war era.

According to testimony we heard last year from former U.S. Surgeon General Dr. C. Everett Koop, the VA has a 5-year window to "head off very high rates of liver disease and liver transplants in VA facilities over the next decade" when those exposed to infected blood and blood products 20 to 30 years ago will seek care for acute symptoms, cirrhosis and liver cancer.

Early this year, VA Under Secretary Dr. Kenneth Kizer launched what he termed "an aggressive public health approach" to HCV by issuing guidelines to all VA facilities for screening, counseling and expensive drug therapies. His program calls for ambitious initiatives to educate patients and medical providers, expand epidemio-

logical and clinical research and extend treatment to all who might benefit, regardless of other eligibility criteria. He has set the VA on a bold, proactive, high risk course.

It was the right thing to do. In less than a year, the VA has made an impressive start toward the HCV awareness, testing, treatment and research some have been demanding for a decade. The challenge now, and the subject of our discussion today, is how the VA plans to sustain and expand that promising beginning.

We asked the VA to describe their program to translate a headquarters initiative into effective implementation strategies in all 22 VA service networks. We asked the department's partners in this effort—veterans service organizations and the American Liver Foundation—to describe the barriers to outreach and care they see every day, and which the VA must still overcome.

The hepatitis C initiative tests the VA capacity to inform patients, to educate physicians, to counsel those at risk and to deliver consistent care across a decentralized health system. For the VA, the price of success may be too high if estimates of prevalence are low, outreach is effective, and a $15,000 course of treatment is indicated for more than a fraction of those with the disease. For veterans with HCV, and for the Nation, the price of failure will be incalculable.

Our goal this morning: To keep the wind in the sails of the VA hepatitis C initiative and help guide the program toward sustainability and success. We appreciate the time, expertise, and dedication our witnesses bring to this important discussion, and we look forward to their testimony.

Let me introduce our first panel, Dr. Thomas Garthwaite, Veterans Administration, Deputy Under Secretary for Health, accompanied by Dr. Tom Holohan, Chief Patient Care Service Officer; Dr. Toni Mitchell, chief consultant Acute Care, Strategic Health Care Group; and James Farsetta, director, VISN, and Dr. Simberkoff. Dr. Simberkoff, your background is?

Dr. SIMBERKOFF. I am the infectious disease doctor and the chief of staff for the New York Harbor Health Care System, which are two of the facilities in network 3.

Mr. SHAYS. It is wonderful to have all of you here. At this time I will swear you in and then we will see a quick advertisement on the screen and then we will take your testimony.

[Witnesses sworn.]

Mr. SHAYS. I note for the record that all have responded in the affirmative.

At this time before taking your testimony I would like to see the new public service announcement on hepatitis C which is going to air soon. It is sponsored by the American Liver Foundation and Vietnam Veterans of America.

[Video shown.]

Mr. SHAYS. OK, Dr. Garthwaite, you have the floor. My assumption is that we have testimony from you, doctor, and then I will be happy to take comments if any of you want to make a point or two. It is important to put your comments on the record. Thank you for being here.

STATEMENT OF DR. THOMAS L. GARTHWAITE, VETERANS ADMINISTRATION, DEPUTY UNDER SECRETARY FOR HEALTH, ACCOMPANIED BY DR. TOM HOLOHAN, CHIEF, PATIENT CARE SERVICES OFFICER; DR. TONI MITCHELL, MBA, CHIEF CONSULTANT ACUTE CARE, STRATEGIC HEALTH CARE GROUP; JAMES J. FARSETTA, DIRECTOR, VISN REGION III; AND DR. SIMBERKOFF, CHIEF OF STAFF, NEW YORK HARBOR HEALTH CARE SYSTEM

Dr. GARTHWAITE. Thank you, Mr. Chairman. We submitted a written statement for the record and I would just like to make several points before we get into the question and answer portion. First, I would just like to say that we believe that we have made significant progress since the previous hearing on hepatitis C. We have developed and promulgated policy about the diagnosis and screening for patients with hepatitis C. We have developed policy and promulgated it to patients with hepatitis C and we have dramatically increased the number of veterans who have been tested for hepatitis C. We have conducted a 1-day surveillance study of patients presenting to our medical centers who have had blood tests for other reasons and tested their blood for hepatitis C, which has given rise to a better sense of what the actual incidence might be in the total veteran population. We have founded two centers for the leadership in study and education, and our strategy is to meet the challenge of providing care for veterans who are infected with the hepatitis C virus.

We have conducted a conference where 500 caregivers came to Washington and heard and were educated about strategies for diagnosis and treatment of hepatitis C. We have participated in an interagency work group with the Department of Defense Health and Human Services and VA about strategies of the government toward hepatitis C. We have introduced a budget initiative in our fiscal year 2000 budget to provide additional funding so we might meet the treatment and diagnostic needs for patients.

Finally, we have continued our research of about $12 million, 137 projects with 30 investigators. All of this is designed to aggressively approach what is a very significant problem for veterans and for all Americans infected with this virus. We face several challenges. One of the challenges is how to do outreach and how to reach the right people without inducing undo concern in those who don't have the virus, and the video that we just saw will be an important part of that effort, and we will face significant challenges in treating and teaching each of those individuals about the risks and concerns about hepatitis C.

Second, we have an issue about how to take all of the patients that we do treat on a regular basis and make sure that we appropriately screen those and then for those who are screened at high risk, make sure that we test and educate them as well. We have a policy that says we will do that today. The question is how do you get policy to happen 100 percent of the time in a very large system.

One of the things that we can do is education and we have taken significant steps in education, including various conference calls that we have had, and a variety of other methods. Another way is to improve our computer systems and put automated reminders

into the encounter software so that it automatically checks to see if screening and testing has been done, and if it hasn't to remind clinicians to do such things, and we are pursuing that as an avenue to make sure that it only happens because of education, but there are reminder systems to remind the myriad of clinicians who come and go through VA hospitals to take that into account.

Finally, we need to make sure that treatment is uniform. We have guidelines, but guidelines require education and human beings are fallible when it comes to education so we need to provide additional systems to make that happen and we are undertaking a match of our pharmacy data bases with that of our test data bases to see whether of those who are tested how many are treated, and then we will sample that to see if those who are not treated, whether the patient has refused treatment or whether there are contraindications. I think our biggest fear is pressures on the budget will prevent people from getting treatment, and we don't find that acceptable and want to make sure that does not happen.

We have a series of challenges ahead of us, but we have made significant progress. Like many other diseases of veterans, they are highly complex issues and it is a very large system and it requires a significant amount of teamwork and that is why we brought a number of team members here to the hearing today. We hope that we will be able to answer all of your questions and look forward to dialog on this important topic. Thank you.

[The prepared statement of Dr. Garthwaite follows:]

Statement of
Thomas L. Garthwaite, M.D.
Deputy Under Secretary for Health
Department of Veterans Affairs
Before the
Subcommittee on National Security, Veterans Affairs,
and International Relations
Committee on Government Reform
U. S. House of Representatives

June 9, 1999

Mr. Chairman and members of the committee, I am pleased to appear before you today to discuss VA's efforts to respond to health problems caused by hepatitis C infection.

Since the issuance of the patient evaluation and diagnostic guidelines in June of last year, VA has made significant progress in combating hepatitis C infection (HCV) in our patients. These efforts include the further development and full implementation of our Emerging Pathogens Registry, the preparation and dissemination of enhanced guidelines for diagnosis and treatment, the establishment of Centers of Excellence in HCV, the completion of a large national surveillance project, and the expansion of educational and informational activities for both patients and providers throughout the VA.

Registry

The Emerging Pathogen Registry (EPR) is a national database that includes the results of all HCV antibody tests performed VA-wide and a compilation of the unique veteran patients whose tests indicate infection with HCV. The Registry can also be accessed to determine the medical center and Veterans Integrated Service Network (VISN) to which individual HCV patients are

assigned. At the end of calendar year 1998, approximately 26,000 veterans had positive tests for HCV and were in the registry.

VHA is in the process of merging Registry data with data from our Pharmacy Benefits Management Program. This merger of data should enable us to generate a list of individual patients who have been prescribed interferon alone or in combination with ribavirin. Most such patients are under treatment for HCV although a few might be receiving the drugs for other reasons. A review of patients who have tested positive but who are not on drug treatment is planned and will allow us to understand the reasons behind a decision to not treat. At present, we have only expert opinion regarding the proportion of HCV-positive patients who are appropriate for treatment with current therapy. We believe VA will provide the first sizeable database in the United States to assess treatment strategies.

Centers of Excellence

Four months ago, two Centers of Excellence in Hepatitis C were established by VHA; these are located at the Medical Centers in San Francisco and Miami. The Centers are currently involved in a number of projects, including:

- Modification of our current diagnostic guidelines to maximize the identification of HCV patients while minimizing the cost of detection,
- Drafting recommendations for counseling veteran patients regarding HCV,
- Developing, in cooperation with the American Liver Foundation (ALF), veteran-specific educational materials,
- Developing a VHA Cooperative Studies Protocol for a formal epidemiologic study of HCV in the VA,
- Conducting clinical research on new drugs for the treatment of HCV. These therapies include compounds such as long acting (pegylated) interferon, inhibitors of inosine monophosphate dehydrogenase, and cytokines (such as interleukin). The VA Centers have been directly involved in the development of all the current FDA-approved treatments for HCV and will continue their government-industry collaborative activities.

Surveillance Study

Veteran patients have risk factors known to be associated with HCV infection more often than the civilian population. Thus, we have suspected that the prevalence of HCV in our patients is significantly higher than that in the general population. However, the only data available were from relatively small studies in urban medical centers. On March 17, 1999, VA conducted the largest single HCV surveillance study in the United States. Approximately 26,000 veteran patients who were having blood drawn on that date for any reason agreed to be tested for HCV. Nationwide, 8% of those tested were antibody-positive. This prevalence is more than fourfold the national rate reported by the Centers for Disease Control and Prevention. We expected geographic variations in the observed proportion of HCV-positive patients and our results confirmed that assumption. Both the conditions necessary for completion of this testing on a single day, as well as the preliminary information on the local and national demographics of patients tested, have led us to conclude that 8% is more likely than not to be a low estimate of the true prevalence of HCV in VA patients. Risk factor questionnaires from this surveillance day are currently being analyzed and may be used to adjust or modify our diagnostic guidelines.

Education

A national symposium on HCV in VA was held on June 2-4. Representatives from every VISN were in attendance to hear presentations reviewing the epidemiology, natural history, diagnosis and treatment of HCV, presented by speakers with clinical and research expertise in public health, infectious disease, hepatology, and pharmacology. Each attendee was provided a detailed handbook on HCV, and a VA-specific set of slides. Slide sets will also be made available to all VA medical centers. The attendees are expected to act as a "core group" for HCV information and education to providers in each Network.

A web page has been established for VA providers and patient support groups. The site contains up-to-date clinical information on HCV, lists of current treatment trials, and data on advances in research.

Outreach

VA is working with the American Liver Foundation to target specific educational and informational programs to veterans. VA has been in contact with several Veteran Service Organizations and the Foundation, and has participated in editing and reviewing the information provided. VA will endeavor to work with both groups in a partnership for outreach within the veteran community.

VA is committed to minimizing any inconsistencies in the screening and testing of patients. As we have published and implemented our testing guidelines, our rate of testing for HCV has doubled (FY1998 to FY1999). To further increase testing in appropriate cases, we are studying the development of a reminder system in our VISTA patient care information system that will remind clinicians to screen and test high-risk patients who have not been previously screened or tested. In addition, we are enlisting coordinators at the network and medical center level to track and ensure compliance.

Summary

Mr. Chairman, VA has come a long way in a short period of time with regard to meeting the health needs of veterans with hepatitis C. We have additional work to do. We look forward to working with Congress to assure that current treatments are available to veterans and that better treatments for this serious disease are developed. This concludes my statement. I will be pleased to respond to the committee's questions.

Mr. SHAYS. Thank you. Any other comments before the questioning?

OK. What is the capacity of the VA to ensure that this program is implemented uniformly and equitably nationwide in all of our facilities?

Dr. GARTHWAITE. When you say capacity?

Mr. SHAYS. Capacity, financial facilities.

Dr. GARTHWAITE. Well, we have certainly made the commitment that we will make resources available to diagnose and treat hepatitis C among those veterans certainly for this year, and we assume into the future. So capacity in terms of budget, at least in the immediate future, I think we made a commitment that that is not an issue. We will diagnose and treat hepatitis C veterans.

There are some other clinical issues and I will ask my colleagues to amplify, but one of the issues is how do you get the expertise to each individual place a veteran can show up in the health care system and that has been part of our education initiative in having conferences and educating people from each network.

Mr. SHAYS. What would be helpful—let's just focus on the costs first. Break down the different elements that are involved. One is just educating—one is to educate all of your facilities on what they need to do. Another is how you educate the potential person with the disease in terms of coming forward and being tested. So there are costs involved there. Then there are other costs in terms of just diagnosis and then there are other costs in terms of treatment and maybe you can just—I would think if I were part of the VA system, and if I was one of the veterans groups my biggest concern would be that Congress will simply appropriate the same amount of money and you will have to find it somewhere else. So just give me a sense and make it a part of the record as to what the range of costs could be.

This is kind of a long question so I am happy to have others of you participate in the answer.

Dr. GARTHWAITE. Our budget estimate for the fiscal year 2000 budget was $250 million. But there are a lot of assumptions in there that we don't know whether they are accurate or not, but we think——

Mr. SHAYS. Which budget, the one that we are in now?

Dr. GARTHWAITE. The fiscal year 2000, the cycle that is being debated at the present time.

Mr. SHAYS. The budget we are going into. By the way, I am taking off my coat and if any of you want to do the same feel free. I would think of you better if you would remove your coat.

Mr. FARSETTA. Just don't ask us to step outside.

Dr. GARTHWAITE. We believe the cost for testing and treatment per case is about $15,000.

Mr. SHAYS. I just wanted to welcome our member from the minority side, Ms. Schakowsky, and if I could get some business out of the way, I would ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and the record remain open for 3 days for that purpose and without objection, so ordered. And ask further unanimous consent that all witnesses are permitted to include their written statement

in the record and without objection, so ordered. Is there any point that you would like to make?

Ms. SCHAKOWSKY. As a freshman I have proven that showing up counts because I am the ranking member on this side.

Mr. SHAYS. And I want you to treat her with the respect that a ranking member requires. It is very nice to have you here, Ms. Schakowsky. Right now we are going to have the VA walk through the potential cost of getting the system to know how to deal with this issue, how to alert veterans that they need to come forward and also the cost of diagnosis and the cost of treatment.

Dr. GARTHWAITE. Let me ask Tom Holohan, who has done a lot of our cost estimating.

Dr. HOLOHAN. Let me briefly go through some of the factors that are involved in any cost estimates and one of the distressing things from a scientific or medical point of view versus a budgetary point of view is the budget people don't like ranges. They like a precise figure. They want a number that they can write a check. Unfortunately in this instance, that is not really possible. The cost of testing an individual patient can run anywhere from $10 to $50. The initial test is an immunoassay antibody test. If that is positive, it is automatically repeated and depending on the risk factors you may ask for an additional test called the RIBA, radio immune blot assay. Subsequent to that testing if the patient is positive and you are considering that they may be treatable, there are other tests that are indicated. The standard of care now includes measuring viral RNA, which is a moderately expensive test. It also requires—it is recommended that a liver biopsy be performed prior to treatment and there are also now recommendations for viral genotype testing which are in the range of $200 to $300 because those provide you with prognostic factors which may tell you how long the treatment should go on for. Mr. SHAYS. So if we add that up, it amounts to how much per patient?

Dr. HOLOHAN. At that point you are probably talking about several thousand dollars before you initiate treatment. That is not including opportunity costs, physician time, nurse time.

Mr. SHAYS. First the test to show if someone has hepatitis C, what does it cost?

Dr. HOLOHAN. The initial testing would be in the range of $10 to $20 per head.

Mr. SHAYS. By then we know that they are at risk?

Dr. HOLOHAN. Yes.

Mr. SHAYS. And the next test is to decide what kind of treatment is advisable?

Dr. HOLOHAN. The next test is the radio immune blot assay. That is a confirmatory test that is in the range of $50. Subsequent to that——

Mr. SHAYS. And that tells you what?

Dr. HOLOHAN. That confirms that the patient is antibody positive, it is not a false positive.

Mr. SHAYS. They are at risk, and the next one is they have it or don't have it, and we are up to about $70 give or take?

Dr. HOLOHAN. That is correct. The next set of tests would include measurement of viral RNA, and that is in the range of $200 and that is both diagnostic and prognostic. That is repeated during any

treatment phase so you know whether or not you are in fact eliminating the virus. It is recommended that every patient prior to treatment have a liver biopsy, and the private sector estimates of those costs are in the $1,000 to $2,000 range. The VA estimates are that we can do that for about $500 in round numbers.

Mr. SHAYS. You do it internally?

Dr. HOLOHAN. Yes. We can do it for less cost than the private sector. The viral genotyping is approximately $300. These are estimates. You might get a better buy in California than in Peoria.

Those tests would have to be repeated at various intervals. The viral RNA test you would repeat because one of your determinations at the end of treatment is whether the patient has in fact responded to treatment and there are two measures of that. One are routine liver function tests which are relatively inexpensive and whether in fact you have eliminated the viral RNA. The treatment costs for the currently recommended dual therapy are probably in the range of $12,000 to $15,000 for a course, which is recommended to be 48 weeks or approximately a year.

Mr. SHAYS. What does that buy you?

Dr. HOLOHAN. That buys you treatment with interferon and ribavirin.

Mr. SHAYS. And the outcome is what?

Dr. HOLOHAN. I am not sure, what do you mean? What proportion of patients——

Mr. SHAYS. We treat patients because we hope to have a positive impact. What is the positive impact?

Dr. HOLOHAN. In general most studies have shown that combined treatment with ribavirin with interferon will clear the virus 6 months after treatment in somewhere between 40 and 50 percent of cases. That is about twice as high as the viral clearance rate with treatment with interferon alone. I should caution, however, that we don't know that those data will necessarily apply when we treat veteran patients because the demographics of the patients treated in most of the published literature with those regimes are dissimilar demographics from our veteran demographics. We have a higher number of minority patients who tend not to respond as well to treatment. In the VA we may get a lower rate of viral clearance, but we don't know that yet.

Mr. SHAYS. I was told that when we do this type of treatment, about 40 percent will see a very noticeable benefit.

Dr. HOLOHAN. Right.

Mr. SHAYS. But I didn't pursue it to know—are we extending someone's life? Is the liver going to last a little longer? Are people literally healed? I have been led to believe that hepatitis C, you are not going to be healed, at least what we know now.

Dr. HOLOHAN. Again, some of the answers—the difference between what we can provide an opinion on medically——

Mr. SHAYS. I don't mind a range of possibilities here.

Dr. HOLOHAN. There are liver specialists who have used the word "cure" with respect to sustained viral elimination in hepatitis C. Dr. Schiff, who works with the VA in the Miami Center of Excellence, has used that word, but then we will routinely qualify it and say as far as we know.

Mr. SHAYS. Your expertise primarily is on the financial side of this?

Dr. HOLOHAN. No, which should be apparent as I continue to speak.

Mr. SHAYS. You have endeared me to you already.

Dr. HOLOHAN. Thank you.

The bottom line is we are not certain if there will be an absolute cure. We do have data that show patients who have cleared virus and have remained virus free for some years after completion of dual treatment therapy. There is some hope that you can put yourself in the circumstance of HIV infection where you can very strongly effect the prognosis of the patient but perhaps not totally cure him. We don't know the answer to that yet.

Mr. SHAYS. We really got into the whole issue of hepatitis C kind of as a silent disease following the infection of blood supply with AIDS.

Dr. Simberkoff.

Dr. SIMBERKOFF. Yes, if I can amplify on Dr. Holohan's answer, the cure rate that is being quoted involves precisely that, eradication of the virus from the blood. None of the patients have been followed long enough to determine whether their life expectancy is affected by these treatments or whether or not they will go on to develop further liver disease. So I think these treatments are relatively new and we need to have lots and lots of followup of patients, particularly in our population.

Mr. SHAYS. How much is spent so far? How much did we put in this year's budget just capturing from other parts of your budget. You are asking for 250 in our next year's budget, in fiscal year 2000, but what did we put in 1999?

Dr. GARTHWAITE. There is no specific targeted amount for hepatitis C in this budget.

Mr. SHAYS. You are just absorbing it?

Dr. GARTHWAITE. Right.

Mr. SHAYS. Do you know how much you have spent so far?

Dr. GARTHWAITE. I don't know that we are able to make that assessment.

Mr. SHAYS. Can you give me a sense what you have learned to date, and we can go from there.

Dr. GARTHWAITE. We have tested approximately 200,000 veterans and diagnosed 38,000 give or take.

Mr. SHAYS. Out of 200,000?

Dr. GARTHWAITE. Right. 200,000 individual tests have been done in the last 18 months, and about 38,000 unique individuals tested positive for hepatitis C.

Mr. SHAYS. Let me ask you the basic question, a veteran comes in routinely or you ask them to, or is it a combination of both? Then tell me how they are told about hepatitis C and then what you do.

Dr. HOLOHAN. Well, the information letter that was sent out last June instructs clinicians to ask patients if they have any of the specific risk factors for hepatitis C. If they do, they are supposed to be counseled on the advisability of antibody testing for hepatitis C. We don't routinely test everyone who walks in the door because

the false positive rate is not insignificant in this disease and it would be——

Mr. SHAYS. Give me a sense of what not insignificant means to you?

Dr. HOLOHAN. If the prevalence in the population that you are testing is below 10 percent, the likelihood of the test reported as positive being true positive is lower than the likelihood that it is false positive. And most of that data are available from the routine hepatitis C testing of donated blood.

Mr. SHAYS. You have a double negative in there. I am having a hard time in sorting that out.

Dr. HOLOHAN. The likelihood of a positive test being true positive relates to what the pretest probability of the disease was.

So if you screen all donated blood from let's say healthy active duty military people and you get a positive result from John Smith, the likelihood is that is a false positive.

Mr. SHAYS. And you have to spend $50 more to find that out?

Dr. HOLOHAN. Right. The biggest problems in our assumptions about the financial implications of hepatitis C relate to the problem that we don't know at least two facts, one of which is what is the true prevalence of hepatitis C in our patients. We think we have a better handle on it now than we did 6 months ago, but we are uncertain and the projected cost is very dependent on the prevalence of the disease. The second thing we don't know is what percentage of our patients are treatable. You will hear testimony later today that talks about 10 percent. One of our hepatology experts has provided her opinion that it is 20 percent and other people in the VA who are equally knowledgeable have said 40 percent. So when you are making predictions on the cost, it is extraordinarily dependent on that. Finally, we are not sure what percentage of our patients will continue with the full 48-week treatment course. As you will probably hear, these drugs have very, very significant side effects and it takes a high degree of motivation for a patient who may not feel ill when you start treatment and you make him feel much worse.

Mr. SHAYS. I am going to give up the floor but I will want to come back later and see how we deal with it in a particular area. Mr. Farsetta, I will be coming back to you.

Ms. SCHAKOWSKY. Thank you, Mr. Chairman. I wanted to ask a couple of questions about health care workers and the exposure and the risk that they are at. According to the Centers for Disease Control, health care workers are one of the groups that are most at risk of hepatitis C infection due to needle sticks and so I was wondering if the Veterans Administration plans to adopt the use of safety design needles and sharps in order to reduce the risk to health care workers?

Dr. GARTHWAITE. Clearly we have already been using universal precautions for a long period of time. To my knowledge a significant number of our medical centers already have adopted safe needles and advanced needle and IV designs that decrease the likelihood of needle sticks in health care workers.

Ms. SCHAKOWSKY. Is that policy though or is that just procedure at some of the places?

Dr. HOLOHAN. It is not policy. Actually this has been around for a little while. There are differences of opinion on the design of various needle arrangements that have automatic sheath retraction and so on and so forth. In fact, I guess within the past 6 months I have discussed this with the FDA, and there doesn't appear to be a single design that stands out above the others, although some of the early studies indicate that there is a reduced likelihood of accidental needle stick.

Ms. SCHAKOWSKY. Apparently OSHA in California did a cost-benefit analysis on the use of these safety design needles and sharps and found because of the testing and treatment costs it saves, businesses and facilities across the State would save a $103 million each year if safer needles and sharps were utilized, not to mention that we might save—the estimates of the number of workers that become infected, it is a wide range but the outside is 5,900 health care workers who are potentially affected and it seems to me that this would be a reasonable procedure. What would it take—I am a cosponsor of legislation that would require that, but I am wondering if that is in the works anyway.

Dr. MITCHELL. Actually, the area that is involved, that is not Patient Care Services. It is the Division for Public Health and Environmental Health. And they are reviewing the use of that. I have not seen final data, although I have seen a draft review of that. The major step that was taken that has probably improved that more than anything else is just not recapping needles because the initial reason that most people were—had needle stick injuries was attempting to recap a needle that had already been used. We do have a policy of not recapping open needles and that they should be disposed of and every room should have an appropriate OSHA approved disposal area. So that has been the major thing. And I know that Dr. Fran Murphy is looking at the issue of needle sticks. However, the CDC also does not recommend routine testing for health care workers. What they say is that the testing should take place only in the circumstance where the needle stick occurred with a known hepatitis C positive patient so that the testing is very focused in that particular situation.

Dr. GARTHWAITE. I would just say that we totally agree with you that we must do everything that we can to minimize any chance of a health care worker being infected and we will double-check where the review from our occupational health people is and get back. We have no disagreement whatsoever, we fully believe that we have to do everything to protect our health care workers.

Mr. SHAYS. Bernie, do you want to vote?

Mr. SANDERS. First of all, my apologies for being late and thank you for calling this hearing on this very important issue. If I am asking a question that you already asked, Chris, I apologize. Many of us have been concerned that the budget for VA health care has been grossly inadequate, no ifs, ands or buts. My understanding is that treating hepatitis C is a very expensive proposition. I ask you a very simple question. If you treat folks with hepatitis C, what does this mean? Do you have the resources to do it? If you do it, are you taking money away from other desperately needed areas? We won't tell anybody what you said, just between us.

Dr. GARTHWAITE. We put forward a budget initiative in the fiscal year 2000 budget for an additional $250 million to treat hepatitis C. The President's budget that was submitted did contain the initiative for $250 million. The total budget level kept to the previously agreed upon balanced budget agreement which was no increase, only any increase of medical cost recovery funds we could make. Therefore, any money for hepatitis C will come from offsets in efficiencies in other parts of the system.

Mr. SANDERS. In other words, you are going to have to take from Peter to pay Paul? And Peter is really hard pressed today.

Dr. GARTHWAITE. In the ideal circumstance, we will find efficiencies that don't affect patient care, obviously.

Mr. SANDERS. I know that you share that concern.

Mr. SHAYS. The bottom line is that there is a line item in the budget but no money in essence for it.

Dr. GARTHWAITE. Right. There is no additional money because the President's budget did conform to the previously agreed upon balanced budget agreement.

Mr. SHAYS. It is important for that to be part of the record for me because I want to stay within the budget agreement if we can, but you would do a disservice if we don't acknowledge it up front. The ball is in our court now how we deal with it.

Mr. SANDERS. I don't agree that we should stay within the caps.

Mr. SHAYS. But we both agree that this is going to cost a plenty sum, and the money has to be there. I can't say that it has to come from within the budget.

Mr. SANDERS. I don't think there is any great secret that VA hospitals all over this country are hurting and to take money away from already underfunded areas to deal with this tragedy, people are going to be worse off.

Mr. SHAYS. In Connecticut, we combined some hospitals and made some tough decisions. We didn't see that same success in Boston. So we have some disputes within our own district which says there are some savings to be made but frankly those savings are needed in a whole host of areas besides this.

Mr. SANDERS. But we don't want to see VA health care undermined, and we are at that point. Now we have to vote.

Mr. SHAYS. We are going to have to recess. This is the only vote that we have for about 2 hours. We are just going to walk over and come back but it will probably take us about 15 minutes.

[Recess.]

Mr. SHAYS. I would like to call this hearing back to order and Bernie Sanders will begin asking questions and also I recognize Vic Snyder from Arkansas. It is great to have you here.

Mr. SANDERS. Having come—just one question and again I apologize if this issue has been gone into before. The rate of infection for veterans of hepatitis C is much higher than in the general population. Can somebody explain briefly why that is the case? Is that because veterans in general being young males primarily are more at risk or what is the connection?

Dr. GARTHWAITE. We believe right now we can say that when we tested veterans who showed up for care and were getting blood treated, it was at the 8 to 10 percent level. What we can't tell you exactly is whether that is a true representation of the entire vet-

eran population since smaller number—only a portion of the total number of veterans use the VA health care system. I think our population is skewed in that we take people who are disabled, often combat disabled, which implies that they were wounded in service or had transfusions in relation to their disabilities perhaps or we have patients—one of the other selection criteria is the highest priority for veterans is that they are poor. Often in America people are poor because they are ill to begin with or in some cases because they suffer from mental illness or disability, including drug and alcohol use, and we know that drug use is highly correlated as well. So we think that at least the population that we have tested so far has some significant risk factors, combat wounds, transfusions, multiple surgeries with transfusions prior to 1990 when testing was available. Certainly the theaters of Vietnam in particular where we see the highest prevalence certainly had risk factors associated with them. These are areas in which medics were often called upon to treat people who were bleeding so there was a fair amount of mixture and potential cross infection out in the field.

Mr. SANDERS. You think that service in Vietnam is a significant cause for—perhaps for the disparity of incidence?

Dr. GARTHWAITE. I am not sure——

Dr. HOLOHAN. There is an increased risk for patients with hepatitis C who have been in country in Vietnam, yes. They have a higher ratio of being positive than veterans who were not.

Mr. SANDERS. On top of the fact that they may be low income and may use drugs, just presence in Vietnam, everything being equal, will give you a higher risk factor?

Dr. HOLOHAN. Yes.

Mr. SANDERS. Thank you.

Mr. SHAYS. Congressman Snyder.

Mr. SNYDER. Thank you. I am sorry I'm late, there was a Veterans Subcommittee meeting on health. I have an opening statement that I ask to be submitted in the record.

Mr. SHAYS. Without objection, so ordered.

[The prepared statement of Hon. Vic Snyder follows:]

VIC SNYDER

COMMITTEE ON ARMED SERVICES
COMMITTEE ON VETERANS' AFFAIRS

Congress of the United States
House of Representatives
Washington, DC 20515-0402

OPENING STATEMENT
REPRESENTATIVE VIC SNYDER
COMMITTEE ON GOVERNMENT REFORM
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

PREPARED FOR HEARING TITLED "VA OUTREACH TO VETERANS AT RISK FOR HEPATITIS C INFECTION"
WEDNESDAY, JUNE 9, 1999
2203 RAYBURN

Thank you Chairman Christopher Shays and Members of the Subcommittee for the opportunity to appear here today to discuss the status of the Department of Veterans' Affairs' initiative on Hepatitis C (HCV). Mr. Chairman, I commend you for taking an active role in the problems of veterans and HCV. My interest in this issue is to better understand the extent to which our nation's veterans are affected by HCV. My overriding goal is to ensure that veterans who contract the disease while serving their country get the treatment they need and deserve.

As you are aware, I am a veteran and a family physician who trained in the VA medical system. Over the past year, I have learned a great deal about HCV, including information on its epidemiology, its effect on the veteran population and their families, and the fact that a disproportionate number of veterans are affected by this disease. Further, I discovered that information surrounding the natural history of HCV is limited, that the disease has an extremely long latency period, and as a result, many veterans have a difficult time under current law obtaining service-connection for their illness.

Because of these factors, I decided to introduce H.R. 1020, the "Veterans Hepatitis C Benefits Act of 1999." H.R. 1020 would provide a presumption of service-connection for veterans with hepatitis C who during service were exposed to one or more of the bill's ten enumerated risk factors. Establishing presumptive service-connection relieves veterans—many already sick from the disease—from this burden of proof. In other words, if a veteran was exposed during service to something that is known to cause HCV and the veteran is diagnosed with the disease after military service, my bill would presume that it is at least as likely as not that the illness is due to the in-service risk factor, and thus by law service-connected. I welcome your comments and suggestions on this bill.

My focus today isn't on H.R. 1020, however. Rather, I am interested in the status of the VA's hepatitis C initiative, introduced last November. The department's five-pronged program includes patient education, provider education, epidemiological assessment, treatment, and research. Additionally, the VA created two hepatitis C centers of excellence—one in Miami, the other in San Francisco—to develop national, coordinated patient and provider programs, among other activities, for use by the 171 VA medical centers across the country. The VA is to be commended for leading, and in many ways advancing, the national discussion on HCV.

While the department deserves praise for undertaking this massive system-wide initiative, there are many matters that remain unexplored and questions that remain unanswered. Principal among them concerns the implementation of the program. For instance, given the decentralized nature of the VA's network system, how is the central office ensuring that its guidelines and directives are reaching the appropriate personnel within each of the medical centers? Moreover, what checks and balances has the VA headquarters instituted to ensure that each network is using its allotted funds to expeditiously implement the program?

I raise these questions because some veterans tell me that a disconnect exists between what they hear from those at the national level (e.g., from Congress, their respective Veteran Service Organizations and the VA central office), and the information they receive from their local VA medical center. Namely, veterans report not being told about the Department's initiative by local medical center personnel, and that they have to initiate the conversation about HCV and request testing and screening. Some report that when they raise the subject of HCV, medical personnel discourage them from seeking testing because medications are not available for treatment if they test positive. If any of this is true, we need to do better.

Addressing a national VA hepatitis C meeting attended by VA clinicians and counselors on June 3, Undersecretary for Health, Dr. Kenneth Kizer said that that ***all*** veterans, regardless of service-connection, should be treated if diagnosed for the disease. It is imperative that all veterans get diagnosed and, if they test positive, treated. The Administration and Congress must adequately fund the activities necessary to implement the VA's programs now and in the future. Failure to address the issue, head-on, will increase the occurrences of end-stage liver disease and the demand for liver transplants among veterans. Failure to properly address this problem now will also raise the death toll among infected veterans and devastate their families.

Again, Mr. Chairman, I thank you for holding this hearing to address my concerns and those of Members of this subcommittee. I look forward to the witnesses' testimony and their responses to questions posed by subcommittee Members.

Mr. SNYDER. I have been grappling with this issue of how a veteran picked up an illness in 1968 and we didn't test for until 1989 or 1990.

No. 1, do any of you have any comments on this issue of how well we are doing in the VA system in terms of our accuracy of either affirming or turning down claims for service connection with regard to hepatitis C? And No. 2, what do we think at this current state of knowledge is the percentage of those with hepatitis C that we don't have a good guess what the etiology is and we just put them in the unknown category? I don't know who to direct those questions to.

Dr. GARTHWAITE. With regards to the accuracy of ratings, no one here is really an expert on that. We could get you for the record obviously what a reasonable response is about the rating decisions that have been made. We are reviewing I believe your bill on presumption and getting comments on that so I think as part of our analysis of that rating, the rating decisions being made, we would like to provide that for the record.

Tom, do you have any comment on the other part?

Dr. HOLOHAN. I think the bottom line is that in an individual case from a medical point of view, not a medical legal necessarily but from a medical point of view, it is almost impossible to determine what the precise proximate cause of infection with hepatitis C is. A patient may have one, two or many risk factors and to determine which was in fact the proximate cause of the disease is in my opinion impossible.

Mr. SNYDER. And that does have some revocations. I like your phrase almost impossible to determine because in 20 to 30 years of history, some risk factor may be service connected and some risk factors may not be service connected. I don't know if my bill is the best way to get at this problem. I haven't seen anything better out there and I think there really are some challenges, having talked to some of the people who do the ratings. I am a family doctor and I would hate to be the one who had to flip that coin and make that kind of determination on this illness. I think doctors are used to making evaluations on things that you can evaluate, but this is different. You are talking about a point in time. We are physicians, not detectives. At what point in time did that virus enter that bloodstream. I will say any comments, criticisms, suggestions on H.R. 1020, I would be more than receptive to. We are trying to solve what I think is a problem for some veterans.

Thank you, Mr. Chairman.

Mr. SHAYS. Thank you very much. I have a few questions before we go to the next panel that I would just like to get on the record. The first, what outreach initiatives does the VA have underway to reach the veteran population considered most at risk? If you just put it in fairly simple terms, what the outreach initiatives are?

Dr. MITCHELL. I think that we have tried to approach the problem in general by first educating our clinicians because they will be the front line contact with all veterans and the point of the information letter was to help us in risk stratification, which patients are at greatest risk and therefore need testing and are more likely to be eligible for treatment.

Second, we have developed a Web site which will be Internet accessible by patients and their families.

Mr. SHAYS. When will that be done by?

Dr. MITCHELL. It is actually up now. It is not terribly sophisticated at this point in time, and we are working on that and plan on soliciting articles both from veteran service organizations, from our networks, from the facilities, from the American Liver Foundation, from other Federal agencies to provide further information, but I will be glad to provide to you later the exact Web address because I have learned quickly that a number of them are Web savvy. We are working with the American Liver Foundation to develop specific materials, one of which was the PSA that you just saw; others are written materials which will be delivered to them. We also have asked and have been working directly with the networks to have counselors specifically trained to discuss these issues with patients and their families. We have also been working with the networks and the ALF to set up support groups so that when a patient tests positive, whether or not they are eligible for treatment yet, that support groups will be made available to them so that they can meet on a regular basis.

So there are a number of activities that are going on, both nationally and at the local level. When there has been a request for assistance for testing, for instance in New York State, the VA had asked for our assistance in helping to set up a testing program, and we participate in those kinds of collaborative outreach kinds of programs as well.

Mr. SHAYS. The testimony so far is that some say 10 percent can be treated, some 20 and potentially up to 40 percent successfully, and we still haven't defined success. We would all agree I am assuming that everyone has a right to know that they have hepatitis C, not knowing that it would be a tragedy for them not to know how and to begin to find ways to deal with it, and certainly not to spread the disease and so on. My first question is even if we didn't think that we could successfully treat someone with hepatitis C, we do feel that it is important that they know that they have it; is that correct?

Dr. MITCHELL. That is correct.

Dr. GARTHWAITE. One of the criteria is patient requests for screening.

Mr. SHAYS. Any patient who requests will be tested?

Dr. GARTHWAITE. Yes.

Mr. SHAYS. But you don't test everyone. Everyone who comes in is not tested for hepatitis C?

Dr. MITCHELL. As I said, with the information letter the point was if they have absolutely no risk factors, we would not test them unless they requested to be tested because, as Dr. Holohan described earlier, the risk of a false positive is fairly high. So if they have no risk factors we do not test. We say you have none of the known risk factors and we have been more inclusive than the CDC in that by adding the Vietnam veteran as one and——

Dr. HOLOHAN. Even alcohol abuse, tattooing, or body piercing, none of which are considered to be risk factors by CDC we do include.

Mr. SHAYS. Mr. Farsetta, you have one of the VA service networks?

Mr. FARSETTA. That is correct.

Mr. SHAYS. Can you describe your area?

Mr. FARSETTA. My area is New York City, Hudson Valley and most of New Jersey.

Mr. SHAYS. As I recall, we had a hearing in one of your areas.

Mr. FARSETTA. Yes, we had a hearing in Waterville, which is about 2 miles north.

Mr. SHAYS. I will never forget that hearing as long as I live.

Mr. FARSETTA. Neither will I.

Mr. SHAYS. I felt like I was a western judge preventing a lynching.

Mr. FARSETTA. Thank you very much.

Mr. SHAYS. And in the process I almost got lynched myself. If the choice was between you or me at the end I would have made——

Mr. FARSETTA. The right choice. Public service, wonderful. Go ahead.

Mr. SHAYS. I got out all right, just a few bad articles in the process. Describe how the HCV initiative has been implemented in network 3?

Mr. FARSETTA. First of all, we have the highest prevalence of HIV in the Nation in my network. We really have been dealing with HIV and hepatitis C for a number of years. We actually have had a collaborative effort between the infectious disease physician, the GI physicians and the chiefs of medicine and we have been looking at hepatitis C and have been concerned about hepatitis C, as I say, for a number of years.

We have tested in excess of 14,000 people in the network. This year alone we have tested from October 1 to the current date over 10,000 veterans.

Mr. SHAYS. You tested 14,000 total?

Mr. FARSETTA. Roughly, and 10,000 since October 1. We have 2,700 who are positive and we have about 250 who are in treatment and we are adding about 50 per month for treatment. We are actively testing about 800 veterans per month.

Mr. SHAYS. You just answered the next three questions and you did it the right order.

Are you taking this out of your own budget?

Mr. FARSETTA. Yes, I am.

Mr. SHAYS. Have you put a cost to it?

Mr. FARSETTA. So far probably this year about $4 million. And in essence every time we engage a veteran in treatment, we will be incurring over the course of 48 weeks roughly $15,000. So I am incurring costs of perhaps $750,000 each month and it doesn't work out to be each month but I am essentially using a credit card and saying whatever it costs to treat you, we will treat you. While this year is not problematic, with what we are hearing about the budget for next year it will be terribly problematic and I don't know how I will be able to continue to do that.

Mr. SHAYS. I think it is important that the VA know that alarm bells are going off and putting Congress on notice. We will be debating the VA–HUD bill and it has less money total than last time,

and we really have to come to grips with this and you should not allow me or anyone else to escape the reality of that.

We have been joined by Judy Biggert. I don't know if you have any questions.

Mrs. BIGGERT. I have one question. I understand that there really is no cure, but there is the antiviral treatment. And if somebody is not a good candidate for that and you find out that they have this, what happens to them?

Dr. SIMBERKOFF. The risk factors that preclude treatment are often things like alcohol, drug abuse and depression. One of the things that we are doing is to try to counsel patients about the fact that either alcohol or drug abuse perpetuates the problem and often makes it much worse so we are trying to get the patients into treatment programs so that they can—can deal with those problems. Certainly depression itself is a treatable medical problem. So again, we are trying to get patients into treatment for those things which for the most part are keeping them from being candidates, individuals who are not candidates for treatment.

Mrs. BIGGERT. Is something like depression as a result of having this or is it a cause?

Dr. SIMBERKOFF. In some cases the medical illness may lead to the depression. If it doesn't respond, we will try to deal as best we can with the medical illness. But in many instances there are other medical problems. PTSE is another, and these are illnesses that the VVA has a great experience in trying to deal with. So I think we are hoping that many of these patients who are not candidates for treatment today will be better candidates for treatment in days or weeks to come.

Mrs. BIGGERT. Thank you.

Dr. MITCHELL. I would like to add, if they need other supportive therapy, in other words they are cirrhotic and that is the reason that they have advanced liver disease, the reason they are not eligible for treatment, we would continue to provide all of that ongoing supportive medical care to which they would normally be provided. So we do not stop or not do any of the other things simply because they are hepatitis C positive.

Mrs. BIGGERT. Thank you. Thank you, Mr. Chairman.

Mr. SHAYS. Mr. Sanders.

Mr. SANDERS. Let me get back to dealing with the financial situation of the VA. My understanding, I think, Mr. Farsetta, you indicated that or somebody had mentioned to me in the past if I understand correctly, the VA treats more HIV patients than any other institution in the world; is that correct?

Mr. FARSETTA. Yes.

Dr. SIMBERKOFF. Yes.

Mr. SANDERS. And that is pretty expensive?

Dr. SIMBERKOFF. Yes.

Mr. SANDERS. Is that also true with hepatitis C?

Dr. GARTHWAITE. I don't know that we have the data on that.

Mr. SANDERS. I ask that question for the following reason. Treatment of AIDS is obviously very expensive. Treatment of hepatitis C is very expensive and you asked a moment ago about outreach. He who has an institution struggling with inadequate financial resources, if in fact somebody said to them we want you to be very

aggressive and do the right thing for this country and for the people involved, reach out, bring all of those people in who are veterans and who have AIDS, bring all of those people who are suffering with hepatitis C, and it is going to cost you $10,000 or $15,000 to treat hepatitis C, of course we are cutting the budget in the process but we want you to be very aggressive and do the right thing. I think we are sending you a rather mixed signal, and I think if I were an administrator, I would probably turn my back. Or if I were aggressive, I would have to cut back on the World War II veterans that we are not treating with the respect that they are due. What am I missing here?

Try to be as honest as you can. I think because ultimately we are going to have to deal with this issue, if we want these people to do the right things, we are going to have to fund them or else we say don't do the right things.

Mr. SHAYS. I know he is going to be more honest because he hasn't been in Washington long enough to know he has to be careful.

Mr. SANDERS. Yes. Be honest. I think it is important that the U.S. Congress hear the truth, because it is not acceptable because we want to help the veterans, we are deeply concerned about the veterans but we are going to cut them and, by the way, we are critical of you for not doing the right thing.

Mr. FARSETTA. I am not sure you have missed anything. I think it is as we approach 2000, it is really problematic. I think it is something that from an ethical perspective—I had a conference call with many of my treating clinicians yesterday on this very issue. And they are troubled not by today, but by the uncertainty about tomorrow, that when you engage in screening and make a diagnosis and treatment, then you are really ethically committed to provide that treatment. And do we want to engage a population that we are not quite certain that we are going to have the wherewithal to treat 6 months from today when we know the treatment is 48 weeks. So it is really problematic.

Mr. SANDERS. In other words, something is coming in, we have bad news for you, hepatitis C, but we can't treat you.

Mr. FARSETTA. Well, I think what we are doing is we are saying, we have bad news, you have hepatitis C, we are going to treat. The clinicians right now are not saying, but in 6 months we are not going to have the money, but they are saying to me, based upon the dialog we have had about based upon what the budget looks like for next year, do you have the resources to provide the wherewithal that is necessary for next year, and my response is A, I don't know; and if I don't, then something else will have to go, because we are really committed to doing this.

Mr. SANDERS. But in the back of your mind—you were asked about outreach. I would assume if I were sitting in your chair, I would not be all that aggressive. I mean you don't have to tell me whether you are or not and I know there are ethical concerns here, but in the real world, how are you going to launch a major outreach campaign if you are going to have to tell folks that you can't treat them? Anyone else want to comment on that?

Dr. GARTHWAITE. I think you raise very valid concerns. We have had internal discussions where we have really talked about what

are some alternatives if the money doesn't stretch, to provide all benefits to all comers, does that mean we then stop seeing priority 7 veterans. The reality is with the third-party insurance payments we get from priority 7 veterans and the fact that on average they cost less, it appears that they do not cost the VA a lot of money; i.e., if we stop seeing priority 7 veterans, we wouldn't save a lot of money.

So that I think was at least an initial concern about how to make all, you know, balanced budget numbers work was, in part, if you really get tight for money, you don't have to see the higher income veterans. The reality is they don't necessarily—by stopping seeing them, you don't necessarily save a lot of money. So then you are really talking about, since there aren't really that many priority 6 veterans, you are really talking about priority 5 veterans who do meet a means test for poverty.

My guess is if you had a hepatitis C-positive priority 5 veteran who meets a means test for poverty, that they are likely going to seek public resources for the treatment of their hepatitis C. You know, if the VA is not seeing them, I don't think that means that the taxpayer isn't going to help out here, and I think that we do a good job and would like to see us be able to do that.

So I think we just have to work our way through how many we can see within the budget we are given, but I think it is probably good public policy to let the VA treat a fair number of hepatitis C patients. We learn a lot, I think we do a lot of research at the same time, and I think we do it compassionately as well, over the years that we have seen these patients, and I think it makes a lot of sense.

Mr. SANDERS. Let me just conclude by making a request. I think, and Chris or anybody else can disagree with me, but I am not sure that the average Member of Congress is fully aware of the financial stress that the VA system is under, given the load that they have to deal with, and I don't know that the VA has done—and I know that you are not able to lobby also, but I think you could do a better job in saying to the Members of Congress, just explaining.

I talked to Dr. Kizer about this as well, but to say, look, with this amount of money, this is what we can't do. Congress ultimately has to make that choice and they should make that choice with their eyes open, and I would hope that you would give us those facts.

What does it mean if your budget is cut? Tell us the honest truth. Is that something you think you could perhaps work on a little bit?

Dr. GARTHWAITE. In fact, we are in the process, fairly far along in the process of looking at scenarios of the exact President's budget and at several increments as to what that would mean in terms of what we could or couldn't do at a local level and at a national level.

Mr. SANDERS. I know there are political ramifications to it, but I think you are not doing your job well unless you tell Congress what the truth is; and I would appreciate it. We are going to have to make those decisions very shortly, so the quicker you could get us that information, the better.

Mr. SHAYS. It makes it more awkward if the administration hasn't honored a request, because then you are in the administration having to speak out about something that wasn't put in your budget. But I do think that there really is almost a moral necessity that happens. I think one way we can help your cause is to ask the GAO to step in and try to look at the cost of some of your big ticket items. I would assume HIV is one; another is hepatitis C potentially, and another is the costs dealing with Gulf war veterans based on our hope that we will make presumptions, and that will certainly increase costs a lot.

Let me do this. There are other questions that if we need to, we will put them to you in writing, and we will get to our next panel. Thank you very much.

Our next panel is Mr. Terry Baker, Vietnam Veterans of America and president of Veterans Aiming Towards Awareness; Mr. George C. Duggins, president, Vietnam Veterans of America, accompanied by Mr. Rick Weidman, director of Government Relations, Vietnam Veterans of America; and Dr. Adrian DiBisceglie, professor, Department of Internal Medicine, St. Louis University, and medical director of the American Liver Foundation; and finally, Dr. Alan Brownstein, president of the American Liver Foundation.

It is very good to have all of you here. The first thing we do is, as you know, we swear in all of our witnesses, and I would ask you all to stand and I will give you the oath.

[Witnesses sworn.]

Mr. SHAYS. For the record, all have responded in the affirmative. We will use our clock, but let me explain how we will proceed. You have 5 minutes, and then I will tip it over again, and if you didn't finish in the first 5 minutes, if you would certainly finish within that 5 to 10 minutes, that would be helpful.

So we will start with you, Mr. Baker.

STATEMENTS OF TERRY BAKER, VIETNAM VETERANS OF AMERICA AND PRESIDENT OF VETERANS AIMING TOWARDS AWARENESS; GEORGE C. DUGGINS, PRESIDENT, VIETNAM VETERANS OF AMERICA, ACCOMPANIED BY RICK WEIDMAN, DIRECTOR OF GOVERNMENT RELATIONS, VIETNAM VETERANS OF AMERICA; DR. ADRIAN DIBISCEGLIE, PROFESSOR, DEPARTMENT OF INTERNAL MEDICINE, ST. LOUIS UNIVERSITY, AND MEDICAL DIRECTOR OF THE AMERICAN LIVER FOUNDATION; AND DR. ALAN BROWNSTEIN, PRESIDENT, AMERICAN LIVER FOUNDATION

Mr. BAKER. Mr. Chairman and members of the subcommittee, my name is Terry Baker. As the executive director of Veterans Aiming Towards Awareness, a support group for veterans with hepatitis C, and national service officer for the Vietnam Veterans of America, I am honored to be here today to present my views on the Department of Veterans Affairs' handling of the hepatitis C epidemic.

I want to thank you for your leadership and for holding this hearing on the VA's responsibility to help the men and women who risk their lives for their country and who now face an even greater risk. I am particularly pleased that the committee is focusing on if the national VA initiative is being carried out.

As a veteran with hepatitis C, I want to begin by saying thank you to Dr. Kenneth Kizer and the Department of Veterans Affairs for recognizing the seriousness of this disease and for launching a major initiative to address it.

In June 1998, the Department of Veterans Affairs issued guidelines to the VA health system regarding the proactive testing of veterans with any of 10 risk factors for hepatitis C. Beginning last June, every patient visiting a VA facility should have been evaluated for HCV. The results should have been entered into the patient's chart and an antibody test should have been performed on any veteran presenting with one or more risks.

In January of this year, Dr. Kenneth Kizer announced further initiatives to deal with the hepatitis C virus. Among these was the creation of two hepatitis C Centers of Excellence where medical professionals and research scientists could coordinate treatment and research efforts, as well as develop education for patients and their families, health care providers and counselors. When Dr. Kizer established these centers he stated that, "VA's goal is that every patient who needs and wants treatment will receive it."

Mr. Chairman, Dr. Kizer's initiative and his leadership on this issue are appreciated. However, the Department's ineffectiveness at the service delivery level in actually providing screening, counseling and treatment to hepatitis C infected veterans is most disconcerting. The VA hepatitis C initiative has been in place for 1 year now. During this time, the Department has not succeeded in communicating the objectives of this initiative to hospital personnel. I know of numerous cases of veterans who are not being assessed for hepatitis C risks, not being offered testing in a systematic fashion, and not being evaluated routinely for the suitability for treatment.

In fact, many veterans have gotten just the opposite from the VA, the old runaround, by VA personnel and roadblock after roadblock in their pursuit to be treated for HCV, a disease they most probably contracted while defending their country.

For example, I know a veteran in Idaho who was wounded in combat in Vietnam. I suggested he request a test for hepatitis C the next time he visited the VA hospital in Spokane, WA. When he did ask to be tested the staff at that facility gave the impression they had no idea of what he was talking about, and claimed that they were not aware of any such test. To date, the service-connected veteran has yet to be tested for hepatitis C even though he specifically and proactively went out and asked to be tested.

Another veteran, this one from Montana, was actually diagnosed with hepatitis C during a nonVA-sponsored HCV testing last year. After discovering he was positive, he attempted to have the test confirmed at his local VA clinic, but they refused to test him. He then visited an Arizona VA clinic and the diagnosis was confirmed. Even though the VA doctor from Arizona contacted the Montana clinic and recommended followup, the VA clinic has continued to refuse the vet treatment for his hepatitis C.

My final example comes from a hepatitis C-infected veteran in Newark, NJ. This veteran served with the 173rd Airborne Brigade in Vietnam where he was twice awarded the Bronze Star for Valor for coming to the aid of wounded soldiers on the battlefield. His

military service records contained clear evidence that he was directly exposed to blood during combat in Vietnam. Even so, the VA denied his claim for service connections stating that he met none of the risk factors for hepatitis C, and that his records contained zero evidence of having hepatitis C. This statement completely contradicts VA's public acknowledgment that HCV symptoms often do not manifest for 10 to 30 years after the victim is infected. So right now, there is a Vietnam veteran who has been forced to seek out private medical attention at his own expense, because now he is in the last stages of liver disease.

Members of the committee, I must stress that while I applaud VA's plan for dealing with hepatitis C, it is not enough to have a plan. This war against a deadly disease will require a fully deployed assault by all of us. The VA must act swiftly to educate its physicians, staff and all rating officers all about this disease. While training one physician and one nurse from each of the 172 medical centers may seem ambitious, it is not adequate.

Mr. SHAYS. Excuse me. Mr. Baker, this is a little unusual. But ma'am, how many students do we have? Because they could sit up here if we don't have too many. How many students do you have? They can just sit on the side. You don't mind, do you?

Mr. BAKER. No.

Mr. SHAYS. I find any time—you young people can sit right up along this side here.

Mr. TOWNS. They come from my district, Mr. Chairman.

Mr. SHAYS. I figured as much.

Any way we can get Mr. Towns here, we will take it, because he has been such a wonderful member of this committee. How many other students do you have? You can sit right up over here if you want. You can sit on the floor up front. If you don't mind sitting on the floor, you can do that. You young people, if you don't mind, we are running out of seats up here, but you can sit up front here if you don't mind sitting on the floor. You can come in, and sit this way. Thank you for letting me do this.

For the benefit of our guests, we are having a hearing on our veterans who have been affected with hepatitis C and ways that we can help them. There is some more room over here. The gentleman speaking now is a veteran.

Mr. Baker, you are coming close to finishing and then we will get to the next speaker. Thank you.

Mr. BAKER. Members of this committee, I must stress that while I applaud the VA's plan for dealing with hepatitis C, it is not enough to have a plan. This war against a deadly disease will require a fully deployed assault by all of us. The VA must act swiftly to educate its physicians, staff and all rating officers all about this disease. While training one physician and one nurse from each of the 172 medical centers may seem ambitious, it is not adequate. The Portland VA Medical Center sent a computer specialist to the HCV training session held last week here in Washington. This does not seem to indicate a clear commitment from the Portland VA Medical Center.

If VA's efforts must be limited, these efforts must also be focused, focused on persons most likely to interact with people affected by HCV. Something as simple as large posters at every VA medical

center enumerating the risk factors for HCV and encouraging veterans to get tested have not been posted in VA facilities. These posters do not even exist. The VA said it would aggressively fight this disease, and yet few, if any, VA medical centers advertise hepatitis C testing. It was even brought to our attention that the VA Excellence Center in Miami was not receiving the proper funding to combat this disease. Dr. Mitchell herself had to personally address that problem. This approach seems inappropriate when a systematic plan has already been outlined. Or has it? Therefore, VA must ensure that every directive about hepatitis C is taken seriously and carried out completely by every VA medical center.

I respectfully request, myself a veteran and on behalf of all veterans, that you hold the VA 100 percent accountable for its plans to fight this battle. If necessary, Congress must give Dr. Kizer the authority for centralized activities against hepatitis C. You alone have the authority to make sure the VA does precisely what it says it will do. Please aggressively pursue answers and results from the VA. I assure you all of America's veterans are counting on you. Please don't let them down.

Thank you.

[The prepared statement of Mr. Baker follows:]

STATEMENT OF
Terry Baker
Executive Director
Veterans Aimed Towards Awareness, Inc.

COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

VETERANS and HEPATITIS C
JUNE 9, 1999

Mr. Chairman and Members of the Subcommittee,

My name is Terry Baker. I am the executive director of Veterans Aimed Toward Awareness (VATA), a support group for veterans with hepatitis C. I am honored to be invited today to present my views on the Department of Veterans Affairs' handling of the hepatitis-C epidemic. I want to thank you for your leadership on hepatitis C generally, and for holding this hearing on the VA's efforts to help the men and women who risked their lives for their country and who now face an even greater fight against hepatitis C. I am particularly pleased that the Committee is focusing on how the national VA initiative is translating into testing, counseling and treatment for veterans at the local medical centers.

As a veteran with Hepatitis C, I want to begin by saying "thank you" to Dr. Kenneth Kizer and the Department of Veterans Affairs for recognizing the importance of this disease and for launching a major initiative to address it. In June of 1998, the Department of Veterans Affairs issued guidelines to the VA health system regarding the proactive testing of veterans with any of ten risk factors for hepatitis C. Beginning last June, every patient visiting a VA facility should have been evaluated for HCV risk factors, the results should have been entered into the patient's chart, and an antibody test should have been performed on any veteran presenting with one or more risks.

In January of this year, Dr. Kenneth Kizer announced further initiatives to deal with the hepatitis C virus. Among these was the creation of two hepatitis C Centers of Excellence, where medical professionals and research scientists could coordinate treatment and research efforts, as well as develop education for patients and their families, health-care providers, and counselors. When Dr. Kizer established these centers, he stated that, "VA's goal is that every patient who needs and wants treatment will receive it."[1]

Mr. Chairman, Dr. Kizer's initiative and his leadership on this issue are impressive. As a Veteran's Service Officer for the Vietnam Veterans of American and as the Director of VATA, however, I am most concerned about the Department's effectiveness at the service delivery level in actually providing screening, counseling, and treatment to hepatitis C infected veterans. To date, I have not seen the evidence of this policy initiative in the treatment of individual veterans in the VA hospitals.

The VA hepatitis C initiative has been in place in one form or another for a year now. In the past year, I believe the Department has not succeeded in communicating the objectives of this initiative to hospital personnel. I know of numerous cases of veterans who are not being assessed for hepatitis risks, not being offered testing in a systematic fashion and not being evaluated routinely for their suitability for treatment. As a Veterans' Service Officer, I have personally spoken with veterans who are not getting the guidance they need to seek testing, to make treatment decisions once they do test positive for hepatitis C, or even the actual medical treatment. In fact, many veterans have gotten just the

[1] "VA Launches Broad Attack on Hepatitis C Epidemic", VA Press Release, 1/27/99.

opposite from the VA – the old run-around by VA officials and roadblock after roadblock in their pursuit to be treated for HCV, a disease they most probably contracted while defending this country.

For example, I know a veteran in Idaho who was wounded during combat in Vietnam. I suggested he request a test for hepatitis C the next time he visited the VA hospital in Spokane, Washington. When he did ask to be tested for HCV, the staff at that VAMC gave the impression that they had no idea what he was talking about, and claimed that they were not aware of any such test. To date, this service-connected veteran has yet to be tested for hepatitis C even though he specifically and pro-actively went out and asked to be tested.

Another veteran (this one from Montana) was actually diagnosed with hepatitis C infection during a non-VA sponsored HCV testing day last year. After discovering he was positive he attempted to have the test confirmed by the VA. His local clinic refused him the test. He visited an Arizona VA clinic during his vacation and the diagnosis was confirmed. Even though the VA doc from Arizona contacted the Montana clinic and recommended follow-up, the VA clinic in this VISN has continued to refuse the Vet treatment for his hepatitis C.

My final example comes from a hepatitis-C infected veteran in Newark, New Jersey. He served with the 173rd Airborne Brigade in Vietnam. This veteran's military service records contain clear evidence that he was directly exposed to blood during combat in Vietnam. Members of the Committee, this is a veteran who during his tour in Vietnam was twice awarded the Bronze Star for Valor for coming to the aid of wounded soldiers on the battlefield. Even so, the

VA denied his claim for service-connection, stating that he met ***none of the risk factors*** for hepatitis-C exposure and that his records contained zero evidence of having hepatitis C. This statement completely contradicts VA's public acknowledgement that HCV symptoms often do not manifest for 10 to 30 years after a victim is infected. So, right now, there is a Vietnam veteran who has been forced to seek out private medical attention – at his own expense – because now he is in his last stages of liver disease, which was caused by the hepatitis C he contracted while serving his country.

Committee Members, I must stress that while I applaud VA's plan for dealing with hepatitis C, it is not enough to have a plan—this war against a deadly disease will require a fully deployed assault on the part of the Department. The VA must act swiftly to educate its VAMC physicians and staff AND VA Rating Officers all about this disease. While training one physician and one nurse from each of the 172 medical centers may seem ambitious, it is not adequate. The Portland VAMC sent a "computer specialist" to the HCV training session held last week here in Washington. Why was a computer specialist sent to training on hepatitis C? This does not seem to indicate a clear commitment from the Portland VAMC to fight this infectious disease.

If VA's efforts must be limited, these efforts must also be focused--focused on persons most likely to interact with people affected by HCV. Something as simple as large posters at every VAMC enumerating the risk factors for HCV and encouraging veterans to get tested have NOT been posted in waiting rooms of VA medical centers. These posters do not even exist. The VA said it would

"aggressively" fight this disease and yet few, if any, VA medical centers advertise hepatitis-C testing. It was brought to our attention that the VA Excellence Center in Miami was not receiving the proper funding to combat this disease. Dr. Mitchell had to personally address that problem. This approach seems inappropriate when a systematic plan has already been outlined. Therefore, VA must ensure that every directive distributed about hepatitis C is taken seriously, and carried out completely, by every VAMC.

I respectfully request, myself a veteran and on behalf of all veterans, that you hold the VA 100% accountable for its plans to fight this battle against hepatitis C. If necessary, Congress must give Dr. Kizer the authority for centralized activities against hepatitis C. You alone have the authority to make sure the VA does precisely what it says it will do. Please aggressively pursue answers and results from the VA. I assure you, many thousands of veterans with hepatitis C are counting on you. Please don't let them down.

Mr. SHAYS. Thank you, Mr. Baker. What we will do, I want to acknowledge that the first panel who spoke has stayed to hear your presentation, and that is really appreciated; second, that the particular cases that you have presented should be shared with the VA, and it would be instructive for us to have, Dr. Garthwaite, just follow them up and then just see what the story is of breakdown or where there are other factors involved, and that would be instructive to helping you and helping us understand the system.

Thank you for your testimony.

Mr. Duggins, you are here to give testimony and then you are accompanied by Mr. Weidman who will respond to questions afterwards, is that correct?

Mr. DUGGINS. We both will respond.

Mr. SHAYS. I just meant that Mr. Weidman, you are not here to give testimony, but you will be responding along with Mr. Duggins and the others, as an equal member responding afterward, but Mr. Duggins, if you would give your testimony.

Mr. DUGGINS. Mr. Chairman, my name is George Duggins and I serve as national president of Vietnam Veterans of America. On behalf of Vietnam Veterans of America [VVA], I wish to congratulate and thank you and your distinguished colleagues for your leadership in holding this hearing this morning on the subject of the hepatitis C virus and the efforts of the Vietnam Veterans Health Administration at the U.S. Department of Veterans Affairs to effectively deal with this epidemic that is disproportionately affecting veterans.

Of particular interest to VVA is the apparently high prevalence among Vietnam veterans, particularly those veterans who served "in country;" i.e., the Vietnam theater of operations. Because of combat wounds, exposure to blood on the battlefield and other factors that attend to the most basic and messy nature of warfare, a large number of veterans were exposed and unaware that they should have been tested.

VHA response is: The Veterans Health Administration has responded admirably following the outstanding report issued by this subcommittee in October 1998. The policy directive issued to all VHA facilities on June 11, 1998 is a very reasonable plan for a starting place to begin the process of testing and treatment. The treatment protocol issued by the VHA to all clinical coordinators at the end of December 1998 is a reasonable approach and a good starting basis for each medical facility to move forward with treatment. While we would hope that each of these policy statements and guidance documents will eventually be strengthened, they would be a reasonable start toward dealing with the veterans' aspect of this epidemic, if there is a means of ensuring relative uniform implementation.

Earlier this year, many of the VVA local leaders in virtually every part of the Nation told us that VHA officials in their area were saying that the test would be given and that VHA had the resources and the means to set up their system to properly treat those who are tested and are shown to have hepatitis C virus. Today, it is our belief that most of the facilities are still doing an inadequate job of actually testing for hepatitis C virus in a systematic manner and are slow to treat in many cases. We are still hear-

ing of Pharmacy Chiefs and VAMC directors who are reluctant to order enough of the relatively expensive medication necessary to begin treatment in sufficient quantities to begin early treatment of suitable candidates for this very arduous process.

This lack of a concerted and highly visible outreach and rigorous testing campaign could have potential devastating effects on the veterans involved, as well as on the VA health care system that will have to deal with the aftermath of this not so benign neglect in the future. If left untreated, many of those veterans will develop symptoms of the virus, leading to very serious and debilitating diseases that may result in liver transplant as their only option.

The extreme pressures of the VHA over 3 years of a flat line budget and the disastrous and woefully inadequate requests from the President for the fiscal year 2000 budget for VHA has cast a chilling effect on the motivations of the administrators in the field to move ahead with doing their jobs properly for veterans potentially affected with hepatitis C. Finally, while it is unacceptable and unconscionable for medical personnel to act this way, it is inexcusable for the President and the Congress to put these people in a situation of extreme and needless scarcity.

We ask your help, Mr. Chairman, and that of your distinguished colleagues in helping secure a more reasonable budget for VHA for fiscal year 2000. While VVA believes that $3 billion more than the President's budget request is truly needed, obviously the $1.7 billion more being currently discussed in Congress would help keep the system from diminishing any further.

VHA should work with the veteran service organizations and American Liver Foundation and other public and private entities to mount a comprehensive, significant, extended and prolonged public service campaign to give veterans who may have been exposed to come into the VA, enroll, and be tested. Most veterans do not use the regular VHA facilities for their health care needs and since the virus is silent, most do not know that they are affected or even potentially at risk. This would perhaps be most effectively done as a part of an overall coordinated Federal response to hepatitis C epidemic, while it is still in a relatively early stage.

VVA stands ready to do our part in such an outreach effort to spur testing of veterans and encouraging individuals to get tested now. It is our belief that many private groups as well as public entities and the media will be responsible for such a concrete and organized effort. However, VHA must take steps to assure that the key personnel at the local level stand ready to work with the veterans groups and the rest of the community in a meaningful and sustained manner.

VVA would also note that such efforts must be designed and implemented in such a manner that all subgroups in the veterans population are effectively reached. Ensuring that the community-based groups that serve homeless veterans and others under several populations in greatest need is very important in this matter.

VHA should begin to rigorously ensure that all veterans currently registered for the VHA services who meet the at-risk profile have their blood tested for signs of the hepatitis C virus. This is not happening at many of the medical facilities we are aware of at this moment. Many veterans at risk, such as the former medic ac-

companying me today, have been trying to get tested for hepatitis C at a VHA facility, but on their own initiative, not that of the VA.

It is our belief at VVA that this can be set up as a regular part of intake and yearly physicals by the VHA by making it part of a computer program to indicate certain tests must be given to veterans based on his or her full military medical history that is logged in as a matter of course. This is something that VVA believes should be done for many sound medical reasons in a veterans health care system. VVA has engaged in discussions with top VHA leaders on this subject for several months and VHA has agreed this week to proceed with setting up a task group to begin the process of framing the design and implementation of the basic process.

VHA must also take steps to ensure that much more effective accountability mechanisms are put in place that would enable the key national managers to monitor what is happening in the field. VVA has consistently called for much better and more effective modern accountability mechanisms within the VHA. The problem is one of the top officials in VHA not knowing what is going on at the service delivery level, except by anecdotes told to them by others. There is no mechanism for systematic quality assurance review in regards to hepatitis C or for other vital measures. This is simply no way to manage a system that is as large and complex as the VA Health Administration.

VHA should closely work with the Surgeon General, the National Institutes of Health, and the Congress, to ensure that additional research is undertaken into more effective cures for eradicating the hepatitis C virus. While VVA is appreciative of the approximately $5 million in research funds which will be made available this year, the sum is inadequate in the face of the potential danger of the medical epidemic. Our Nation can do better in pursuit of a more effective cure for this virus.

VVA would urge that the Department of Defense be involved in this effort and that you and your distinguished colleagues help DOD keep a positive attitude that is open to the virus being a potentially serious problem as opposed to denying beforehand that there could possibly be any substantial risk.

Mr. Chairman, this concludes my remarks. I will be pleased to answer any questions you may have. Thank you again for allowing us to present our views here today and for your strong and vigorous leadership on so many vital issues that confront our Nation's veterans.

[The prepared statement of Mr. Duggins follows:]

Statement of

Vietnam Veterans of America

Submitted By

George C. Duggins
National President

Accompanied by

Richard F. Weidman
Director of Government Relations

Before The

House Subcommittee on National Security,
Veterans' Affairs, and International Affairs
Committee on Government Reform

June 9, 1999

Vietnam Veterans of America

House Subcommittee on National Security, Veterans' Affairs, and International Affairs
Committee on Government Reform
June 9, 1999

Mr. Chairman, my name is George Duggins. and I serve as National President of Vietnam Veterans of America. On behalf of Vietnam Veterans of America (VVA). I wish to congratulate and thank you and your distinguished colleagues for your leadership in holding this hearing this morning on the subject of the Hepatitis C virus, and the efforts of the Veterans Health Administration (VHA) at the United States Department of Veterans Affairs to effectively deal with this epidemic that is disproportionately affecting veterans.

Hepatitis C has been referred to as the "silent virus" or the "silent killer" because it can remain dormant for at least twenty to thirty years. and perhaps longer. Until 1989, the Hepatitis C virus was not even identified, but rather referred to by physicians as "non-A, non-B hepatitis." While there is a relatively wide variance of opinion as to the prevalence among veterans, all who have looked into this issue appear to agree that the incidence among veterans is significantly greater among veterans than the general population. VVA believes that *at least* 8 to 10% of veterans are infected. Based on unofficial verbal reports of the results of the "snapshot" at VA Hospitals taken in March, we have reason to believe that the prevalence rate may be possibly as high as 14%. Whatever the rate actually turns out to be in retrospect, the problem for the men and women veterans in the so-called "high-risk" groups is a potentially devastating one for many thousands of veterans.

Of particular interest to VVA is the apparently high prevalence among Vietnam veterans, particularly those veterans who served "in country" (i.e., in the Vietnam theater of operations). Because of combat wounds, exposure to blood on the battlefield, and other factors that attend to the most basic and messy nature of warfare, a large number of veterans were exposed and are unaware that they should even be tested.

VHA Response

The Veterans Health Administration (VHA) has responded admirably following the outstanding report issued by this Subcommittee in October of 1998. The Policy Directive issued to all VHA facilities on June 11, 1998 is a very reasonable plan for a starting place to begin the process of testing and treatment. The Treatment Protocol issued by VHA to all Clinical Coordinators at the end of December 1998 is a reasonable approach, and a good starting basis for each medical facility to move forward with treatment. While we would hope that each of these policy statements and guidance documents will eventually be strengthened, they would be a reasonable start toward dealing with the veterans aspect of this epidemic, if there was a means of ensuring relatively uniform implementation.

"Don't Ask, Don't Treat"

Earlier this year, many of the VVA local leaders, in virtually every part of the Nation, told us that the VHA officials in their area were saying that the tests would be given when the VHA had the

resources and the means to set up their system to properly treat those who are tested and are shown to have the Hepatitis C virus. In response to this concern. VVA asked Dr. Toni Mitchell to meet with our VVA Veterans Affairs Committee, our officers, and many of our state presidents in late March. It was only in response to action taken by Dr. Kizer and by Dr. Mitchell subsequent to that meeting that many facilities started to actually order the riboflavin and interferon needed for treatment, and
at least starting the systematic process of testing the veterans in the ten risk group categories.

Today it is our belief that most facilities are *still* doing an inadequate job of actually testing for the Hepatitis C virus in a systematic manner, and are slow to treat in many cases. We are still hearing of Pharmacy Chiefs and VAMC Directors who are reluctant to order enough of the (relatively expensive) medications necessary to begin treatment in sufficient quantity to begin early treatment on suitable candidates for this very arduous process.

This lack of a concerted and highly visible outreach and rigorous testing campaign will have potentially devastating effects on the veterans involved as well as on the VA health care system that will have to deal with the aftermath of this not so benign neglect in the future. If left untreated many more of these veterans will develop symptoms of the virus, leading to very serious and debilitating diseases that may well result in liver transplant as the only option.

Lack of Resources

The extreme pressure on the Veterans Health Administration (VHA) of three years of "flat line" budget and the disastrous and woefully inadequate request from the President for the FY 2000 budget for VHA has cast a "chilling effect" on the motivation of the administrators in field to move ahead with doing their job properly for veterans potentially infected with Hepatitis C. While it is unacceptable and unconscionable for medical personnel to act this way, it is inexcusable for the President and the Congress to put these people in this situation of extreme and needless scarcity.

As important, VVA is concerned about the preservation of the organizational capacity (and in many cases the restoration of the organizational capacity) to have the physicians, nurses, and allied health care personnel to actually *do* the needed testing and treatment. The actual cost of the drugs is significant, but much less than the cost of the professional people to actually properly care for these sick veterans.

We ask your help, Mr. Chairman, and that of your distinguished colleagues in helping secure a more reasonable budget for VHA for FY 2000. While VVA believes that $3 Billion more that the President's budget request is truly needed, obviously the $1.7 Billion more being currently discussed in the Congress would do much to help keep the system from diminishing any further.

What Should Be Done

VHA should work with the veterans service organizations, the American Liver Foundation, and other public and private entities to mount a comprehensive, significant, extended, and prolonged public service campaign to get veterans who may have been exposed to come into the VA, enroll, and be tested. Most veterans do not regularly use the VHA facilities for their health care needs, and since this virus is "silent" most do not know that they are infected or even potentially at risk. This would perhaps be most effectively done as part of an overall coordinated Federal response to the Hepatitis C epidemic, while it is still in a relatively early stage.

VVA stands ready to do our part in such an outreach effort to spur testing of veterans, encouraging individuals to get tested now. It is our belief that many private groups as well as public entities and the media will be responsive to such a concerted and organized effort. However, VHA must take steps to ensure that their key personnel at the local level stand ready to "partner" with the veterans groups and the rest of the community in a meaningful and sustained manner.

VVA would also note that such efforts must be designed and implemented in such a manner that ***all*** subgroups in the veterans population are effectively reached. Ensuring that the community based groups that serve homeless veterans and other under served populations in greatest need is very important in this matter.

VHA should begin to rigorously ensure that all veterans currently registered for VHA services who meet the "at risk" profile have their blood tested for signs of the Hepatitis C virus. This is not happening at any medical facility we are aware of at the moment. Many veterans at risk (such as the former medic accompanying me today) have been trying to get tested for hepatitis C at a VHA facility, but it is on their initiative, not that of the VA.

It is our belief at VVA that this can be set up as a regular part of intake and yearly physicals by VHA by making it part of a computer program that indicates certain tests that must be given to a veteran based on his or her full military/medical history that is logged in as a matter of course. This is something that VVA believes should be done for many sound medical policy reasons in a "Veterans Health Care" system. VVA has engaged in discussions with top VHA leaders on this subject for several months, and VHA agreed this week to proceed with setting up a task group to begin the process of framing the design and implementation of this basic process.

VHA must also take steps to ensure that much more effective accountability mechanisms are put into

place that would enable the key national managers to monitor what is happening in the field. VVA has consistently called for much better and more effective modern accountability mechanisms within VHA. The problem is one of the top officials in VHA not knowing what is going on at the service delivery level, except by anecdotes told to them by others. There is no mechanism for systematic quality assurance quality assurance reviews in regard to Hepatitis C or for other vital measures. This is simply no way to manage a system as large and complex as the Veterans Health Administration.

VHA should work closely with the Surgeon General, the National Institutes of Health, and the Congress to help ensure that additional research is undertaken into more effective cures for eradicating the Hepatitis C virus. While VVA is appreciative that approximately $5 million in research funds will be made available this year, this sum is inadequate in the face of the potential danger of this medical epidemic. Our Nation can do better in pursuit of a more effective cure to this virus.

VVA would urge that the Department of Defense (DoD) be involved in this effort, and that you and your distinguished colleagues help DoD keep a positive attitude that is open to the virus being a potentially serious problem, as opposed to denying *a priori* that there could possibly be any substantial risk.

Mr. Chairman, that concludes my remarks. I would be pleased to answer any questions you might have. Thank you again for allowing us to present our views here today, and for your strong and vigorous leadership on so many vital issues that confront our Nation's veterans

Mr. SHAYS. Thank you very much.

At this time we are going to do the video for the 3 Members that weren't here, and then we will go to you, Mr. DiBisceglie, and then we will go to Mr. Brownstein.

[Video shown.]

Mr. SHAYS. Dr. DiBisceglie, if you would give us your testimony.

Mr. DIBISCEGLIE. Thank you, Mr. Chairman and other members of this committee. I have submitted written testimony.

First, I will say that I am a physician, a hepatologist, that is a liver doctor, and I have been involved in the care of patients with hepatitis and researching viral hepatitis for more than 15 years now. Part of that was while I was at NIH and when I left there I was chief of the liver diseases section. I am currently at St. Louis University and medical director of the American Liver Foundation.

I was asked to comment specifically on some aspects of hepatitis C, including appropriate standards for diagnosis. I think Dr. Holohan in panel I covered those points adequately enough; nothing to add, really.

Next was appropriate standards for treatment. Here I would say that the standards I think were set by the NIH consensus conference which was held in 1997. It laid out criteria for selecting patients for treatment. For example, they needed to have raised liver enzymes, positive hepatitis C RNA, a liver biopsy showing significant liver disease, and then they said also that patients who already have advanced liver disease, cirrhosis, or those where the liver disease was very mild could still be treated, but on an individual basis. Then they laid out conditions for categories of patients who should not be treated outside of clinical trials or with extreme caution, those who have normal liver enzymes, decompensated or very advanced cirrhosis, or the contraindications that we have heard about already this morning, active alcohol or drug abuse or a history of severe depression. I believe that these standards still are appropriate today.

What has changed since that NIH consensus conference is the development of an expanded array of therapies to treat patients. There are now 4 forms of interferons available and approved by the FDA. In addition, we have the use of ribavirin, which is used as an adjunct to interferon. To give you some numbers on that, because this came up with panel I, the data on developing a sustained response to the combination treatment overall is about 36 percent versus 16 percent using interferon alone.

I was also asked to comment on my view of the status of the VA program to test and treat veterans, and I am certainly aware of the designated VA Centers of Excellence and the information reported by panel I, and their achievements in such a short time have been remarkable and I commend them for that. But in order to find out what was happening at the local level, I sought information from the director of the division of gastroenterology at my local VA, the St. Louis VA Medical Center, to find out what was actually happening on the ground. This is an unusual VA because it is affiliated with two major medical schools, both of which have a strong interest in viral hepatitis, great expertise. They in fact had established a hepatitis C clinic about 2 years ago. So far in this clinic they have evaluated and counseled more than 200 patients testing posi-

tive for hepatitis C. They found that only about 1 in 10 of the patients in their specific clinic met the criteria for treatment and they are currently treating about 20 such patients.

This director of gastroenterology pointed out to me several problems that they have identified. Although they have been successful on the service, they have several problems. The first was the waiting list. To be seen in this clinic is about 6 months, so a patient diagnosed with hepatitis C to be evaluated by an expert would need to wait 6 months to be seen by these specialists.

Second, he felt that he was receiving insufficient support by pathology and laboratory services, and this concern relates to the limitations put on the use of HCV RNA testing, the blood test, and lack of formal training and experience in liver pathology by people seeing the liver biopsies done in these patients. Third, really insufficient knowledge about hepatitis C by their referring sources. Thus, many patients are referred inappropriately to the hepatitis C clinic or may not have had an adequate workup before they are referred then.

So I suspect that these issues at the St. Louis VA represent a microcosm of the situation nationally with some local variability.

Moving on from there, I would make a couple of additional points. Most of the focus so far has been on getting the veterans tested and evaluated for antiviral therapy now, but I think thought needs to be given to the future, to the expected rise in the incidence of liver failure and liver cancer or a hepatocellular carcinoma that will occur over these veterans over the next 2 decades and the resources for the wave of morbidity and mortality need to be developed.

Another important element of the VA program that I believe could be strengthened is research. Although there is already considerable VA-funded research, not much of it appears to be VA-specific. That is, there are many important questions to be addressed that could best be answered in the VA system.

For example, what exactly is the role of combat exposure in the transmission of hepatitis C? What are the mechanisms of resistance to therapy in some patients and how does this apply to the VA?

Finally, an issue key to the success of the VA program I believe is that it not be required or seem to require taking away resources from other VA programs. This is an element of discussion earlier with panel I.

Mr. Chairman, I will conclude my remarks there.

[The prepared statement of Mr. DiBisceglie follows:]

Testimony before the Subcommittee on National Security, Veterans Affairs, and International Relations on June 9, 1999.

Adrian M. Di Bisceglie M.D., FACP, Professor of Internal Medicine, Saint Louis University and Medical Director, American Liver Foundation.

Mr Chairman, firstly I am very pleased that the Veterans Administration and this committee have taken an interest and developed initiatives regarding hepatitis C among veterans. Those of us who are involved in the field and involved in the care of veterans have suspected for some time that this represents a major health problem for this population.

I have been asked to testify on some aspects of hepatitis C, including:

Appropriate standards for diagnosis.

We are very fortunate in having reliable and accurate screening tests available for hepatitis C. In particular the enzyme-linked immunoassay (ELISA, EIA) is able to detect close to 100% of infected individuals. This test is somewhat prone to false positive results, however, and to sort this out we sometimes have to rely on supplementary testing including RIBA (recombinant immunoblot assay) which confirms the detection of antibody to the hepatitis C virus (anti-HCV) and determination of hepatitis C viral RNA (HCV RNA). Tests for HCV RNA are detecting the virus itself in the bloodstream. This test is very sensitive but unfortunately very expensive. It is also subject to considerable variability because of lack of standardization between tests, none of

which are FDA approved. HCV RNA can also be assessed quantitatively - so in addition to being reported as positive or negative, one can determine the amount of virus in the blood. This has some limited use in predicting the outcome of antiviral therapy. Finally, determination of HCV genotype has recently become more clinically relevant. Thus there are at least 6 major recognized HCV genotypes. Some genotypes are more resistant to therapy than others (e.g genotype 1 and 4). Recent data suggest that patients infected with genotype 1 should be treated for 48 weeks rather than the 24 weeks recommended for genotypes 2 and 3 could be treated for shorter periods, thus decreasing cost of therapy.

Screening using the ELISA assay is recommended by the CDC for all individuals (veterans or otherwise) who meet the following criteria:

1. Persons who ever injected illegal drugs.
2. Persons with selected medical conditions, including: those receiving clotting factors before 1987, ever on chronic hemodialysis, who have persistently abnormal alanine aminotransferase levels
3. Prior recipients of blood transfusions or organ transplants (before 1992).
4. Health care workers after exposure to HCV-positive blood.
5. Children borne to HCV-positive women.

Appropriate standards for treatment

The NIH Consensus Conference of 1997 stated that patients meeting the following criteria should be treated 1) elevated serum aminotransferase (raised liver enzymes) 2) positive HCV RNA in serum 3) a liver biopsy showing significant liver disease in the form of fibrosis or inflammatory activity while patients with established cirrhosis or mild liver disease on liver biopsy could be evaluated and treated on an individual basis. They also felt that certain categories of patients should not be treated outside of clinical trials or with extreme caution, including those with normal serum aminotransferase levels or decompensated cirrhosis. Other contraindications to therapy listed include active alcohol or drug abuse and a history of severe depression. I believe these standards are still appropriate today.

These standards imply that each patient should undergo an initial evaluation by someone expert in this area. The evaluation should include a detailed history and physical examination, determination of a panel of blood tests aimed at establishing the severity of liver disease and excluding other forms of liver disease, virological tests including HCV RNA and HCV genotype (if need for treatment has been established) and liver biopsy which should be interpreted by an experienced pathologist.

Another important conclusion of the NIH Consensus Conference was the establishment of definitions of outcomes in response to therapy. Thus an "end of treatment (ETR) response refers to aminotransferase becoming normal by the end of therapy (biochemical response) or HCV RNA becoming undetectable by the end of treatment (virological response). Many patients who

have an ETR subsequently go on to have their hepatitis relapse in the months after therapy, and so what we have come to focus on is the rate of "sustained response (SR)" which refers to biochemical or virological response at least 6 months after stopping therapy. Patients who experience a sustained virological response usually remain in remission and in most cases remain virus free for years and even decades.

What has changed since the NIH Consensus Conference is the development of an expanded array of therapies to treat patients. The mainstay of therapy is still alpha interferon, of which there are four forms now available (interferon alpha-2b [INTRON A], alpha-2a [ROFERON], alpha-n1 [WELLFERON] and alpha con-1 [INFERGEN]. A major development has been the introduction of the nucleoside antiviral agent, ribavirin (REBETOL), as an adjuvant to interferon. Large scale controlled trial have shown the combination of interferon alpha-2b and ribavirin (REBETRON) significantly increase the rate of sustained response. Thus, among patients previously treated with interferon alone who initially responded but then relapsed, the combination therapy increased the response rate on re-treatment from about 5% to 47%. Similarly, among patients who have never been treated previously, the combination of interferon and ribavirin for a period of 48 weeks was associated with a sustained response rate of 36% compared to 16% with interferon alone. This combination therapy has now received FDA approval and has rapidly come to be considered the standard of therapy.

I must point out that these drugs are associated with significant side effects. Interferon is administered by subcutaneous injection - patients are usually taught to do this themselves. Possible side effects of interferon include a 'flu-like syndrome initially, with fatigue, bone

marrow suppression and emotional lability possibly occurring later. Most of these side effects are manageable and improve or resolve on decreasing the dose or stopping the drug. Deaths have ben reported due to suicide in patients with preexisting depression. Ribavirin is associated with a dose-dependent hemolysis (break down of red blood cells) which, if severe enough, may result in anemia. Rare patients with preexisting heart disease have experienced angina or even heart attacks while taking ribavirin because of the drug induced anemia. Thus, there are some patients for whom ribavirin is contraindicated, and in these cases interferon can be used by itself. At this stage, ribavirin is not available by itself and in fact it is marketed as a bundled package.

Status of VA program to test and treat veterans.

I am aware of the efforts of the two designated VA centers of excellence and their recent accomplishments with regard to education and research related to hepatitis C. Their achievements in such a short time have been remarkable and I commend them. I think it is important though to find out at the local level what these developments have led to. In order to best address this issue, I sought information from the director of the division of gastroenterology at my local VA, the St Louis VA Medical Center. Because this VA is affiliated with two major medical schools, both of which have strong interests in viral hepatitis, this station already has considerable experience in implementing a treatment program for hepatitis C. They established a hepatitis C clinic about 2 years ago. So far they have evaluated and counseled more than 200 patients testing positive for hepatitis C. They have found that only about 1 in 10 patients meet the criteria for treatment and they are currently treating almost about 20 patients with the combination of interferon and ribavirin. This station has not done much prospective screening for hepatitis C, except that all patients being evaluated and treated for substance abuse have a

hepatitis C test done routinely. Thus this clinic could be expected to expand considerably when all at risk veterans are tested. Although the St Louis station would seem to be a success story, they have identified several problems:

1. A waiting list to be seen in the clinic of about 6 months. Factors contributing to this include limited number of gastroenterology staff or others dedicated exclusively or largely to this activity. These staff also have responsibility for routine GI care of veterans, implementation of other mandated initiatives such as colorectal cancer screening as well as their academic (teaching and research) duties. These staff have also been told that according to the Lewin Report, they are overstaffed in gastroenterology.

2. Insufficient support by pathology and laboratory services. This concern relates to limitations imposed on HCV RNA testing and lack of formal training in liver pathology for histopathologists seeing liver biopsies.

3. Lack of knowledge about hepatitis C by referring sources. Thus many patients are referred inappropriately to the hepatitis C clinic or may not have an adequate workup done before they are referred.

I suspect that these issues at the St Louis VA represent a microcosm of the situation nationally, with some local variability. For example, there may be many stations that do not have the high level of expertise in liver disease and hepatitis C or the foresight found at our station. On the other hand, some stations may be better off because they have staff entirely dedicated to

evaluating and treating veterans with hepatitis C, while for our staff it is an added-on responsibility.

Most of the focus so far has been on getting veterans tested and evaluated for antiviral therapy. Only a small proportion seem to be eligible for treatment and I have heard little about plans for those who do not qualify for treatment. They will require observation and monitoring. In addition, thought needs to be given now to the expected rise if incidence of liver failure and hepatocellular carcinoma that will occur among veterans over the next 2 decades and resources for this wave of morbidity and mortality need to be developed.

An important element of the VA program that could be strengthened is research. Thus, although there is already considerable VA funded research already being conducted in viral hepatitis and liver disease, not much of it appears to be VA specific. There are many important questions to be addressed that could best be answered in the VA system. For example, what is the role of combat exposure in transmission of hepatitis C? What are the mechanisms of apparent resistance to therapy in some patients and how does this apply to the VA? An example of outcomes research would be an evaluation of proposed algorithm for diagnosis and treatment. Because the VA has such a strong research infrastructure, it is well positioned to develop and fund its own hepatitis C research agenda and I urge it to do so.

Finally, an issue key to the success of the VA program is that it not be required, or seen to require, taking away resources from other existing VA programs. Thus it is important that resources be made available to test, diagnose and treat veterans but <u>not</u> at the expense of their

other health care needs. If this is the requirement, my concern is that the system may not be able to get the job done and it may build resentment and therefore lack of cooperation among VA medical staff.

Mr. SHAYS. Thank you very much.

Mr. Brownstein, we will go with you and then I will have Mr. Towns ask questions, Mr. Sanders, and then I will ask questions.

Mr. BROWNSTEIN. Mr. Chairman and members of this subcommittee, my name is Alan Brownstein, and I am the president and CEO of the American Liver Foundation. I thank you for giving us an opportunity to have our organization present our views to you today concerning the risk of hepatitis C infection to veterans.

As a national voluntary health agency, our mission is to prevent, treat and cure hepatitis and other liver diseases through research and education. We are made up of chapters throughout the country, and we provide information to over 400,000 patients and families and over 70,000 physicians in America.

The prevalence of hepatitis C in the United States is staggering. We have 4 million Americans who have hepatitis C, 10,000 with hepatitis C die every year, and as you heard before, hepatitis C is the leading cause of liver transplantation. Overall, 1.8 percent of all Americans have hepatitis C. What is shocking for this meeting here, as if that isn't shocking enough, is that 8 to 10 percent of all veterans have hepatitis C.

Clearly, hepatitis C is a major health challenge for America, and in fact, will be the most significant infectious disease challenge as we enter the 21st century for us, but it is also an incredible challenge for U.S. veterans. Because hepatitis C is a quiet, a silent kind of virus, the vast majority of veterans with hepatitis C are not aware that they have it, because they do not have symptoms. We have heard a lot about treatment and that somewhat less than 40 percent of those who are eligible for treatment to receive it have a sustained response. It is also important to identify all veterans who have hepatitis C because there are other interventions that can help.

Concretely, it is incredibly important that people with hepatitis C not drink. Drinking is like throwing gasoline onto a fire, so it is very important that this kind of message is given to those with hepatitis C. Also, it is of great importance that those with hepatitis C be vaccinated to protect them against hepatitis A and hepatitis B. While that is important for all Americans in many important areas, it is especially important for those who are infected with hepatitis C so that they are protected against additional liver damage.

I would like to thank this committee and the chairman of this committee, because we appreciate the leadership that you have provided to focus America on hepatitis C. In your October 1998 report, Hepatitis C: Silent Epidemic, Mute Public Health Response, that is incredible, because I think the humor in that title really underscores how serious the problem is. You have really opened our eyes, so I thank you for that. It says indeed, your input has paved the way for this veterans initiative, as the report pointed out, to the problem in U.S. veterans where you said that the Department of Veterans Affairs should conduct additional studies of the prevalence of hepatitis C in veterans' populations.

As the chairman knows, on March 17, 1999, the VHA conducted a very significant national blood test of 26,000 veterans for hepatitis C antibody and found a prevalence rate of 8 to 10 percent as

I mentioned before. This is more than 5 times the national rate. And we also—the committee's foresight in calling for this test has confirmed the need and has paved the way for the $250 million that we hear has been requested by the Department of Veterans Affairs for fiscal year 2000.

Our view of what the Veterans Health Administration has done is, others say that we are really very impressed with the mobilization that they have put forward in launching an attack against hepatitis C among veterans, and that the mobilization has been put into place. Now we are looking at implementation, full implementation in the year, in the years ahead. We believe that this implementation presents several critically important challenges.

First of all, the $250 million of treatment that has been committed will not happen, it will not occur unless the infrastructure is developed. You cannot just have money for treatment without having the mechanisms to deliver the care. So the worst thing that could possibly happen is you reconvening this body next year and finding out that only $30 million, $50 million or $75 million was spent in the year 2000. That would indeed be a tragedy, because that would not signify that there isn't a need, it would signify that we haven't effectively translated that need into an effective demand that can be responded to.

So that is the first challenge, and we believe that this is an important challenge to the Department of Veterans Affairs; it is also an important challenge to Congress and also to the private sector and the American Liver Foundation is prepared to assist in whatever way we can from the private side, as I know other organizations are willing to do as well.

The second challenge is that $250 million of treatment will not happen unless providers, the health care providers, the primary care providers within the VA are well—and all of those who are associated with the VA are well educated, well educated about hepatitis C. It is interesting because the American Liver Foundation has done many consumer awareness campaigns and our hotline gets about 15,000 calls a month. After we do campaigns, what we have learned is that people call us and they tell us we followed your advice, we went to the doctor and the doctor said it wasn't necessary to get tested, or we were tested and the doctor told us that it wasn't necessary to pursue treatment or not to worry about it. So while we are doing this campaign, we have an incumbent responsibility to make sure that the providers who are associated with treating veterans are well educated about hepatitis C.

The third challenge is that the $250 million of treatment will not occur unless there is an effective awareness campaign directed at U.S. veterans. In other words, most are not aware they have it; most don't have the—the overwhelming majority don't have symptoms. Often, when you have symptoms, it is too late. So it is very important that we spark public awareness. And this again, public and private sector partnerships offer a great potential for us to really attack hepatitis C among veterans. One example is the public service announcement that you see here, but a heck of a lot more is needed to get that message across. So we have to use health education techniques, but also commercial techniques at

selling hepatitis C, explaining what hepatitis C is all about to veterans in the broadest sense.

But again, the broadest sense is not enough. The attention of veterans is captured. Once that happens, we will not succeed unless we meet the challenge of veteran education and outreach. It is extremely important that we reach those who are affected in culturally appropriate ways. We need to address the different subgroups within the veterans population. It is no longer a one-size-fits-all world. We must have targeted messages at veterans from different cultural, racial and ethnic backgrounds. There need to be different literacy levels to make sure those messages reach those veterans, and there needs to be a system of support groups so that the veterans have that background of support as they are struggling through the difficulties that many experience in their treatment, as well as the difficulties that will be faced by many who will not respond well to the treatments.

The next challenge is that if we are going to commit $250 million to fighting this disease among veterans, it is extremely important that we put accountability mechanisms in place so that we can figure out and we can look in the mirror and say, are we succeeding in this enterprise, and if we are not, how can we develop the corrective strategies to better do what we need to do to reach the veterans who are affected by hepatitis C, and to us, we believe accountability includes performance measures for testing, diagnosis and treatment; performance measures for outreach and education, establishing a data base to measure performance, and also having an annual report of results so that we can constructively move forward.

And then the last challenge that I would like to present in closing is that we need to maintain the momentum. As Dr. DiBisceglie and others have pointed out, it is extremely important that we understand this is not going to be a 1-year solution. We have to be in this for the long haul. And from the private sector side, the American Liver Foundation has formed its own veterans hepatitis C and liver disease council that will include members from leadership from the top veterans service organizations and top medical and scientific people in and out of the VA. So we are prepared to work with you, and we need to have that kind of a partnership.

We really need to look at this headline that was in yesterday's USA Today. It says millions hit hepatitis C deadline. What it means is that unlike HIV, which moves pretty quickly, hepatitis C is a slow burn in its natural history progression for most people. However, even though it progresses slowly, we now have veterans who have been exposed to hepatitis C for 10, 20 and even 30 years. So now we are in a race against time for those where there is inexorable damage that is being done to their livers. So that really now is the time to act and we need to have the urgency.

I thank you, Mr. Chairman and the members of this subcommittee, for creating this sense of urgency about this very serious public health challenge that we face today. Thank you.

[The prepared statement of Mr. Brownstein follows:]

STATEMENT
OF
THE AMERICAN LIVER FOUNDATION

PROVIDED
TO
THE UNITED STATES HOUSE OF REPRESENTATIVES
COMMITTEE ON GOVERNMENT REFORM

SUBCOMMITTEE ON NATIONAL SECURITY,
VETERANS AFFAIRS
AND
INTERNATIONAL RELATIONS

BY

ALAN P. BROWNSTEIN, MPH
AMERICAN LIVER FOUNDATION
PRESIDENT AND CHIEF EXECUTIVE OFFICER

JUNE 9, 1999

The American Liver Foundation

Mr. Chairman and members of the Subcommittee, my name is Alan P. Brownstein and I am the President and Chief Executive Officer of the American Liver Foundation (ALF). Thank you for giving our organization the opportunity to testify before you today regarding the vulnerability and risk of veterans to hepatitis C infection and the response of the Department of Veterans Affairs.

ALF is a national voluntary health organization dedicated to the prevention, treatment and cure of hepatitis and other liver and gallbladder diseases through research and education. ALF has 30 Chapters nationwide and provides information to more than 300,000 patients and families. More than 70,000 physicians and scientists, including primary care practitioners and liver specialists, also receive information from ALF.

The ALF Board of Directors is composed of scientists, clinicians, patients and others who are directly affected by liver disease. Every month, ALF receives approximately 15,000 calls requesting information about hepatitis and other liver diseases. Over 90% of those calls are about hepatitis.

ALF was founded 23 years ago by the American Association for the Study of Liver Diseases. In recent years, ALF has provided more than eight million dollars to support hepatitis/liver disease research and more than seven million dollars to promote public awareness about hepatitis.

The Prevalence and Impact of Hepatitis C in the United States and Among Veterans

Hepatitis C as an "emerging infectious disease" is one of the most serious public health problems that the United States will face as we enter the 21st century:

- Four million Americans have hepatitis C and most don't know it.
- Ten thousand hepatitis C patients die every year in the United States.
- Hepatitis C is the leading cause of liver transplantation.

Hepatitis C is a democratic disease that affects everyone – all races, men, women and children. It mirrors mainstream America…doctors, lawyers, teachers and even soccer moms, not just those who received blood transfusions prior to 1992 and illegal injection drug users. However, it is important to recognize that some populations are more vulnerable to chronic hepatitis C than others. For example:

- 1.8% Overall U.S. population
- **8-10.0% Veterans**
- 3.5% Overall population between the ages of 35-55
- 1.5% White
- 3.2 % African-American
- 2.1% Mexican-American.

Clearly, hepatitis C is a major health challenge for U.S. veterans that has now been well documented. Because hepatitis C is a "quiet" virus, the vast majority of veterans with hepatitis C do not have symptoms, and thus, are unaware that they are affected. This combined with the prevalence of hepatitis C, and the fact that it is a serious, potentially life-threatening condition, underscores the importance of identifying those veterans who are infected. And further, new studies show that treatment succeeds in about 40% of patients who are suited for treatment. And even for those who do not respond to treatment, it is important that they become aware, because there are interventions that can significantly slow down the progression of hepatitis C damage to the liver – for example, by abstaining from drinking alcohol, and making sure they are immunized to protect them from hepatitis A and B.

Mr. Chairman, the American Liver Foundation greatly appreciates your leadership to focus the Executive Branch's attention and resources on the fight to increase testing and treatment for hepatitis C and other liver diseases. In many ways the report issued by the Committee in October 1998... "Hepatitis C: Silent Epidemic, Mute Public Health Response" paved the way for the very significant progress we are now seeing in the Veterans Health Administration (VHA).

That report recommended that... "The Department of Veterans Affairs should conduct additional studies of prevalence of HCV in veterans populations." As the Chairman knows, on March 17, 1999, the VHA conducted a very significant national blood test of 26,000 veterans for HCV antibody and found a prevalence rate of 8 to 10%, or more than 5 times the national rate of 1.8%. The Committee's foresight in calling for this test has confirmed the need and paved the way for a $250 million hepatitis C testing and treatment program at the Department of Veterans Affairs proposed for FY 2000.

Veterans Health Administration Response

On April 30, 1999, the American Liver Foundation presented Drs. Kenneth W. Kizer and Toni Mitchell with our Government Achievement Award at our Annual Awards Banquet. This award was presented in recognition of their numerous accomplishments in a short period of time in order to meet the hepatitis C health needs of U.S. Veterans:

- Commitment of $250 million of VHA budget to treat hepatitis C
- Issued hepatitis C standards for provider evaluation and testing (June 11, 1998).
- Established two "Hepatitis C Centers of Excellence" at VA Medical Centers in Miami and San Francisco.
- On March 17, 1999, conducted a Hepatitis C Day in which 26,000 blood samples were drawn at VISN/VAMCs across America in one day in order to document the prevalence of hepatitis C in the veteran population. (This is an unprecedented public health achievement!)
- Conducted a National Hepatitis C Symposium on June 3-4, 1999 in which health professionals throughout the VHA network were provided two days of in-depth training about hepatitis C testing, diagnosis, treatment and counseling.

Over the past year, ALF has witnessed an impressive mobilization on the part of the leadership of VHA and the two Hepatitis C VHA Centers of Excellence. In fact, ALF and the American

Digestive Health Foundation provided VHA with 50,000 copies of our brochure, "The Hepatitis Information You Need to Know" (attached). These brochures were distributed on Hepatitis C Day described above.

Challenges for the VA Hepatitis C Testing, Diagnosis & Treatment Program

While it is clear that the commitment and significant budgeted support (i.e., $250 million) is in place to launch a public health campaign directed at hepatitis C among U.S. veterans, many challenges lie ahead. If these challenges are not addressed, it will not be possible to spend anywhere near the $250 million that has been budgeted. This is largely due to the fact that hepatitis C is, for the most part, without symptoms. Therefore, the hepatitis C "need" has not been translated into an effective "demand." More public awareness, education, and outreach are needed to correct this problem. To the extent that we succeed and the "need" is more recognized, the "demand" will increase, which is happening at this time. It is essential that the "supply," or the "infrastructure" be developed to meet the increase in demand. Some of the challenges facing this major public health undertaking are identified below along with the identification of some public and private sector partnership opportunities.

Challenge #1 - Infrastructure Development

In order to meet the increased demand for hepatitis C services, additional health personnel will be needed at the VA's VISN/VAMC Network in the following areas:

- **Medical**
  - Specialty
  - Primary Care
- **Psychosocial** dimension needs priority consideration
  - Depression (e.g., PTSD)
  - Alcohol
  - Drug Dependence
- **Managerial/Communications/MIS Personnel Support**

- **Public Sector**

  Additional funding support needs to be identified to provide the additional personnel that will be needed over the next 4-6 years to meet the demand for hepatitis C treatment.

- **Private Sector**

  Methods for training primary care personnel to manage hepatitis C patients in consultation with specialists need to be explored. One such method being considered at ALF involves a Draft Plan (Attachment 2) designed to increase the "Quantity and Quality of Health Care Services Provided in the Management of Chronic Hepatitis C Through the Expanded Use of Nurse Personnel" (attached). This plan has the potential for developing a training module coupled with a recruitment strategy to bolster the supply of hepatitis C certified nursing personnel available for employment within the VHA Network or through some external contract mechanism should the expansion of FTEs not be feasible. Developing and implementing this recruitment and training initiative could be done for $1.5 million over two years.

Challenge #2 – Health Provider Education

Many health care providers know very little about hepatitis C, and even less about new diagnosis and treatment opportunities. It is essential that VHA provides ongoing education to primary care providers within the system.

- **Public Sector**

  Over the past year, VHA communications, the designation of the "VA Hepatitis C Centers of Excellence" and the National Hepatitis C Symposium (June 3-4, 1999) are excellent examples of how VHA is seeking to educate its personnel. It appears that VHA is seeking to make sure information on hepatitis C is communicated to its health personnel on an ongoing basis.

- **Private Sector**

  ALF and the American Digestive Health Foundation were proud to provide their "The Hepatitis Information You Need to Know" brochure (attached) to all medical personnel throughout the VISN Network during Hepatitis Day on March 17.

  ALF has been running an ad "Combating a Crisis" (see attached) in numerous primary care journals. It is also using this ad in conjunction with mailings to primary care physicians through health departments. This ad, which provides succinct information for primary care practitioners about hepatitis C, can be easily adapted to be specific for VA primary care practitioners. ALF would be pleased to do this in consultation with VA hepatitis C leadership and have it distributed throughout the VA system.

  ALF is currently exploring ways in which it could assist in training primary care practitioners through its nationwide network of chapters and their medical leaders, many of whom are involved in their local VISN/VAMCs. There are numerous ways in which public and/or private resources can be used for this purpose.

Challenge #3 – Veteran Education and Outreach

Educational materials and outreach strategies must be employed to stimulate the vast reservoir of unmet needs among undiagnosed veterans with hepatitis C.

- **Public Sector**

  Ongoing communications between VHA and VSOs. Development of educational materials through the VA Hepatitis C Centers of Excellence.

- **Private Sector**

  Educational Materials

  ALF is currently developing low literacy informational brochures about hepatitis C directed to the 3.5 million veterans associated with the VA system. This will be completed in June and ALF is currently seeking to identify resources for distribution of this information to all VA-affiliated veterans. Spanish and other languages are being explored.

  ALF Chapters

  ALF is currently working with its chapters to develop two programs targeted to veterans:

  - **Meet the Researchers** – ALF's educational series featuring leading liver specialists. Working with local VISN/VAMCs, ALF plans to hold up to 36 symposiums the first year throughout the U.S. focusing on issues specific to veterans. These half or full day conferences will be sponsored by both ALF's local chapters and National Office. The symposiums will provide veterans with access to current information on treatment and disease issues that might not otherwise be readily available.

  - **Support Groups** - ALF chapters will be forming support groups targeted to veterans. Support groups provide a forum to share concerns about diagnosis and treatment, discuss coping issues and provide support from other veterans. These support groups also provide another opportunity for education as local health care providers are invited to participate by speaking at these meetings. Over the next year, ALF expects to form 30 support groups meeting monthly through local chapters. A health care professional will be hired to coordinate and facilitate each group.

  - **Outreach** – ALF has developed cultural "blueprints" targeted to different racial and ethnic populations for hepatitis awareness. These efforts and materials need to be developed and implemented in culturally appropriate ways.

Challenge # 4 – Stimulating Hepatitis C Awareness Among Veterans

ALF is conducting market research as part of our effort to get a better understanding of what veterans "know" and "don't know" about hepatitis C. Attachment 1 provides you with some sample veteran survey questions that were asked over the past week to 700 veterans. Question 14 and a number of related questions probe what veterans "know" and "don't know" about hepatitis C. Question 20 and a number of other related questions address veteran behaviors in relation to health information. And lastly, question 27 along with a number of others address perceived physician behaviors on the part of veterans. This data is currently being tabulated and we will be pleased to share the results with this Subcommittee when the analysis is completed over the next two weeks. The analysis will include different demographic features that will enable us to better organize and target our overall education and outreach programs.

ALF has initiated a public awareness initiative called "Veterans Join Forces Against Hepatitis C" which includes the public service announcement that you have already seen. This PSA profiles Terry Baker, a Vietnam veteran infected with hepatitis C. The PSA will be distributed to all major networks and their affiliate stations.

Press materials for "Veterans Join Forces Against Hepatitis C" are being developed for distribution to national media outlets. TV and radio interviews will be given. Articles and veteran profiles will be written to capture the human impact of the disease. All this is being done in close consultation with VSOs so that we get the input that we need to educate American veterans about hepatitis C. Through these alliances ALF will continue its advocacy at the local, state and national levels.

Challenge # 5– Accountability

For all the challenges listed above, it is important that accountability mechanisms be established by the VA that include the following:

- performance measures for testing, diagnosis and treatment
- performance measures for outreach and education
- establishing a database to measure performance
- annual reporting of results.

Challenge # 6– Maintaining the Momentum

The hepatitis C liver disease problem facing veterans is not a one-year campaign. Instead, it will require a long-term commitment from the public sector and the private sector. It will also require a comprehensive use of different medical, psychosocial, and economic supports if it is to be successful in the long term. Towards that end, in April 1999, the ALF authorized the creation of the "ALF Veterans Hepatitis C and Liver Disease Council" that will be made up of leading research scientists, leading clinicians, and leadership from VSOs. It is important that the public

sector appreciates the importance of maintaining this commitment with adequate funding through the VA-HUD Appropriations Subcommittee. Additionally, Mr. Chairman, in keeping with your October 1998 report, we support the Committee recommendation that "the Department of Defense should test recruits, active duty personnel and those about to be discharged for hepatitis C infection." We are hopeful that with your leadership, Defense Appropriations Subcommittee Chairman Jerry Lewis would include such a requirement in the Committee bill report language.

Again, we thank you for your leadership on these important matters.

COMBATING A CRISIS: 4 MILLION REASONS TO IDENTIFY PATIENTS WITH HEPATITIS C

A looming threat to public health

Approximately 4 million Americans are infected with the hepatitis C virus (HCV), making it the most common chronic blood-borne disease in this country. And while there is ample reason for concern, there is also reason for new hope. New studies show that recent advances and new therapies greatly improve the chances of patients achieving a lasting response.

Because hepatitis C is a "quiet" virus, the vast majority of hepatitis C patients do not experience or display any overt symptoms of liver disease, and are unaware that they are infected. This, combined with the prevalence of hepatitis C and the fact that it is a serious, potentially life-threatening condition, highlights the importance of identifying patients who are infected.

Recent NIH conference on hepatitis C

Due to the rapid pace of change with this viral disease, the National Institutes of Health (NIH) convened a closed symposium entitled "Hepatitis C: A Meeting Ground for the Generalist and the Specialist" in December 1998.

The goals of the meeting were to discuss the prevalence and seriousness of this condition, as well as present data on the latest advances in diagnosing and treating hepatitis C. The meeting also emphasized the need for careful teamwork between primary care physicians, specialists, and their hepatitis C patients.

Primary care and hepatitis C

As many as 70% of those patients infected with HCV are unaware that they carry the virus. There are few "warning signs" that a patient is infected. Thus, familiarity and recognition of the risk factors associated with HCV infection becomes crucial.

The Centers for Disease Control and Prevention (CDC) has identified risk factors clearly associated with HCV transmission, as well as potential risk factors that have not been definitively established at this time. These risk factors are listed below.

RISK FACTORS FOR HEPATITIS C

Established risk factors	Potential risk factors
Receipt of blood transfusion or organ transplant prior to 1992	*Unprotected sex with multiple partners or having a history of sexually transmitted disease*
Intravenous drug use—even once	*Tattooing or body piercing in unsanitary conditions*
Long-term hemodialysis	*Intranasal cocaine use*
Receipt of clotting factor made prior to 1987	
Household exposure—sharing razor or toothbrush with an HCV-infected person	
Healthcare, emergency medical, and public safety workers exposed to needle sticks, sharps, or mucosal exposures to HCV-positive blood	
Being born to an HCV-infected mother	

Like other diseases of the liver, hepatitis C often does not cause recognizable symptoms until patients have progressed to severe liver disease. Often, an elevation in ALT levels is the only indication of hepatitis C infection. The elevation in ALT doesn't have to be severe—even slight elevations can indicate the presence of HCV. Physicians should consider the presence of hepatitis C in patients with elevated ALT levels, particularly in the presence of one of the risk factors listed above. (Note: there is a significant subgroup of patients with hepatitis C who have normal ALT levels.)

HCV antibody testing

The enzyme immunoassay (EIA) test is generally the first test used for hepatitis C. A positive response to the test indicates the presence of antibodies to HCV. The test is inexpensive and easy to conduct. A positive response to this test usually indicates that consultation with, or referral to, a specialist is in order.

Staying involved in your hepatitis C patients' care

It has been estimated that roughly one in fifty (1.8%) Americans is currently infected with hepatitis C. Only a small fraction of these individuals are aware they are HCV positive. The availability of better treatment means that it is more important than ever to identify hepatitis C patients.

As a primary care physician, you are the healthcare professional your patients trust most. Your role in treating hepatitis C is crucial. Successful treatment of this serious condition requires coordinated teamwork between you, your patients, infectious disease specialists, gastroenterologists, and hepatologists. The proper blend of compassion, counseling, and treatment can ensure that your patients are given a real chance to overcome the obstacles hepatitis C presents.

This bulletin is brought to you by the American Liver Foundation, as part of our mission to prevent, treat, and cure hepatitis C and other liver diseases through research and education. If you have any questions you would like answered by a liver specialist, or if you would like any further information about hepatitis C for you or your patients, please contact us at:

www.liverfoundation.org

1-800-GO LIVER (465-4837)

American Liver Foundation

Attachment 2

APB – 3/99
DRAFT #2
For Discussion Purposes Only

DRAFT

Increasing the Quantity and Quality of Health Care Services Provided in the Management of Chronic Hepatitis C Through the Expanded Use of Nurse Personnel

Problem

There are 4 million Americans with chronic hepatitis C, with most in the 30-55 age cohort, entering into their second or third decade of infection. There is an inexorable natural history progression of hepatitis C disease in this cohort to more serious, life threatening, liver disease. At the same time, there are more initiatives that are stimulating public and health professional awareness about hepatitis C as well as increased educational materials available. Lastly, more promising treatment results have been documented offering more attractive therapeutic options for patients with chronic hepatitis C. These three factors have contributed to converting the unmet needs of millions of patients with hepatitis C into an effective demand that is now overtaxing the capacity of the existing supply of health professionals. This demand is expected to further outpace the supply of health resources to respond. Most immediate, a major increase in demand is expected over the next year as the Department of Veterans Affairs launches a major initiative among veterans to screen and treat those who have chronic hepatitis C. Therefore, there is an urgent need to focus on developing the infrastructure to more effectively meet this demand over the next one to two years.

Expanding the Use of Nurses in the Management of Hepatitis C Patients

Nurses represent a resource that should be targeted for development for expanding the capacity to treat patients with chronic hepatitis C. Nurses have a body of medical knowledge that is complemented by knowledge needed for the overall management of the patient's other-than-medical health-related needs. In order to meet this urgent infrastructure problem, nurses represent a priority resource for developmental focus. Nurses can be recruited from within existing institutions as well as being recruited for career reentry in full or part-time positions. A hepatitis C nurse development program should be developed with the following objectives in mind:

Short-Term

- By the end of 2000, increase the supply of hepatitis C certified nurses to increase the service capacity by 25%.

Intermediate-Term

- By 2002, develop models for the delivery of comprehensive health care services for patients with hepatitis and liver disease with the nurse in the position of leadership for overall patient management.

In order to achieve this, a training program would be developed to provide interim certification of nurses to meet the short-term (year 2000) objective. It is envisioned that nurses would be trained and designated as "hepatitis/liver disease certified." Certification would be provided upon successful completion of an intensive two-day course that may be organized as follows:

DRAFT

Topic	Hours
Orientation to the Liver	2
Children's Liver Diseases	1
Auto-Immune and Cholestatic Liver Diseases	1
Hemachromatosis and Other Genetic Liver Disease	1
Alcohol-Related Liver Disease	1
Hepatitis A, B and C	4
Psycho-Social Dimensions of Liver Diseases	2
Healthcare Delivery and Financing	2
Case Presentations	2

The development of this curriculum would be done in such a way so that experienced nurses and newcomers would both be able to benefit. For example, the medical content would be reasonably thorough for a nurse beginning in the position of clinical responsibility. This would be of great benefit to the newcomer, but would be largely known by the experienced nurse. However, the overall presentation of the material would have a distinct focus on patient and family health education skills development for the nurse as well as treatment compliance issues. Each of the topic areas would be designated as modules with the development of a teacher's handbook accompanied by leave-behind materials to share with patients and families. A mentoring program is envisioned for newly certified inexperienced nurses.

Efforts will be made to recruit other health professionals (e.g., physician assistants, residents) to become certified.

Dr. Adrian Di Bisceglie has agreed to serve as medical advisor to the development of the curriculum and modules.

Process/Timetable

The American Liver Foundation would seek to form an alliance with SGNA to form an ALF Nurses Committee that would be made up of nurse leaders from different regions of the country who are involved with SGNA as well as some balance of nurses in leadership positions with various manufacturers. The Committee would have "members" or "liaisons" providing input from other health professionals targeted for certification. The Nursing Committee would review the above curriculum outline model and then proceed to develop their own within certain time and budget constraints for Phase 1/Objective 1 of this project. The Committee would be staffed by ALF.

DRAFT

The following timetable would be used:

May 1999	Convene Nursing Committee - 1 full day - Review/finalize curriculum outline
May-June 1999	Professional writers/health educator develop first draft of modules designed for nurse educators and patients/families.
July 1999	Nursing Committee meets to review draft modules.
August 1999	Nursing Committee meets to finalize educational materials for modules.
October 1999 - April 2000	Workshops are organized at 22 sites throughout U.S. in collaboration with VA, VSNs.
June 2000	Nursing Committee meets to review effectiveness of regional workshops and to begin to address objective to the development of comprehensive care models for the delivery of Hepatitis/Liver Disease Services.

ATTACHMENT 3

SAMPLE VETERANS SURVEY QUESTIONS

14. Based on what you know or have heard, is hepatitis C spread by any of the following:

- ❑ Exposure to Contaminated Blood
- ❑ Contaminated Food
- ❑ Shared Intravenous Drug Needles
- ❑ Sex with Multiple Partners
- ❑ Blood Transfusions Prior to July 1992
- ❑ Tattooing with Improperly Sterilized Equipment
- ❑ Other

20. Medical studies have shown that veterans are at increased risk for hepatitis C. Now that you know this, how likely are you to get tested?

- ❑ Very Likely
- ❑ Likely
- ❑ Not Very Likely
- ❑ Not at All
- ❑ Don't Know

27. Because you are a veteran, has your physician suggested that you get tested for hepatitis C?

- ❑ Yes
- ❑ No
- ❑ Don't Know

American Liver Foundation

DHI® Viral Hepatitis Education Campaign

The American Digestive Health Foundation™ (ADHF™) and the American Liver Foundation (ALF) have formed an alliance to combat viral hepatitis A, B, and C. The Digestive Health Initiative® (DHI®) Viral Hepatitis Education Campaign is educating consumers, patients, physicians, policy makers, and other healthcare professionals about hepatitis to improve the prevention, diagnosis, and treatment of these diseases.

The American Digestive Health Foundation™ (ADHF™) is a cooperative effort of the American Gastroenterological Association, the American Society for Gastrointestinal Endoscopy, and the American Association for the study of Liver Diseases. ADHF™ promotes digestive health for all Americans by supporting educational initiatives and research into the causes, prevention, diagnosis, treatment and cure of digestive and liver diseases.

The American Liver Foundation (ALF) is a national voluntary health organization dedicated to preventing, treating and curing hepatitis and other liver diseases through research and education.

The activities of the DHI® Viral Hepatitis Education Campaign are made possible through unrestricted educational grants from: Major Sponsors Amgen, Inc., Chiron Corporation, Glaxo Wellcome, Inc., and Schering-Plough Corporation.

For additional information about the DHI® Viral Hepatitis Education Campaign contact:

American Digestive Health Foundation™
1-800-668-5237 www.ADHF.org
American Liver Foundation
1-888-4HELP-ABC www.liverfoundation.org

The Veterans Affairs Health Administration (VA) is dedicated to the identification, counseling and treatment of all veterans with viral hepatitis.

© American Digestive Health Foundation and American Liver Foundation

Vaccines Stop the Spread of Some Hepatitis Viruses

Vaccines for hepatitis A and B can provide long term protection from these diseases. Unfortunately, there is no vaccine for hepatitis C.

Hepatitis A Vaccine

The hepatitis A vaccine is recommended for people over the age of two who:

- Travel to countries with high rates of HAV infection (Mexico, the Caribbean, Central and South America, Africa, and some parts of Asia)
- Are children living in communities with high rates of the disease or regular outbreaks
- Have chronic liver diseases, including HBV and HCV infection: HAV can increase liver damage and can be fatal to these patients
- Engage in oral/anal sex

The HAV vaccine is given in two doses, 6 to 18 months apart, and it takes 30 days to take effect. For people already exposed to the virus, immune globulin can reduce the risk of infection if given within 14 days of exposure.

Hepatitis B Vaccine

This vaccine is recommended as part of the routine schedule of childhood immunizations. Many states require this vaccination for entry to elementary school.

Because the vaccine was not routinely given to infants until 1991, children born before then may not be protected. Immunization experts recommend vaccination of all children up to age 18 to fill this gap. The government's Vaccine for Children program will pay for immunizations for eligible children up to 18 years old.

Experts also recommend immunization for:

- Infants born to HBV-infected mothers
- People with chronic liver diseases, including HCV infection
- People who have unprotected sex with more than one sexual partner
- People who are exposed to blood in the workplace, including health care and emergency service workers

Impact of Viral Hepatitis

Hepatitis A infects up to 200,000 Americans each year. Some communities have cyclical outbreaks every decade, and 29 million people travel to places with high rates of HAV infection. Although hepatitis A rarely causes long-term health problems, it can create economic hardship through wages lost during the recovery period.

Hepatitis B is a preventable tragedy. Yet, 128,000 – 320,000 Americans become newly infected every year. Although 95% of infected adults fight the virus successfully, more than one million people have chronic HBV infection, and 5,000 people die each year. We can eradicate this virus. Preteens through young adults are at risk, as the vaccine was not available to them as infants. All pregnant women should be tested so that infection can be prevented in their newborns.

Within the next 20 years, the hepatitis C epidemic is expected to cause more deaths annually than AIDS. Although the rate of new infections is now greatly reduced, most of the almost 4 million people with HCV were infected years ago and are unaware of their condition. If they are not tested and evaluated for liver damage and the potential to benefit from treatment, many may develop liver damage and liver failure.

Getting Help and Information

Sources of information and support for people affected by hepatitis include:

American Liver Foundation (ALF) for more information about hepatitis and to link with local ALF chapters and support groups.
1-888-4HELP-ABC, www.liverfoundation.org

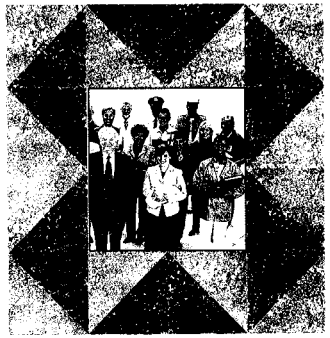
American Digestive Health Foundation for educational materials for physicians, other health care providers and consumers,
1-800-668-5237, www.ADHF.org

Centers for Disease Control and Prevention (CDC),
1-888-4HELP-CDC, www.cdc.gov/ncidod/diseases/hepatitis

National Digestive Disease Clearinghouse,
1-301-654-3810, www.niddk.nih.gov

Local public health department for information about possible free or low-cost testing, vaccination, and referral for treatment

The Hepatitis Information YOU Need to Know



The Impact of Viral Hepatitis in Our Community

A Family of Viruses Affects All People.

Viral hepatitis is an infection of the liver that affects people from all walks of life regardless of age, race, gender, or sexual orientation.

The Hepatitis A Virus (HAV)

HAV infection can cause an acute, flu-like illness with yellowing of the skin (jaundice), nausea and vomiting, fatigue, loss of appetite, abdominal pain, or diarrhea. It lasts from 3 to 6 weeks, but can persist up to 6 months. Most patients recover with no serious long-term health problems. Symptoms are more severe in adults than in children who often have no symptoms. HAV is spread when infected human feces is ingested by mouth.

The Hepatitis B Virus (HBV)

HBV infection can cause symptoms similar to HAV. Most adults fight off infection and have no long-term health problems. But in 5% of cases it becomes chronic (lasting more than 6 months), and can then cause cirrhosis (scarring of the liver), liver cancer, and liver failure, resulting in 6,000 deaths a year. HBV is spread through contact with infected body fluids or blood.

The Hepatitis C Virus (HCV)

HCV infection persists in 85% of cases, and often causes no symptoms until liver damage has occurred many years after infection. It too can cause cirrhosis, liver cancer, and liver failure, and it is responsible for 8,000 to 10,000 deaths a year. HCV is spread through blood-to-blood contact.

Viral Hepatitis: A National Health Problem

	ESTIMATED NEW INFECTIONS PER YEAR IN THE UNITED STATES	ESTIMATED INFECTIONS LASTING MORE THAN SIX MONTHS
HAV	125,000 – 200,000	None
HBV	128,000 – 320,000	1 – 1.25 million (5% of all HBV cases)
HCV	36,000 (1996 data)	3.9 million (85% of all HCV cases)

Avoid the Risks of Viral Hepatitis

Avoiding the risks can prevent infection.

HAV Infection Risk Factors: Fecal (Body Waste)/Oral Contamination

- Not washing hands after using the bathroom or changing a diaper
- Eating uncooked food prepared by an infected person who did not wash their hands after using the bathroom
- Drinking contaminated water
- Having oral/anal sex

HBV Infection Risk Factors: Blood and Body Fluids

- Having unprotected sex with an infected partner
- Using illegal injection drugs, even once
- Using the razor or toothbrush of an infected person
- Exposure as a health care worker to infected blood or body fluids
- Being born to an infected mother

HCV Infection Risk Factors: Blood-to-Blood Contact

Known to Transmit Infection

- Using illegal injection drugs, even once
- Having a transfusion or organ transplant before July 1992
- Having long term hemodialysis
- Receiving clotting factor made prior to 1987
- Being injured by a needle or other sharp that has infected blood on it
- Being born to an infected mother

May Transmit Infection

- Having unprotected sex with multiple partners or a history of sexually transmitted diseases
- Tattooing or body piercing in unsanitary conditions
- Using the razor or toothbrush of an infected person
- Other exposure to infected blood

Hepatitis C - An Emerging Epidemic

Nearly four million people in the U.S. are infected with the hepatitis C virus. HCV causes 8,000 to 10,000 deaths each year and this number may increase to 30,000 in the next two decades.

As many as 70% of those infected don't know it, as they have no symptoms or only vague symptoms initially. However, this virus may be causing serious liver damage that will likely not be recognized for several years.

The best way to determine who may be infected is to assess the presence of risk factors for contact with infected blood. Some people may not want to talk about or be able to recall the following risk factors.

Past Drug Use

The most efficient way to become infected with HCV is through injection drug use. Even people who experimented with injection drugs just once many years ago may be infected and should get tested.

Blood Transfusions Prior to 1992

An estimated 300,000 people in the U.S. are infected with HCV as a result of a blood transfusion or organ transplant before July 1992, when a reliable test came into use. As many as one-third to one-half of people infected prior to 1988 contracted HCV this way. Many people may not know that they had a transfusion. People may have been transfused if they:

- Had an injury and were unconscious and hospitalized
- Gave birth by Caesarean section
- Were a premature or low birthweight baby
- Had any kind of major surgery
- Were hospitalized as an infant or child
- Were adopted and have no early medical records

Getting Tested and Getting Treated

If anyone thinks that he or she may have been exposed to infected blood, they should consider getting tested. Blood tests for HAV, HBV, and HCV are available through a physician and in some cases through a public health clinic.

Those who test positive for chronic hepatitis B or C may need a liver biopsy (a small piece of liver tissue is obtained) to determine the existence or extent of liver damage. Early diagnosis and management of hepatitis viruses may have long-term health benefits.

Treatment for hepatitis A involves bed rest, good nutrition, and the intake of extra liquids. HAV infection does not usually lead to long term health problems and is rarely fatal.

Treatments are available for chronic hepatitis B and C. Therapy with interferon or lamivudine is available to help people with chronic hepatitis B. Therapy with interferon alone or in combination with other drugs can help many people with chronic hepatitis C. Additional treatment options are being developed. More research is needed to develop cures for chronic hepatitis.

Many people live with chronic hepatitis (B or C) without experiencing liver damage. Others, however, may develop serious liver disease. People with chronic hepatitis should be monitored by a physician who is knowledgeable about liver disease.

Diet and Alcohol

Adoption of a healthy lifestyle with a good diet, plenty of rest, and stress reduction can improve one's health and well being.

Studies show that the use of alcohol substantially increases the risk of serious liver damage in persons with chronic viral hepatitis, and it should be avoided.

Mr. SHAYS. Thank you. Mr. Brownstein, Mr. Towns and I were very involved, as well as Mr. Sanders, in this when we were looking at HIV, and it was that silent epidemic, just kind of that shadow epidemic, and it really hit us all that we needed to deal with it. So we thank you for your nice words, but it just kind of hit us in the face and slapped us around. We needed to deal with it. We appreciate all that you are doing and others on the panel that you are doing, and we also appreciate what the VA is doing to try to get a good handle on this. We have a ways to go, though.

Mr. Towns.

Mr. TOWNS. Thank you very much, Mr. Chairman. Let me begin by thanking you for really sticking with this and working on it. You have put a lot of time on this, and of course it is a very serious problem and I want to congratulate you on the kind of effort that you have put forth. Also Mr. Sanders, who has also been involved in this issue for quite some time, and I want to salute both of you before I raise any questions.

The first question I have, why do you think that it is much higher among veterans? I saw the video, but is there anything else that we need to know as to why it is so much higher among veterans than the general population?

Mr. DUGGINS. Well, I think one of the reasons is it is the exposure to blood products in the combat environment. The general population do not have that effect. We might be seeing it in the cities now, but what I am saying in a combat situation, if your friend is wounded or you may have a scratch or something and you are dealing with his blood products, you don't have time to put on rubber gloves or take the necessary precautions to make the environment safe for you to deal with blood products. For us who are Vietnam veterans, at the time we were getting blood transfusions and blood products, the testing for hepatitis C or the testing of the blood products wasn't anywhere near where it is now.

So we got bad blood. That is just the bottom line. I think more veterans were exposed to that. I don't think our conduct and behavior is any different than any other portion of our society.

Mr. BAKER. I also believe that in the veteran community, even though combat is definitely one of the biggest risk factors, veterans, they acclimate back into their own communities, they acclimate back into the armed forces, they are still with veterans, they are still amongst each other, and there are possibilities of transmitting other ways. As we said, possibly tattooing and other ways like that. So as they acclimate back in with other veterans and even when they come into the civilian world, veteran communities seem to stay together. So there is that process that we are more of a community and we are interacting more together, so the possibilities and the risk factors are higher for us as well, from point of service to being in the world again, and still to this day we interact with each other. We are always with each other.

Mr. TOWNS. You just said something there that raises another question in my mind. You mentioned tattoos. All the young people today are going out and getting tattoos.

Mr. BAKER. Correct.

Mr. TOWNS. It is a big thing among the young people. Nobody seems to be making the statement that this might be a connection

here and nobody is saying it. So I am concerned about the education and prevention part of all of this. I would like to hear you on that.

Mr. DIBISCEGLIE. Let me comment specifically on tattoos, Mr. Towns. I think that the CDC has not been able to identify tattoos as a risk factor, but I think what they are thinking of is the kind of tatoo that is what is done commonly these days, in a tatoo parlor where there is awareness of the risk of transmitting blood borne viruses. I think what is of more concern is tattoos that are done perhaps in other countries while somebody was in the service, for example, in a back street or by a friend or something like that, where we are uncertain about the sanitary conditions. That does pose a potential risk. The usual kind of tatoo that is done commonly these days I don't believe represents a big risk.

Mr. BROWNSTEIN. I agree completely with what Dr. DiBisceglie has said, because tatoo parlors now by and large are aware of it. But I would just say, for any young person who is considering getting a tatoo, you ought to think twice and make sure you check out whether there are the sterilization techniques. Ask to be shown what techniques are being used, and it should not be done in any casual way. So tattoos themselves do not spread it, it is when unsanitary conditions exist, if I might add that.

Mr. TOWNS. The other thing that—do you want to add something?

Mr. WEIDMAN. I did want to mention just one other thing, Mr. Towns. Things that President Duggin pointed out having to do with the very nature of the combat situation itself and exposure to blood for those of us who served in Vietnam on the ground was one of the factors, as well as the other known risk factors. But there is something else that began that everybody went through, whether you served in country or not, that we have raised as an issue continuously with the CDC just recently, again with a long letter to them, and that is the air guns. The Department of Defense earlier this year has discontinued any use of the air gun whatsoever of any manufactured variety. You talk to any veteran in your district, Mr. Towns, or anywhere who went through, particularly the Vietnam era, they can tell you stories about long lines of hundreds of folks lined up with the air gun moving person to person with the blood running down their arm and dripping off the air gun. So because we know from the work of Dr. Siev at NIC and others that as early as 1948 the hepatitis C virus was present in the United States, you had transmission before people even got into basic training.

Mr. TOWNS. I am concerned about the fact that the education prevention part is not stressed enough for me. Why, doctor, do we not deal with the education prevention? There are some things, based on what people are saying, that if people do it is possible for them to avoid it.

Mr. DIBISCEGLIE. We are coming along. I think one needs to recognize that is a fairly recently discovered virus. This was only discovered in 1989, 1990. It is only 8 or 9 years old. So it took 3 or 4 years after that to recognize how big of a problem, how widespread of a problem it was in the United States. So with that now, we have seen more and more. In the last 3 years I would say we

have seen an acceleration of awareness among both physicians and the general medical public, and I think that education is coming along. However, I think more is clearly needed, as we have heard from the testimony today. Even among physicians who are not involved in treating these patients, their awareness may be somewhat limited, and I think we need more efforts in this area.

Mr. TOWNS. What would you say to the veterans? What recommendations would you have to the VA regarding the nationwide implementation of the hepatitis C testing treatment initiative? I am listening to Mr. Duggin and Mr. Baker, and I am hearing that people are having difficulty getting tested. What suggestions do you have or recommendations do you have to the Veterans Administration?

Mr. DUGGINS. I think one of the recommendations I would have to the Veterans Administration is that they have to do more outreach. I heard them say that they had a web page, but I also heard them say that the people at the most who would be affected are the underemployed and the unemployed. You can't convince me that these guys are going to sit there in front of a computer.

Mr. TOWNS. And a lot of them don't have computers.

Mr. DUGGINS. Right. So the outreach effort has to be rethought. One of the things that I have seen here recently is that in the State of Virginia, and I am from the Virginia Beach area, is that the Commonwealth of Virginia is dealing with the problem of convicts who are HCV positive. And they say well, I don't have the resources to treat these guys. So I am saying, how many of these guys are veterans and who should be treating them. Should the commonwealth be treating them if they are service connected? I can see 50 governments coming to Congress and saying look, guys, this is your problem, clean it up. Therefore, the outreach is limited. I found out about hepatitis C at a leadership conference that we were having and Terry and I both were tested at the same time. Hadn't heard about hepatitis C from the VA system up to that point. It wasn't the VA system that was doing the testing, it was an independent concern who was doing the testing. I ask veterans in my every day walk of life, have you heard of hepatitis C, have you been tested for it, and they look at me like what are you talking about? What is hepatitis C? So the VA can reach people in the system, but they are not reaching the people outside of the system who are veterans. I think that outreach has to be broadened.

Mr. BROWNSTEIN. I think that you had mentioned your involvement with HIV earlier. I think we have a lot of lessons we could learn about HIV. I would venture to say that probably every one of these young people here knows about AIDS, knows something about AIDS. I bet a whole lot of them didn't know too much about hepatitis C until today. I think that we need to get that word out so that it is on the street. It needs to be on the street, because 400 percent more people are infected with hepatitis C than with AIDS. So just looking at the order of magnitude, we have a heck of a lot of work ahead of us.

And the same applies to veterans. The average veteran has no idea about hepatitis C until you were tested just about a year or so ago.

Mr. DUGGINS. Right.

Mr. BROWNSTEIN. I think that what we need—I don't think every veteran should be tested, but I do think every veteran should be screened with some sort of a health risk assessment that doesn't have—put the burden on them to acknowledge what risks they are acknowledging, but just to say, if any of these eight areas apply to you, you ought to be tested, and those in that health risk assessment should be directed at the known risk associated, both on the battlefield as well as other risks that the veterans may have. Dr. DiBisceglie can speak to those risks.

Mr. TOWNS. I have to go vote. That is the reason I am jumping up.

Mr. SHAYS. Kind of weird talking to somebody who asks a question and he gets up and leaves.

Mr. BROWNSTEIN. Maybe it is because of what I said before.

Mr. DUGGINS. I also think that veterans who have third-party insurance, if they knew about the hepatitis C virus, they would go to their own PCP for testing. I don't think they would overburden the system any. But I do think it is up to the system to get the word out to veterans. I know I would have gone to my own PCP to be tested, and I came to the VA system to be tested. I think all veterans who have that insurance would do that versus burdening down the system.

Mr. SHAYS. Let me ask you about the intake process. What could be done, and I will start with you, Mr. Baker. What could be done to follow a process where we guarantee that there is some uniformity, and that we are making sure that no one is—we are missing anyone. If you put the mic a little closer to you.

Mr. BAKER. I think the first thing that could be done is the VA has a data base of all of their veterans within their system, and if the VA can send out form letters for issues about how much money on a cost of living allowance that a veteran gets every year, they could send out a form letter to every veteran within the system and explain to get tested for hepatitis C at your local VA clinic or your local VA hospital. That is an easy step to send out that form letter there.

Second is when veterans come into the system or come into a VA hospital and request to be tested or also when veterans are there to explicitly make it a point that these veterans be tested, to talk to their directors of VA medical centers and directors of VISNs who have their own priorities on how they want to run their VISN or their hospitals and what they feel is important to bring it down from the top that this is the No. 1 priority issue that all people, all veterans be tested and we do our outreach to make sure that everybody finds out about it.

Mr. SHAYS. Before I go to the other panelists, when you say all veterans, some veterans don't need to be tested, correct?

Mr. BAKER. That is a—I tend to disagree. I think because we have an epidemic on our hands and because it is within our veteran community that sometimes is spread to our spouses and to other family members, that maybe we should aggressively just test all veterans and get a real idea of what is going on here instead of testing 141 veterans at one hospital when you have 15,000 at that one hospital.

Mr. SHAYS. Let me throw it out to the others. The first part of the question, do you recommend a particular procedure that should be followed to guarantee that there is some uniformity.

Mr. DUGGINS. I think what they should do is to clone the director of division 3. I mean as I travel around the country, VISN 3 seems to be the poster child and others should adopt the procedure that they are using in VISN 3. That is the problem that veterans have. They hear good things that are going on in one division, and then they get denied these kinds of services and then they wonder why.

Mr. SHAYS. Mr. Duggins, if we cloned and had more than one Mr. Farsetta in this world, this would be a dangerous world.

Mr. DUGGINS. Right. And truly VISN 3 is the poster child of VISNs. I always hear good things about that VISN. But some of them don't seem to be getting in the ballpark.

Mr. SHAYS. They have gotten in it early and we should be seeing their successes and failures and so on.

Mr. Weidman.

Mr. WEIDMAN. Incidentally, I am from New York, and Jim Farsetta loves to come to Washington because sometimes he is more popular here than he is up there. But he is an excellent VISN director.

You will notice that a question was skirted earlier today. There is no rigorous plan for taking the entire catchment of each hospital of folks already enrolled for treatment, matching that up against the 10 risk factors and then making sure that everybody who meets the 10 risk factors is tested, it is not happening. It is not happening in any facility that we are aware of. I met one of those risk factors by having been a medic in I Corps in 1969. I asked about testing at the Washington VA Medical Center last July. I was put off and asked again in October and was put off. I have been put off several times and then I started pressing the matter beginning in March. I am due to be—scheduled to be tested this Friday. I am a fairly tenacious guy, and it took that long to get the test even though I had requested it, even though I met one of the risk factors.

The one thing that is missing from the plan, and we would agree at VVA that VA has done a good job in putting together a plan, but putting together a plan is not the action part, No. 1. No. 2, within the actual procedures of testing, it is just simply not there at the local hospital nor is it in the protocol that they should go through as part of their normal physical and make sure that this test happens.

The other thing is when people initially enroll in reaching outside of the VA, as George Duggins just commented on, to draw people in, people can enroll and if they can go through a battery of tests having to do with what happens to folks, what branch of service did they serve, what years did they serve, what was their military occupational specialty, where did they do service and what actually happened to them, and that is not just hepatitis C, that is lots of other things, ranging from exposure to dioxin to exposure to cortisol, exposure to DU, all kinds of things that would be reasonable for folks to screen for if in fact it is a veterans health care system, and that is not currently happening.

We have had discussions with VHA on this and have what we believe is agreement to move forward to put together a task force of veterans service organizations, VA officials and DOD officials to move in that direction so when you go into the VA hospital in my instance automatically because of when and where I served, I would have gotten a hepatitis C screen.

Mr. SHAYS. Let me do this. We are probably going to have a 2-minute recess to enable our young people who are probably a little awkward sitting down all this time to leave if they want. That would probably be helpful. So we will just take a 1-minute recess to allow our students—is that good?

Mr. DUGGINS. That is great. Thank you.

Mr. SHAYS. We welcome you to our hearing and thank you for coming.

[Brief recess.]

Mr. SHAYS. Let me call the hearing back to order.

What I really think is on the table is the first panel is obviously having to wrestle with the fact that there are limited resources and we are starting to find ways to get the word out and then the question is who gets tested and who doesn't get tested. It is such a gigantic network some VISNs are going to do a good job and some are not. The VA has to find a way to get a handle on that. What I want to do is ask what recommendations would you make to the VA regarding the nationwide implementation of the testing and treatment? One, should we agree that all of the ones at risk should be the ones first and foremost? Second, is there a protocol that you are aware of that is there that you are certain that the right questions are being asked to determine the people at risk, and are you convinced that there is the proper follow on. And I would be happy to have VA respond to this question as well.

Mr. DIBISCEGLIE. Well, I think certainly the CDC has considered the question should we be screening the general population, and they have discarded that option. They feel it is not cost effective. Along those lines I would say the same for the VA, but it depends on what the definition of screening is. Everybody should be screened by a health risk assessment questionnaire. If everyone has the 9 or 10 risk factors, if there is any one that is positive, that should move you to the next step of getting a blood test, which is very doable, I think.

Mr. DUGGINS. I think that the main thing that the VA has to do is make certain that the VISN directors buy into the program. If they don't, the implementation is going to fail in their area and the veterans are not going to be tested. I agree that the at risk categories should be the first ones tested and, if dollars allow, any other veterans who seeks this test should have it. I know some of the at risk factors but I think we should put all of the at risk factors out there and then those veterans will know whether they should bother being tested for this.

Mr. SHAYS. Anyone else?

Mr. BROWNSTEIN. I think that—your part of the question about getting the word out, the American Liver Foundation last week conducted a market research survey of 700 veterans across America, Bruskin survey research firm and I will share this data with you in the next week or two. We are basically trying to find out

what the veterans know and don't know about hepatitis C. Also what their behaviors would be if they thought they might be at risk for hepatitis C as well as what they see as perceived provider responses. So based on that data we are going to try to target messages that are directed at veterans to try to capture, to best educate people about that. And toward that end we are preparing a brochure that we are prepared to distribute to 3½ million veterans associated with the VA and we are already talking with VA officials, and we are going to get their involvement.

But the first step is entry into the system. In other words, it has to be stimulating that unmet need into and effective demand based on knowledge from those veterans.

Mr. SHAYS. I am going to be asking one last question on research, Dr. DiBisceglie, probably directed toward you but let me ask if Mr. Sanders has any other questions.

Mr. SANDERS. I do have questions.

Mr. SHAYS. Why don't we go to your questions.

Mr. SANDERS. I thought this was an excellent panel and I think all of your presentations were important. What I am hearing, and correct me if I'm wrong, and maybe, Mr. Brownstein, you want to start off and others can pipe in, is that there are large numbers of veterans who are sitting out there with hepatitis C who don't know it. Are we all agreed on that?

Dr. DIBISCEGLIE. That is correct.

Mr. SANDERS. The other panel was indicating that perhaps the numbers that they had seen were perhaps disproportionately high or we don't know the answer to that but I gather that we are looking at—how many folks are sitting out there with hepatitis C who are veterans who don't know it now? Does anyone have a wager or guess?

Dr. DIBISCEGLIE. I think we are lacking the data, but those who tested positive in that 1 day sample is 8 to 10 percent. Extrapolating from the general population, 80 to 90 percent of the population with hepatitis C do not know it; 8 to 10 percent would make 350,000, and 80 to 90 percent do not know it. This is a silent disease. It either has no symptoms or they are so vague and nonspecific that would not lead you to think of hepatitis as being the likely cause.

Mr. WEIDMAN. Our estimate is 8 to 10 as a minimum and it may be greater, 8 to 10 percent.

Mr. SANDERS. You think that is the low end?

Mr. WEIDMAN. Yes. And you asked the question before having to do with resources of the panel, if we don't test now and start to deal with—first of all, I think it is unconscionable not to test. And second, it flies in the face of the wellness model and we are going to pay a heck of a lot more down the line if we don't catch people before they start to show symptoms. It is just not reasonable for—don't ask, don't tell. Don't ask, don't treat is not a policy that we should be pursuing in this, and so rigorous testing and outreach of people already in the catchment who are doing blood work anyway is simply not reasonable to move forward in a methodical manner.

Mr. SANDERS. I agree. If VA tomorrow did all of the right things, you are talking about a mammoth outreach and beginning treat-

ment for these hundreds of thousands of people. That is a monumental effort, is it not?

Dr. DIBISCEGLIE. Yes.

Mr. SANDERS. The only other question I would ask is have we tested for incidence of hepatitis C in Korean veterans? Is there anything particular about Vietnam as opposed to World War II or Korea?

Dr. DIBISCEGLIE. I think it is 4 percent of Korean veterans have hepatitis C?

Mr. BROWNSTEIN. I don't know. I did see data presented last Thursday that showed it was somewhat of a bimodal distribution. It was real heavy on Vietnam and then there was some data that showed that Korean and I think even World War II, and I would defer to anyone from the VA who is more familiar with that data.

Mr. SANDERS. Should there be any difference of incidence? Should there be differences between Vietnam and Korea?

Dr. DIBISCEGLIE. I think hepatitis C was a disease that was emerging in the general population after Korea and that explains it in good part.

Mr. SANDERS. Thank you.

Mr. SHAYS. Thank you. Just to end the hearing, tell me is there any value in having research that is focused directly on veterans' populations?

Dr. DIBISCEGLIE. I think there definitely is. Clearly just getting patients tested and evaluated for therapy is just the beginning step. There will be some who don't meet the criteria for treatment now or do not clear the virus therapy, and so those individuals will remain within the system and some will have their liver disease progressing or require medical care there. And there are some I think veteran specific questions that can be answered related to perhaps the demographic variation of the veterans versus the general population. I think we need to look toward the future as well in terms of new treatments. I think the VA needs to stay at the forefront of new treatments as they become available to be able to test and develop them or ways of minimizing the liver disease to avoid it progressing. I think all of these are very valid areas for research.

The VA has a large infrastructure and there is now this large cohort of patients, a couple hundred thousand, I think that represents a wonderful research opportunity.

Mr. SHAYS. Yes, sir.

Mr. BAKER. I think the other thing, and Mr. Sanders talked about it before with the other panel, is their funding. I didn't hear anyone actually say out of that panel but they are underfunded, and they know that they are. Their employees are overworked, understaffed at most facilities and now they have this tremendous new incident that has come upon them.

Sure, directives will come down, and I even talked to a director at an RO, and he said directives will come down. But how are we supposed to take care of it. They are losing people every day. Kizer has to make more cuts but we are asking that patients with hepatitis C and veterans be taken care of. And the issue is really money. The VA is trying to do a job at the top to the bottom and their facilities don't have the resources, don't have the people to

even try to take, like I said, from Portland. They had a computer specialist more than likely because there was nobody else that they could spare.

The other issue is they need funding real bad.

Mr. DUGGINS. We have heard the rob Peter to pay Paul scenario, but Peter doesn't have any money. You are robbing somebody who is already broke.

Mr. WEIDMAN. There was talk of the caps and how we need to squeeze in under the caps. Let me say that veterans health care was the only health care for a discrete group of Americans that was flat lined in 1997. Had that been done to African-Americans, to women or to any other discrete group of people that you were going to take over the next 5 years a 50 percent cut in your health care because we are going to flat line you, all the dickens would have broken loose, and we did it to veterans in that kind of a discriminatory way and it slid on through.

The cap was wrong to begin with. Let the Congress not be like George Armstrong Custer. Let's go back on this Custer decision and set it right by raising the cap on veterans health care.

Mr. SHAYS. Let me ask you, though, as related to the cap on veterans, there was no determination that we would flat fund it for 5 years. It was a determination that the overall budget would have a slight growth. So I am not quite comfortable with your description.

Mr. WEIDMAN. If we went back to 1990 and we charted out medical inflation, we charted out Medicaid, the Federal portion of it and Medicare——

Mr. SHAYS. So is your point that more money is being spent but less than the required need?

Mr. WEIDMAN. And when you factor in inflation.

Mr. SHAYS. So you are basically saying that we are losing ground on inflation.

Mr. SANDERS. I would just add to what Mr. Weidman says, and correct me if I'm wrong, if the VA does the right thing and they reach out to all of the veterans, the 10 percent who are infected are treated, you must be talking about astronomical numbers that there is no way on God's green Earth you can deal with within the budget.

Mr. Brownstein or Dr. DiBisceglie, is that correct?

Dr. DIBISCEGLIE. That is correct.

Mr. SANDERS. If they do the right thing and respond to hepatitis C——

Mr. SHAYS. I think the record will demonstrate that we are putting tremendous demands on the VA and someone like myself, who does believe that we need to find a way to honor this agreement as best we can, we either have to find the money from some other area, not within VA, or we have to break the cap. Those would be my two options.

Let me do this. Since I said responding to the cloning of Mr. Farsetta would make the world a more dangerous place, he is clearly allowed to come back and make any comment he would like.

I would like to dismiss this panel and thank them and just invite the VA. If they have any closing comments I am happy to have

them make any comments, Dr. Garthwaite, or anyone that accompanied you.

Dr. GARTHWAITE. Thank you, Mr. Chairman. I would just echo your comment for any specific cases, we would very much like to fix the individual case and understand why it happened.

Mr. SHAYS. Mr. Baker, we are hearing that request. Given that you have come forward with some individual cases, it is important that you share them with the VA and share them with our office as well. Let's followup. There is no attempt to blame anyone, but let's say why is this not working and what can be done. And if there are other factors, we would like to know that.

Dr. GARTHWAITE. We have already fixed some specific communication issues. It helps us get uniformity. I am very much interested in how we can use posters and letters to veterans and other things to improve our outreach and to make sure that we let veterans know what else we can do. I think the panel did an outstanding job and we are basically in agreement.

Mr. SHAYS. The only other thing, and I am happy to have you do this in communication with my staff, is how do you provide some uniformity so that everybody is getting that message and it is not just going to a few, and I do think that a lot can be learned from your VISN where you are actually finding that they are already into it, and by reexamining what they are doing well and see how you can use it in other facilities.

Dr. GARTHWAITE. Certainly. One of the concerns people have had about some decentralization of control is the nonuniformity. The good news is that allows creativity which often identifies much better ways of doing business. It is our challenge to find that creativity and the better ways and export that to the other networks.

Mr. SHAYS. I happen to agree that I will take creativity over uniformity, so I have a lot of license in that.

In other words, you don't want to hold anyone down who is able to do some things, but to at least make sure that there is a minimum standard of communication, a minimum standard that guarantees you that this word is getting out.

Dr. GARTHWAITE. I agree.

Mr. SHAYS. Thank you very much. With this we will call the hearing adjourned.

[Whereupon, at 12:45 p.m., the subcommittee was adjourned.]

[Additional information submitted for the hearing record follows:]

Statement on

VA Outreach to Veterans at Risk for Hepatitis C Infection

to the

Subcommittee on National Security, Veterans' Affairs and International Relations
House Committee on Government Reform

June 9, 1999

Chairman Shays and Subcommittee Members:

My name is Tracey Powell, Chairman and CEO of Home Access Health Corporation, the leader in "at-home telemedicine" as it relates to AIDS and hepatitis C. At-home telemedicine combines self-specimen collection, diagnostic testing, counseling and referrals for healthcare testing and treatment in a fully integrated service that comes under stringent FDA licensing requirements. Our company operates the nation's only medical call center dedicated to providing counseling and testing services for hepatitis C and HIV, 24 hours a day, seven days a week, in support of its FDA approved test services.

The hepatitis C virus (HCV) is a big problem for the general population, but an even bigger problem for the Department of Veterans Affairs because of a significantly greater prevalence among veterans. As the Chairman knows, hepatitis C is a particular risk for Vietnam-era veterans.

Detection of hepatitis C will soon be easier with a newly FDA approved, first at-home test for the hepatitis C virus, the Home Access® Hepatitis C Check℠ Service.

The baseline task is to work with the VA to better determine the prevalence rate for veterans and those with associated risk factors. Recent VA data displays a wide range of prevalence. Home Access® Hepatitis C Check℠ Service can be utilized to document prevalence.

The prevalence rate of the general population is estimated to be 1.8% by the Centers for Disease Control and Prevention. The following are prevalence rates from recent VA data and studies:

Prevalence Rates for Hepatitis C Among Veterans

52%	Among VA liver transplant patients
31%	Cincinnati VA Medical Center results from 95,447 tests in 1998
20%	DC VA Medical Center results from 6-week inpatient survey in 1998
19.3%	VISN Region III from testing "this year" of 14,000 as presented in testimony before a House Government Reform subcommittee on June 9
18.9%	San Francisco VA Medical Center inpatient survey in 1998
10%	San Francisco VA Medical Center results among inpatients and outpatients undergoing routine blood draw in 1998
8.4%	Testing of 166 at VVA National Leadership in August 1998
8%	Nationwide testing of 26,000 blood draws on March 17, 1999

Home Access Health Corporation · 2401 West Hassell Road, Suite 1510 · Hoffman Estates, IL 60195-5200 · 847 781-2500 · 847 781-2560 Fax

Only approximately 30,000 of 3.2 million veterans utilizing the VA health system are currently aware of their HCV serostatus. This means that anywhere from 250,000 to 500,000 have hepatitis C, and do not know it. In addition to these, the 22 million veterans outside of the VA health system are virtually unaware of their risk to hepatitis C.

Last year, both Senate and House Appropriations Committees stressed the importance of screening veterans to detect and treat hepatitis C and related liver diseases early enough to prevent serious and costly illness.

Veterans who are concerned that they have been exposed to the hepatitis C virus now have a way of finding out confidentially and in the convenience and privacy of their own home.

The Home Access Hepatitis C Check at-home service combines telephone registration/pre-test counseling, collection of a blood sample, shipping, laboratory testing, telephone results retrieval, post-test counseling and referrals to medical specialists skilled in the treatment of hepatitis C. At the lab, Home Access Health will run the same tests used by physicians and hospitals to identify hepatitis C antibodies in the blood sample. Results are available within 10 business days. Test results, healthcare counseling and referrals to medical professionals are available 24 hours a day, except holidays.

Clients testing with the Hepatitis C Check Service use a safety lancet to draw a few blood drops from a fingertip. The drops are placed on special sample collection paper. The sample is then placed in a pre-paid envelope for shipment to a certified laboratory. Each test is assigned a personal identification number, which the client registers via a toll free number before taking the blood sample. The client then calls a toll-free telephone number, and enters a unique personal identification number to receive their results.

We offer two recommendations for veterans.

First, we propose that VA implement a demonstration project to identify HCV infected veterans. We recommend that the routine VA blood testing policy be augmented with a targeted effort to identify Vietnam veterans at high risk for HCV. To provide them access to around-the-clock professional counseling, an economical and convenient FDA-approved at-home testing service (using a toll-free telephone number-based operation) and a turnkey data report on HCV seroprevalence. The hotline services including education, risk assessment and professional counseling can be provided at a cost of $.90 per minute and testing can be provided at a cost of $50.36 per person (excluding shipping).

Second, we propose that VA contract-out its responsibilities for the federally-mandated "lookback" process for Americans who are at high risk for hepatitis C because they received a blood transfusion before 1992, when screening for hepatitis C was not standard. Over the next two years, these people will be notified that they are at-risk, in a letter that is to be issued by the hospitals that transfused these individuals with possibly infected blood products. Specifically, we propose to provide the complete range of notification, testing, counseling and data collection tasks on a turnkey basis for $80 per person.

We appreciate the opportunity to testify and look forward to working with you to improve detection and counseling for veterans with hepatitis C.