HEPATITIS C: SCREENING IN THE VA HEALTH CARE SYSTEM

HEARING

BEFORE THE

SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS

OF THE

COMMITTEE ON GOVERNMENT REFORM

HOUSE OF REPRESENTATIVES

ONE HUNDRED SEVENTH CONGRESS

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HEPATITIS C: SCREENING IN THE VA HEALTH CARE SYSTEM

THURSDAY, JUNE 14, 2001

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 B–372, Rayburn House Office Building, Hon. Christopher Shays (chairman of the subcommittee) presiding.

Members present: Representatives Shays, Schrock, Kucinich, and Platts.

Staff present: Lawrence J. Halloran, staff director and counsel; Robert Newman and Kristine McElroy, professional staff members; Jason M. Chung, clerk; Kristin Taylor, intern; David Rapallo, minority counsel; and Earley Green, minority assistant clerk.

Mr. SHAYS. A quorum being present, the Subcommittee on National Security, Veteran Affairs and International Relations, hearing entitled, "Hepatitis C: Screening in the VA Health Care System," is called to order.

The Department of Veterans Affairs, VA Medical Network, has the potential to function as an indispensable pillar of the Nation's public health system. The question we address this morning, is that potential being realized in the VA effort to screen and test veterans for hepatitis C infection.

With more than 15,000 providers at 1,100 sites, the Veterans Health Administration [VHA], will see and treat almost 4 million patients this year. Those patients may be particularly vulnerable to the silent epidemic of hepatitis C because so many veterans, particularly those who served in the Vietnam era, may have been exposed to blood transfusions and blood derived products before the hepatitis C virus, HCV, could be detected.

In early 1999, the VA launched the HCV initiative, setting a goal to screen and offer testing to all veterans passing through VHA medical centers and clinics. It was a responsible but daunting undertaking in response to a public health crisis afflicting veterans at three to five times the rate of infection found in the U.S. population as a whole.

In three previous hearings on the hepatitis C effort, we heard of frustratingly slow but measurable progress as the decentralized VA health system struggled to implement and fund the program consistently across 22 regional networks. We heard persistent reports

of inconsistent outreach, perfunctory screening and limited access to testing and treatment.

So we asked the General Accounting Office [GAO], to visit a cross section of VA facilities to address the reach and vitality of this important public health effort. The GAO findings indicate the HCV initiative has failed to capture a significant number of veterans who carry the hepatitis C virus. Those veterans show no symptoms, do not know they are infected, but they need medical help to protect their own health and the health of those around them.

After almost 3 years of attempting to implement this high priority initiative across the VA system, access to screening remains inconsistent and limited. Heavy-handed, invasive screening techniques at some VA facilities discourage disclosure of HCV risk factors by patients. Many facility managers see HCV screening and testing as an unfunded mandate, unaware Congress appropriated $340 million this fiscal year for the program.

Due to poor VA communication with regions and facilities, inadequate data systems to measure program performance and faulty budget estimates, more than half that amount will not be spent on HCV related care. Adequately funded, the program still appears to lack focus. According to one estimate, fewer than 20 percent of veterans using VA health care facilities were screened or tested for HCV. Data recently obtained by VA indicates up to 49 percent of VA patients may have been within reach by the HCV initiative over the past 2 years.

But to redeem the promise of the HCV initiative, GAO recommends VA screen 90 percent of regular VHA patients next year. Reaching that target will require a far more sustained and aggressive approach from VA leadership at all levels than has been evident to date. We hope to hear today how the program impediments and weaknesses observed by GAO can be addressed, and how the VA will miss no further opportunities to improve the public health and the health of the Nation's veterans.

We truly appreciate the skilled work of our oversight partners, the General Accounting Office, in this ongoing review of the VA's hepatitis C program. We also appreciate all our witnesses who bring important perspectives, experience and expertise to this discussion. We look forward to their testimony.

[The prepared statement of Hon. Christopher Shays follows:]

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Statement of Rep. Christopher Shays
June 14, 2001

The Department of Veterans Affairs (VA) medical network has the potential to function as an indispensable pillar of the nation's public health system. The question we address this morning: Is that potential being realized in the VA effort to screen and test veterans for hepatitis C infection?

With more than fifteen thousand providers at eleven hundred sites, the Veterans Health Administration (VHA) will see and treat almost four million patients this year. Those patients may be particularly vulnerable to the silent epidemic of hepatitis C because so many veterans, particularly those who served in the Vietnam era, may have been exposed to blood transfusions and blood-derived products before the hepatitis C virus (HCV) could be detected.

In early 1999, the VA launched the HCV Initiative, setting a goal to screen and offer testing to all veterans passing through VHA medical centers and clinics. It was a responsible, but daunting, undertaking in response to a public health crisis afflicting veterans at three to five times the rate of infection found in the U.S. population as a whole.

In three previous hearings on the hepatitis C effort, we heard of frustratingly slow, but measurable progress as the decentralized VA health system struggled to implement and fund the program consistently across twenty-two regional networks. We heard persistent reports of inconsistent outreach, perfunctory screening and limited access to testing and treatment.

So we asked the General Accounting Office (GAO) to visit a cross-section of VA facilities to assess the reach and vitality of this important public health effort. The GAO findings indicate the HCV initiative has failed to capture a significant number of veterans who carry the hepatitis C virus. Those veterans show no symptoms, do not know they are infected; but they need medical help to protect their own health and the health of those around them.

After almost three years of attempting to implement this high priority initiative across the VA system, access to screening remains inconsistent and limited. Heavy-handed, invasive screening techniques at some VA facilities discourage disclosure of HCV risk factors by patients. Many facility managers see HCV screening and testing as an unfunded mandate, unaware Congress appropriated $340 million this fiscal year for the program. Due to poor VA communication with regions and facilities, inadequate data systems to measure program performance, and faulty budget estimates, more than half that amount will not be spent on HCV-related care.

Adequately funded, the program still appears to lack focus. According to one estimate, fewer than twenty percent of veterans using VA health care facilities were screened or tested for HCV. Data recently obtained by VA indicates up to forty-nine percent of VA patients may have been reached by the HCV Initiative over the past two years. But to redeem the promise of the HCV Initiative, GAO recommends VA screen ninety percent of regular VHA patients next year.

Reaching that target will require a far more sustained and aggressive approach from VA leadership at all levels than has been evident to date. We hope to hear today how the program impediments and weaknesses observed by GAO can be addressed and how VA will miss no further opportunities to improve the public health and the health of the nation's veterans.

We appreciate the skilled work of our oversight partners, the General Accounting Office, in this ongoing review of the VA's hepatitis C program. All our witnesses bring important perspectives, experience and expertise to this discussion, and we look forward to their testimony.

Mr. SHAYS. At this time I recognize the ranking member, Mr. Kucinich.

Mr. KUCINICH. I thank the Chair. Good morning. Let me welcome the witnesses from the General Accounting Office and the Department of Veterans Affairs. I'm glad all of you could be here today. The issue of hepatitis C is an urgent one for many veterans in all of our districts. For them, the prospect of blood tests, biopsies, pharmacological treatments and in some cases liver transplants can be tremendously frightening. It's no wonder, therefore, that many veterans and many others are hesitant to even get tested.

And in the case of hepatitis C, symptoms may not arise for years, if not decades. So procrastination and avoidance can have serious impact.

But it's for precisely these reasons that the screening process, which helps veterans identify their conditions and come to terms with them, must be an open process, one that is informative, accessible and encouraging. A system that arbitrarily restricts screening procedures, or worse, makes them embarrassing to endure, will only complicate this process needlessly.

For that reason, I want to thank the Department of Veterans Affairs for their public statements and policies, recognizing their lead role in this process. I'm confident of the agency's commitment to help the veterans in need. However, I remain skeptical that we're doing all we can to attack this problem head-on. My skepticism is renewed today by the testimony that will be presented by GAO.

I want to thank the chairman for calling this hearing, and I appreciate the Chair's continued commitment in this area.

Mr. SHAYS. My colleague told me he has three hearings, I think most of us do, and he already sounds tired.

Mr. Schrock.

Mr. SCHROCK. Thank you, Mr. Chairman. I too, want to thank you for being here. I represent the Second Congressional District, which probably has as many retired people and veterans in it as any place in the world, and I know that's a problem.

And I'm sure you're aware of it, this is National Men's Health Week right now, so I think it's appropriate that you're here, and I look froward to your testimony. Thank you.

Mr. SHAYS. I thank my colleague.

Let me just get the unanimous consents taken care of, and then we will swear in our witnesses. I ask unanimous consent that all members of the subcommittee be permitted to place an opening statement in the record and that the record remain open for 3 days for that purpose. Without objection, so ordered.

I ask further unanimous consent that all witnesses be permitted to include their written statements in the record, and without objection, so ordered.

I'd like to ask if you can hear us in the back of the room. Is it OK? OK.

We have two panels. Our first panel is Ms. Cynthia Bascetta, Director, Health Care, Veterans' Health and Benefits Issues, General Accounting Office, accompanied by Mr. Paul Reynolds, Assistant Director, Veterans Health Care Issues, General Accounting Office. I would invite both of you to stand, we will swear you in and then we will hear your testimony.

Raise your right hands, please.

[Witnesses sworn.]

Mr. SHAYS. For the record, our witnesses have responded in the affirmative. If you can say anything funny to keep us alive and awake here, feel free. It's not required. [Laughter.]

We welcome your testimony. We'll get to the questions afterwards, and then we'll go to our second panel.

STATEMENT OF CYNTHIA BASCETTA, DIRECTOR, HEALTH CARE, VETERANS' HEALTH AND BENEFITS ISSUES, GENERAL ACCOUNTING OFFICE, ACCOMPANIED BY PAUL REYNOLDS, ASSISTANT DIRECTOR, VETERANS' HEALTH CARE ISSUES, GENERAL ACCOUNTING OFFICE

Ms. BASCETTA. Mr. Chairman, and members of the subcommittee, thank you for inviting us to discuss the VA's efforts to identify veterans with hepatitis C.

Three years ago, VA set out to screen all patients for risk factors and test those who had at least one. In its budget justifications, VA made a compelling case that it needed more money to identify veterans with hepatitis C and provide anti-viral drug therapy where appropriate. In response, the Congress provided over $500 million.

Today, we should be commending VA for a model public health initiative, but instead, we're discussing why most veterans still have not been screened. Two months ago, VA estimated that as many as 800,000 veterans had been screened during fiscal years 1999 and 2000, just 20 percent of those using VA health care.

Yesterday, VA told us about a new source of data that had just become available. It focuses on veterans who visited VA facilities during March and April of this year, and it suggests that many more veterans have been screened. This is consistent with our impression that in fact the pace of screening has been improving over the last few months.

However, VA's new data also suggests that significant performance problems remain. Most notably, it reveals that thousands of veterans visited VA facilities during those 2 months and left without hepatitis C screenings. Equally disturbing, VA told us that the data suggests that about 50 percent of veterans screened nationwide were never tested, even though they had known hepatitis C risk factors, results that are consistent with our reviews of medical records at four facilities we visited.

The sobering consequences are that the majority of VA's enrolled veterans with hepatitis C likely remain undiagnosed, potentially as many as 200,000 veterans. These veterans could unknowingly spread the virus to others and miss important opportunities to safeguard their health.

A most notable contributor to VA's disappointing performance was the failure to act in accordance with the high priority set in its budget submissions. Until early this year, headquarters communicated its policy objectives through an information letter that allowed room for interpretation instead of using directives with clear expectations.

And managers and providers at local facilities told us that they were unaware of the ability of funding for screening and testing. As a result, they used their own discretion to restrict screening.

For example, by screening only on certain days of the week or by letting individual providers use their own judgment regarding who to screen.

Besides these restrictions, we found flawed procedures when screening did occur. As you can see on the chart on my left, many of the risk factors address sensitive topics. Yet at some sites, providers required veterans to identify their risk behavior, rather than allowing them to acknowledge that at least one risk factor applied to them. At other sites, these questions were asked in areas that lacked sufficient privacy.

As I mentioned earlier, many providers did not order blood tests, even for patients with known risk factors. Often, these tests were not ordered because a provider thought that a patient's age, psychiatric illness or substance abuse would make them ineligible for treatment.

Mr. Chairman, VA has operated its hepatitis C for almost 3 years without performance targets or adequate oversight. As the chart on my right shows, the new program director is dependent on the line authority of the Under Secretary, which extends through the 22 networks and facility managers to more than 15,000 providers. This management structure suggests to us that a more systematic approach may be warranted to screen veterans appropriately and expeditiously.

This could include three key components. First, making early detection of hepatitis C, a standard for care could convey the higher priority that headquarters would expect local managers to place on screening and testing. Second, performance targets are essential to hold managers accountable. And from our perspective, these should be results oriented and time sensitive. And finally, clearer communication regarding available funding could eliminate misperceptions that the program is not adequately funded.

In summary, VA has the resources and the know-how to make up lost ground very quickly. In our view, additional delays, including this relatively straightforward initiative, are unnecessary and inexcusable. Mr. Chairman, this completes my statement, and we'd be happy to answer any questions that you or other members of the subcommittee might have.

[The prepared statement of Ms. Bascetta follows:]

United States General Accounting Office

GAO

Testimony

Before the Subcommittee on National Security, Veterans Affairs, and International Relations, Committee on Government Reform, House of Representatives

For Release on Delivery
Expected at 10:00 a.m.
Thursday, June 14, 2001

VETERANS' HEALTH CARE

Standards and Accountability Could Improve Hepatitis C Screening and Testing Performance

Statement of Cynthia A. Bascetta
Director, Health Care–Veterans'
Health and Benefits Issues

GAO-01-807T

Mr. Chairman and Members of the Subcommittee:

We are pleased to be here today to discuss the Department of Veterans Affairs' (VA) efforts to identify veterans who have hepatitis C—a chronic bloodborne virus that can cause potentially fatal liver-related conditions. This year, VA expects 3.8 million veterans to use its health care system, which consists of over 700 facilities located in 22 service delivery networks.

Three years ago, VA characterized hepatitis C as a serious national health problem that needs early detection to reduce transmission risks, ensure timely treatment, and prevent progression of liver disease. In a 1998 information letter, the Under Secretary for Health provided background information on hepatitis C and stated that all patients will be evaluated for risk factors and have assessments documented in their patient charts. He also outlined the process clinicians should use when (1) screening veterans for known risk factors for exposure to hepatitis C and (2) ordering tests to detect antibodies and diagnose hepatitis C infection. He also recommended testing of those with the presence or history of any risk factor or at the patient's request.

Subsequently, VA included $195 million and $340 million for hepatitis C screening, testing, and antiviral drug treatment in its fiscal year 2000 and 2001 budget submissions, respectively. In doing so, VA noted that hepatitis C has particular importance because of its prevalence among VA's enrolled population. Specifically, VA cited its one-day survey of over 26,000 veterans (on March 17, 1999) that documented an infection rate of 6.6 percent[1], compared with 1.8 percent in the general population.

My comments today will focus on VA's progress in screening and testing veterans for hepatitis C during fiscal years 1999 and 2000 and ways that performance could be enhanced. Our assessment of VA's efforts to treat infected veterans remains ongoing and results will be available early next year.

Our review of VA's hepatitis C screening and testing was conducted from November 2000 through May 2001 in accordance with generally accepted government auditing standards. It included:

- reviews of relevant VA documents, including a sample of electronic medical records, budget justifications, policy documents and practice guidelines;
- interviews with over 100 VA officials, including the Under Secretary for Health, the former and current Hepatitis C Directors, and officials in seven VA health care networks; and
- visits to seven medical facilities that conducted hepatitis C screening and testing.

[1] Department of Veterans Affairs, Office of the Assistant Secretary for Financial Management, *FY 2001 Budget Submission, Medical Programs* (Volume 2 of 6, February 2000), p. 2-28.

In summary, VA missed opportunities to screen as many as 3 million veterans when they visited medical facilities during fiscal years 1999 and 2000, potentially leaving as many as 200,000 veterans unaware that they have hepatitis C infections. Most remain undiagnosed primarily because local managers adopted restrictive hepatitis C screening practices. Moreover, of those screened, an unknown number likely remain undiagnosed because of flawed procedures. Clinicians at facilities we visited, for example, frequently did not (1) order blood tests for screened veterans who had known hepatitis C risk factors or (2) follow up to ensure that ordered tests were completed.

During fiscal year 2001, VA has taken important steps to enhance hepatitis C screening and testing performance, such as a better communication process that includes lead clinicians at each medical facility. Although the pace of screening and testing appears to be improving, many currently undiagnosed veterans may not be identified expeditiously unless VA (1) establishes early detection of hepatitis C as a standard for care and (2) holds managers accountable for timely screening and testing of veterans who visit VA medical facilities. Communicating more effectively with local managers about the availability of funding for screening, testing, and treatment could also reduce concerns about resources as a barrier to improved performance.

BACKGROUND

Hepatitis C virus infection is the most common chronic bloodborne infection in the United States.[2] It develops into a chronic infection in 85 percent of the cases, through a slow process that is often without symptoms for 20 years or more. Hepatitis C antibodies, however, generally appear in the blood within 3 months of infection. Undiagnosed hepatitis C can eventually lead to liver cancer, cirrhosis (scarring of the liver), or end stage liver disease, which is the leading indication for liver transplantation.[3]

Hepatitis C (previously referred to as non-A, non-B hepatitis) was first recognized as a unique disease in 1989. In 1992, blood tests became available to detect the antibody. This discovery helped curb the rapid spread of the virus by allowing effective screening of blood products to virtually eliminate contamination.[4] Many, however, had already become infected through transfusions and were unaware of their infection because they had no symptoms.

Early detection is important for several reasons. Those who have hepatitis C infections could unknowingly behave in ways that speed up the progression of the

[2] Miriam Alter, et al.,"The Prevalence of Hepatitis C Virus Infection in the United States, 1988 Through 1994," *New England Journal of Medicine* (Vol. 341, August 19, 1999), p. 560.
[3] R. Cheung, "Epidemiology of Hepatitis C Virus Infection in American Veterans," *The American Journal of Gastroenterology* (Vol. 95, March 2000), p. 740.
[4] Centers for Disease Control and Prevention, U. S. Department of Health and Human Services, "Recommendations for Prevention and Control of Hepatitis C Virus (HCV) Infection and HCV-Related Chronic Disease," *MMWR* (Vol. 47, October 16, 1998), p. 1.

disease. For example, alcohol use can hasten the onset of cirrhosis and liver failure. Equally important, undiagnosed persons are missing opportunities to safeguard their health. For example, vaccinations could help those with hepatitis C avoid contracting hepatitis A and B. In addition, some could benefit from antiviral drug therapies.

Early detection is also important because persons carrying the virus could infect others, posing a serious public health threat. Specifically, as a bloodborne virus, hepatitis C can be spread between family members through sharing of razors; to health care workers through unequivocal blood exposure, such as needlestick injuries; and to others who come in contact with contaminated blood such as intravenous drug abusers. The Centers for Disease Control and Prevention also reported potential risks associated with tattooing under certain circumstances, such as in unregulated settings.

Given that the prevalence of hepatitis C may be 3 times greater in the veteran population than the general population, this disease has particular importance for VA's health care system. For example, hepatitis C now accounts for over half of the liver transplants needed by VA patients—costing as much as $140,000 per transplant. In addition, VA treats many other veterans for hepatitis C-related conditions, including some which frequently require hospital stays, costing as much as $40,000 per patient. Also, drug therapy to treat hepatitis C is costly—about $13,000 for a 48-week treatment regimen.

MOST INFECTED VETERANS LIKELY REMAIN UNDIAGNOSED

VA estimates that about 800,000 veterans were screened for hepatitis C during fiscal years 1999 and 2000[5]—about 20 percent of all veterans (4 million) making outpatient visits to VA medical facilities in those years. Moreover, screening and testing practices were sometimes flawed. As a result, the majority of veterans with hepatitis C who visited VA facilities may remain undiagnosed. For example, while the true hepatitis C prevalence rate for the 3.2 million unscreened veterans is unknown, as many as 200,000 could have hepatitis C infections if VA's estimated 6.6 percent prevalence rate is accurate.[6] By contrast, VA has identified about 75,000 veterans with hepatitis C during this time period.

Restrictive Screening Practices

During VA's hepatitis C screening process, providers are to determine, generally through a series of questions, whether veterans who visit VA facilities have any

[5] Department of Veterans Affairs, Veterans Health Administration, *White Paper to Inform Congress of Decisions for Hepatitis C Funding* (April 10, 2001), p. 7.
[6] During congressional testimony last year, VA representatives and others informed members that the prevalence rate could be as high as 10 percent. VA is conducting a study over the next year to determine the prevalence of hepatitis C in its veteran population.

risk factors for hepatitis C. Figure 1 shows the 11 risk factors, as stated in VA's guidelines to providers.

Figure 1: VA's Risk Factors for Hepatitis C

1. Vietnam-era veterans[a]
2. Blood transfusion before1992
3. Past or present intravenous drug use
4. Unequivocal blood exposure of skin or mucous membranes
5. History of multiple sexual partners[b]
6. History of hemodialysis
7. Tattoo or repeated body piercing (circumstances most important)
8. History of intranasal cocaine use
9. Unexplained liver disease
10. Unexplained/abnormal ALT (alanine transaminase)
11. Intemperate or immoderate use of alcohol[c]

[a]As currently determined by dates of service or in the age range of 40 to 55 years
[b]Defined as more than 10 lifetime sexual partners
[c]Defined as more than 50g of alcohol per day for ten or more years (roughly 10-14 grams of alcohol = 1 beer)

Source: U. S. Department of Veterans Affairs, Veterans Health Administration, *Hepatitis C Testing and Prevention Counseling - Guidelines for VA Health Care Practitioners.*

Local facility managers often adopted restrictive hepatitis C screening practices, limiting screenings to primary care clinics or certain days of the week or letting individual providers use their own judgment regarding who should be screened. At most of the seven facilities we visited, managers stated that their decisions regarding screening practices were based, in part, on concerns about the availability of funding for screening, testing, and treating services.

For example, at four of the seven sites we visited, screenings were almost exclusively limited to veterans who used primary care clinics. However, as many as a third of veterans visiting individual VA outpatient facilities may not use primary care clinics. Instead, they receive care from specialists who work in other clinics such as cardiology, substance abuse, or mental health. Most specialty clinics at the sites we visited did not routinely screen veterans for hepatitis C.

In addition, some facilities opted to limit hepatitis C screenings within primary care clinics. For example, one facility rotated hepatitis C screening among its five primary care clinics so that each clinic conducted screenings only 1 day each week, due in part to concerns about the availability of funding for laboratory services. Another facility phased-in screenings, so that only one of its three primary care clinics screened veterans for hepatitis C during fiscal year 2000, with

the other clinics beginning to screen in early fiscal year 2001, due in part to concerns about the availability of funding for pharmaceuticals.

Moreover, facility managers told us that, during most of fiscal years 1999 and 2000, they left it to the discretion of individual providers to decide who should be screened for hepatitis C. As a result, rather than screening everyone, some providers only screened veterans who had symptoms associated with liver disease or other risk factors.

Flawed Screening Procedures

Also, screening procedures used at the sites we visited could result in some veterans with hepatitis C not being identified as at risk. For example, providers at some sites frequently required veterans to identify their specific risk behavior rather than allowing them to generally acknowledge that at least one risk factor applied to them. Such a procedure could embarrass veterans, which could result in some not identifying that they had a risk factor. For example, several staff members responsible for screening at facilities we visited noted that veterans were hesitant to discuss stigmatizing risk behaviors associated with hepatitis C—especially when they were asked to admit their history of sexual behavior and substance abuse—such as alcohol, intranasal cocaine, or intravenous drug use.

In some locations, screening was conducted in areas that lacked sufficient privacy, adding another barrier to obtaining accurate information. For instance, a staff member at one clinic told us that interviews were conducted near the general patient waiting area. She believed this to be problematic when screening veterans, especially those elderly veterans who might be reluctant to answer questions regarding intemperate alcohol use and sexual conduct.

Flawed Testing Procedures

Testing procedures at the sites we visited resulted in many at-risk veterans not being tested despite their being screened. Sometimes tests were not ordered and other times ordered tests were not completed. As a result, any of these veterans with hepatitis C infections would remain undiagnosed.

At four of the seven facilities we visited, we reviewed a random sample of 375 medical records for veterans identified as having at least one risk factor. On average, we found that about 50 percent of those patients were not tested. The percentage of sampled veterans who were not tested at the four facilities ranged between 38 and 84 percent.

Tests were not ordered for a variety of reasons. For example, at one facility, providers thought that veterans would not be eligible for antiviral hepatitis C treatment because of age, psychiatric illness, or substance abuse. At another facility, tests were not ordered for some at-risk veterans who were seen at outlying clinics where providers had not been able to attend training sessions

about hepatitis C screening. Also, some screeners were unsure of their authority to order tests. Nursing staff, who were charged with screening veterans at yet another facility, did not order blood tests because they did not think they had the authority to order tests, when in fact they did.

Also, we found that about 7 percent of ordered tests were not completed at the facilities. Staff at those facilities told us that sometimes veterans do not show up at the laboratory to have their blood tested and providers often do not follow up with these veterans during their next visit to reschedule the blood test. These facilities lacked a mechanism for tracking at-risk veterans to ensure that they were tested.

STANDARDS AND ACCOUNTABILITY COULD IMPROVE HEPATITIS C SCREENING AND TESTING PERFORMANCE

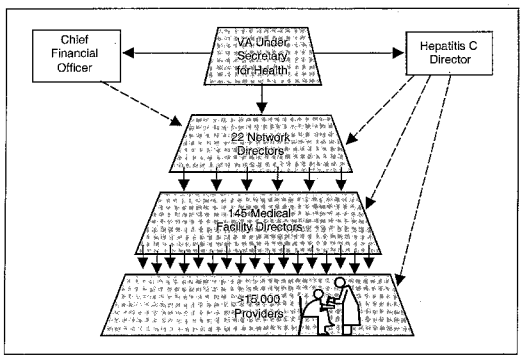
During fiscal year 2001, VA has taken important steps to improve hepatitis C screening and testing performance. For example, VA modified its computerized patient record system to remind providers to screen and document screening results during patients' visits.[7] Also, a new hepatitis C program director was appointed in November 2000 who, among other things, has (1) improved communication processes through the identification of lead clinicians at local medical facilities and (2) convened regional workgroups to identify procedural weaknesses and share best practices.

In VA's management structure, the hepatitis C program director does not have line authority over the providers who screen veterans. Rather, he serves as a catalyst to stimulate ideas and facilitate problem solving. In doing so, he may communicate directly with local managers, but his ability to affect change depends primarily on the level of support provided by managers who have line authority.

In that regard, the size and breadth of VA's health care system poses a significant challenge, when trying to address the types of procedural weaknesses noted earlier. As figure 2 shows, policies and guidance must be communicated from the Under Secretary for Health through 22 network directors and 145 facility directors to over 15,000 health care providers who conduct hepatitis C screenings in over 700 locations nationwide.

[7] When a provider enters a patient name into the computer during a patient visit, the reminder for hepatitis C screening automatically appears on the computer monitor as part of the patient's electronic medical record. When a patient has been screened for hepatitis C, that reminder no longer appears to prompt the physician to screen the veteran, and the provider notes documenting the screening become part of the patient's record.

Figure 2: VA's Management Structure for Hepatitis C Screening and Testing



From our perspective, the pace of screenings appears to be improving, although VA has been unable to provide reliable nationwide data on the number of veterans who were screened this year. Nonetheless, procedural weaknesses noted earlier still persist. This suggests that a more systematic approach may be warranted if all veterans using VA's system are to be screened appropriately and expeditiously. Key steps could include well-defined standards for care and accountability, as well as enhanced communications concerning funding availability.

Establishing Early Detection
As A Standard For Care

VA's hepatitis C initiative has operated for almost 3 years with a general policy objective—evaluate all veterans for risk factors and conduct blood tests for the hepatitis C antibody for those with a history of risk factors or who request testing. VA's stated policy, however, does not specify a timeframe for achieving this objective.

Managers at the seven facilities we visited interpreted VA's policy as encouraging, but not requiring, screening and testing each veteran who visits a VA medical facility. As discussed earlier, these managers, when exercising their discretion, frequently adopted restrictive practices for screening and testing veterans, resulting in relatively limited progress.

Establishing early detection of hepatitis C as a standard for care could convey the higher priority that headquarters would expect local managers to place on hepatitis C screening and testing. VA, for example, could direct clinicians to screen veterans during their next visit to any VA medical facility. Likewise, VA

could direct clinicians to order blood tests in a timely manner for all at-risk veterans as well as others requesting such tests.

Establishing Accountability For Timely Detection of Hepatitis C

VA's hepatitis C program has operated for almost 3 years without performance targets or adequate management oversight information. Local managers told us that if such targets had been set, and tracked, they would have taken steps to achieve them. Last year, VA told this subcommittee that performance targets for screening were under development. In April of this year, VA stated that performance targets will be available for use in fiscal year 2003.

To motivate local managers to aggressively implement other health screening and prevention initiatives, such as smoking cessation or reducing the risk of colorectal cancer, VA has set performance targets and included them in network managers' performance plans. Also, VA has developed processes for collecting information to measure and report results so that managers can be held accountable.

From our perspective, performance targets are most effective when they are results-oriented and time-sensitive. Specifically, such targets should communicate the percent of a target population that is expected to achieve a desired outcome within a prescribed time period. For example, because the use of tobacco products is the single most preventable cause of disease and death, VA set a national goal to reduce the percentage of patients who use tobacco products to 16 percent by 2004. VA has steadily reduced the percentage of patients using tobacco each year from 32 percent in 1997 to 25 percent in 2000, heading toward the strategic target of 16 percent.

A comparable performance target could be established to guide hepatitis C screenings. For example, during fiscal year 2002, VA expects almost 3.8 million veterans to visit VA facilities over 40 million times. With these veterans visiting VA facilities so frequently, setting a target to screen 90 percent or more of these veterans during the next 12 months seems reasonable. Such a goal, if achieved, could enable VA to identify most of the previously undiagnosed veterans.

Likewise, a performance target relating to the timeliness of testing could also help improve hepatitis C detection results. Testing, for example, involves electronic ordering of a laboratory analysis, the drawing of a blood sample from a veteran, assessment of the blood sample for hepatitis C antibodies, and electronic reporting of the results to the ordering provider. This process would be considered timely if completed within a specified time frame from the date of initial screening for risk factors.

If VA managers are to be held accountable for achieving such performance targets, timely information on screening and testing results are needed. Currently, VA has no system to provide essential information. To date, when collecting

hepatitis C data, VA has relied primarily on its Emerging Pathogens Initiative surveillance system which was designed for the limited purpose of monitoring trends in rates of infectious diseases.

Through this system, VA began to track the number of people tested for hepatitis C and the number with positive tests in 1997. However, it was not able to systematically collect data on the number of veterans screened for hepatitis C until VA's electronic clinical reminder process was implemented last year. Nonetheless, information remains unavailable on the numbers of veterans who should have been screened and tested—information that is essential to hold managers accountable for performance.

Moreover, only one of the seven facilities we visited used the clinical reminder system to track provider performance in screening and testing veterans for hepatitis C. This facility distributed screening results periodically to managers and providers to motivate them to more aggressively screen veterans. While this facility has had great success in increasing the number of veterans screened, managers at the six other facilities had not capitalized on the system's capabilities.

VA agrees that its current sources of data on hepatitis C are inadequate. The new hepatitis C program director is working to address the situation by developing standardized hepatitis C-specific reports to track progress at individual facilities.[8]

Communicating Funding Available
For Detection of Hepatitis C

VA budgeted $195 million for hepatitis C screening, testing and antiviral therapy for fiscal year 2000 and $340 million for this fiscal year, and made allocations to network managers as part of its general medical care resource distribution; in turn, network managers made allocations to local facilities. However, VA did not clearly communicate how much of each network's allocation it expected would be spent for screening and testing veterans for hepatitis C infections.

Network budget officers, facility managers, and providers we interviewed were generally unaware that they had received funding to screen and test for hepatitis C. Those who thought funds were available were unsure of how much money was available. As noted earlier, such perceived funding inadequacies resulted in some local managers adopting restrictive screening practices, as well as some providers deciding that blood tests were not warranted for certain at-risk veterans.

[8] Also, VA is designing an electronic database, referred to as a registry, to manage the care and treatment of veterans who, after testing, are diagnosed with hepatitis C infections. This registry, according to VA's hepatitis C program director, will not help managers assess the progress of screening and testing efforts, as it will not contain information on the numbers of veterans who need either screening or testing.

Our assessment shows that amounts distributed to networks were sufficient to allow local facilities to screen all previously unscreened veterans when they visited VA facilities during those years.[9] Thus, clearer communication regarding available funding could eliminate local managers' and providers' perceptions that resources are a barrier to accelerating their screening and testing efforts.

CONCLUDING OBSERVATIONS

VA established a high priority for hepatitis C screening and testing in its budget submissions but failed to follow through, even though sufficient funding was provided to get the job done. In short, managers and providers at local facilities were afforded too much discretion to decide who and when to screen and test without adequate senior management oversight. Faced with the serious health care needs of thousands of veterans who remain at risk of having hepatitis C—as well as the urgent public health implications of hepatitis C—senior managers can no longer afford to take a hands-off approach to its screening and testing efforts.

From our perspective, veterans using VA's health care system should be screened and tested as quickly as possible in order to ensure timely prevention of the progression of liver disease as well as to reduce transmission risks to others. Toward that end, senior managers should take immediate action to establish early detection of hepatitis C as a standard for care, set aggressive performance targets, and hold local managers accountable for achieving them.

Last week, we shared our findings with the Under Secretary for Health and the hepatitis C program director. In general, they agreed that additional management action could improve the pace and quality of hepatitis C screening and testing. In that regard, they indicated that VA would take the results of our work into consideration as they modify their national hepatitis C program.

—

Mr. Chairman, this concludes my prepared statement. I will be happy to answer any questions that you or Members of the Subcommittee may have.

GAO CONTACT AND STAFF ACKNOWLEDGEMENTS

For more information regarding this testimony, please contact me at (202) 512-7101. Key contributors to this testimony include Paul Reynolds, Cheryl Brand, Patricia Jones, and Irene Barnett.

(290013)

[9] *Veterans' Health Care: Observations on VA's Assessment of Hepatitis C Budgeting and Funding* (GAO-01-661T, April 25, 2001).

Mr. SHAYS. Thank you. I'd like to get your response to a few questions, and then we'll get into the next panel. Why weren't network budget officers, facility managers and providers aware that VA had received funding for hepatitis C screening and testing?

Ms. BASCETTA. Mr. Chairman, that's a question that brings to my mind business as usual at the VA. They see their appropriation as available for any medical care regardless of how the budget request was developed. They in turn allocate the money to the networks, and the networks in turn to the facilities. They expect managers to understand the priorities that have been set, and to manage to those priorities.

In this case, hepatitis C obviously was not set clearly enough as an unambiguous priority.

Mr. SHAYS. So the bottom line is, and let me just say, I believe that we have to allow flexibility in anyone who has to manage a Government agency. Sometimes we request nine things and we only fund for eight. But this was clearly a priority of Congress and I thought as well the VA. You basically have literally millions of people who may not know they have this disease. And ultimately, they get pretty hard, and it's life-threatening.

But your testimony is that you one, don't think it's a priority, and two, you think there is the incentive to be using these funds for other reasons?

Ms. BASCETTA. Yes, clearly the funds were used for other reasons. The problem appears to be a disconnect between the high priority in the budget justifications and the way the money was allocated. We agree that the networks and the facilities need flexibility. And we're not suggesting that the money be earmarked. We're suggesting instead that the facilities be made aware of the fact that extra money was provided for this program, and that the clear expectation of headquarters is that is a top priority and funds will be expended to achieve the hepatitis C program goals.

Mr. SHAYS. Basically, we're talking about 4 million patients, not 4 million visits?

Ms. BASCETTA. Four million patients, correct.

Mr. SHAYS. We're talking about 22 network directors, 145 facility directors and 15,000 health care providers. They all need to be into the loop.

Did you determine where the system was breaking down? Did it get as far as the network directors and the facility directors? Did the network directors have different goals? You didn't go into every network, obviously.

Ms. BASCETTA. Correct.

Mr. SHAYS. But can you kind of describe to me where you think it broke down? And I'm talking about the lack of communication through the VA's management structure, and how it affected the screening.

Ms. BASCETTA. Right. I think that the first and most important breakdown is in the vehicle that they chose to communicate their goal, or their policy objective to screen and test all veterans. What they did was they issued, in June 1998, an information letter which is a vehicle that isn't used to convey mandatory policy. In other words, although the information letter stated that all patients will be evaluated for hepatitis C and tested if a risk factor indicates

that it's warranted, so they used an information letter, which is a less formal vehicle for communication.

What happened was, local managers, in reading this information letter, didn't feel that it was a requirement or, I should say, it was ambiguous whether or not there was a requirement to screen all veterans. In addition, there was no timeframe in the information letter. So it wasn't, the information letter didn't convey a sense of urgency about when headquarters would expect it.

Mr. SHAYS. So that leads to what recommendations you would suggest?

Ms. BASCETTA. Well, first of all, if in fact they intend it to be a high priority——

Mr. SHAYS. You know what? I'm going to actually ask this question first. Why hasn't the VA completed a performance standard? In other words, you're talking about, it all relates, there should be certain goals set out, given to the various directors, filtered all the way down to the various health care providers. And I want to know why those standards haven't been put in place and then your recommendations.

Ms. BASCETTA. Unfortunately, I don't have a good answer to that question. The last two budget submissions have indicated those performance standards are TBD, to be developed.

Mr. SHAYS. Say it again?

Ms. BASCETTA. TBD——

Mr. SHAYS. No, I understand to be developed, but the last two?

Ms. BASCETTA. Budget submissions indicated that they intended to set performance standards.

Mr. SHAYS. But this is an issue that, it didn't happen in the last budget and it hasn't happened in this budget?

Ms. BASCETTA. Correct. And they're promising that they will have them for 2003. What we find——

Mr. SHAYS. Let me understand. What's involved with getting—I'm not quite sure why it has to wait until 2003.

Ms. BASCETTA. Well, we're not either. It's clearly not rocket science, and they use performance measures in many of their other programs. It seems to us to be as simple as saying you'll screen 80, 90, 100 percent of your population within 12 months, whatever the timeframe might be.

Mr. SHAYS. So at any rate, what's your recommendation?

Ms. BASCETTA. With regard to performance standards?

Mr. SHAYS. Yes. And how they can communicate better.

Ms. BASCETTA. First of all, they obviously need to set those performance targets. They need to be quantifiable and measurable and results oriented, not process oriented. As I just said, pick a high percentage, 80, 90 or 100 percent of the population to be screened, and to be screened within a specified time limit, say 1 year from the date of the directive.

Another way to emphasize the urgency of screening this population as expeditiously as possible is to write into the directive that veterans are to be screened at their next visit.

In addition, with regard to performance measures that would convey the urgency of the testing portion of the program, we think that they need to minimize the gap between assessing a risk factor and ordering the blood test. And certainly, they need to order the

blood test. As we said, 50 percent of the tests aren't ordered, even when there is a risk factor.

Mr. SHAYS. Describe a risk factor.

Ms. BASCETTA. The risk factors are the 11 on the chart.

Mr. SHAYS. So a veteran who comes in, they want to ask questions about, were you a Vietnam veteran, did you have a blood transfusion, were you a drug user, that's when it gets a little more intrusive, some people may not want to admit to that.

Ms. BASCETTA. Right.

Mr. SHAYS. But they need to be told that if they were, they could have this disease, and they need to have someone describe the impact of this disease on them and their loved ones.

Ms. BASCETTA. That's correct.

Mr. SHAYS. A tatoo, body piecing, all those are issues that you would ask.

Ms. BASCETTA. Right.

Mr. SHAYS. And should be asked. Now, are those questions out to everyone? All the health care providers, they have that list?

Ms. BASCETTA. They are now. Recently, the first one, Vietnam-era vet, was added to their guidance. In our visits, we noticed that some of the sites did not include Vietnam-era vet as one of the risk factors. And of course, as you can see, that's one of the ones that would be easiest to answer, because there isn't a stigma.

Mr. SHAYS. All Vietnam-era veterans should be asked some very significant questions.

Ms. BASCETTA. Right.

Mr. SHAYS. OK. In terms of, we have two different statistics. We have the statistic that basically your feeling is 20 percent were screened, and we have the VA saying their new data, since you've done the report, indicates that up to 40 percent may be screened, 49, I'm sorry. Have you had a chance to look at that data and see—we just received it yesterday. Were you notified of that?

Ms. BASCETTA. Yes, we received it yesterday as well, and we did spend a number of hours trying to do some very quick analysis.

Mr. SHAYS. I'd love to just have your sense of it. I realize, and this is not a criticism of the VA, but this is new information. Depending on its accuracy, and I'm assuming that it obviously points us in the right direction, we should be happy to see that level. But I'd love to just have a sense of how comfortable you can be with it. If you can't tell me your comfort level, I understand.

Ms. BASCETTA. Well, I can tell you that the external peer review program is very rigorous, methodologically sound data. The frustrating part about this whole analysis has been that, of course, the VA doesn't have a management information system that can give us timely and accurate tracking of how well they're doing.

So just as with their external peer review program providing some results yesterday, the system wasn't designed to track and monitor how many veterans have been screened and how many are positive. The timeframes are different than the timeframes that we used to do our analysis and that VA in fact used to do its estimates that it provided for the appropriators a couple of months ago.

So it seems to me that all the data have basic limitations. The uncertainty revolves around three key numbers: the number yet to be screened, the number screened for the risk factor but not tested;

and the overall prevalence. Our conclusion at this point is that our numbers and our analysis are conservative, and that there still need to be about 3 million veterans screened.

So if in fact the conservative prevalence of 6.6 percent is accurate, that leave potentially 200,000 veterans with this virus.

Mr. SHAYS. I'm going to invite counsel to ask questions.

Mr. HALLORAN. So say that again, the prevalence indication from this new data is 6.6? Or is that what you found?

Ms. BASCETTA. No, 6.6 is the number that VA used to develop its budget estimates, based on its 1 day survey.

Mr. HALLORAN. What's the prevalence indicated by the internal review data? None.

Ms. BASCETTA. I don't know.

Mr. SHAYS. When we're talking prevalence—speak my language.

Mr. HALLORAN. How many people were found to have the disease.

Ms. BASCETTA. We don't know the answer to that.

Mr. HALLORAN. It doesn't show that?

Mr. REYNOLDS. If it does show it, they didn't share it with us yesterday.

Mr. HALLORAN. I see. In your work, did you come across any indication, in the places you visited, come across any indications of any other outreach or lookback efforts that VA was feeling the impact of, a local hospital blood center had sent back a lookback notice and did a veteran present themselves to say, hey, I got this letter, I don't quite understand it, they think I have hepatitis C, did you come across any trace of anybody else beating the bushes and driving the veterans toward the VA system on hepatitis C?

Ms. BASCETTA. I believe that in Spokane, there was an outreach letter that went out to all veterans. But I don't know that we have information on the impact at that facility at that outreach.

Mr. HALLORAN. Was it a VA letter, or some externally derived letter?

Ms. BASCETTA. I think it was a VA letter, from the facility.

Mr. REYNOLDS. That was a VA letter that they sent out to everyone in that network. But as we did go around, quite often concerns were expressed that when other private providers or insurers would find people that had hepatitis C, and they found that they were a veteran, that they would strongly encourage them to go to VA.

Mr. HALLORAN. On the screening for risk factors, what did you find in terms of the consistency of the process and the procedure for presenting information about the risk factors, and in particular, the need to get the patient to identify one particular risk factor versus being susceptible to one of those in a less specific fashion? Why one versus the other?

Ms. BASCETTA. Well, in the sites that we visited, a couple of them did require that the veteran admit to a specific risk factor. In one location, the form was presented to the veteran to fill out essentially in the waiting room. And in that case, the disadvantage was that the kind of counseling that you'd like to see happen wasn't happening. But I suppose an advantage was that the veteran didn't have to specify a particular risk factor.

Mr. HALLORAN. What is the standard that is recommended and the VA guidance that you saw in terms of them administering it?

Ms. BASCETTA. Well, the guidance isn't as clear as we would like it to be. It presents the questions and then says, document the risk factor, but it doesn't say document a specific risk factor, or document that the veteran acknowledged one of them. The guidance is unclear.

Mr. HALLORAN. And in your written testimony, you suggested that it would be a reasonable target for VA to look to be able to screen 90 percent of the patients passing through the VHA system in the next 12 months. Given the resources and the current state of play as you found it, do you think that's still possible?

Ms. BASCETTA. Yes, we do.

Mr. HALLORAN. Thank you.

Mr. REYNOLDS. It's especially possible, if I could add, because the veterans come many times during the year. I think that most come four or five times or more. So there's several opportunities to screen them during the 12 months.

Mr. SHAYS. Thank you. I want to ask one last question. You looked at seven facilities, correct?

Ms. BASCETTA. Correct.

Mr. SHAYS. And only one of those facilities used the clinical reminder system. Explain what the clinical reminder system is and why only one used it.

Ms. BASCETTA. The clinical reminder system is a very powerful tool. When a patient is in a physician's office, the computer screen actually displays that the patient needs to be screened for hepatitis. It's essentially a flag that process needs to happen.

And we actually found that at one site, they had tremendous success in using the clinical reminder system. In April 2000, they were at 13 percent screened. They began publishing the results by clinic of the numbers, the percentages that were screened. By September they were up to 50 percent screened, and by the end of the year, they were actually at 89 percent screened, because the peers actually saw one another's data and they did better to perform on that particular clinical reminder.

Mr. SHAYS. And this clinical reminder reminds them to ask questions, not just as it relates to hepatitis C but other issues as well?

Ms. BASCETTA. Correct, yes.

Mr. SHAYS. What was that facility? Congratulations to them.

Ms. BASCETTA. That was the Bronx.

Mr. SHAYS. The Bronx, OK.

Mr. REYNOLDS. If I may, what we're talking about, I think, with the one facility, was using that system as a management tool for the managers to look and see how well the providers were doing screening veterans. All of the facilities we went to used, it was turned on and the providers were getting the message on their screens, although some of them only turned it on a week or two or three before our visit.

So the system, from last July through now, has been slowing been implemented in the system. It's possible that to this day, there are a couple that don't have it turned on.

Mr. SHAYS. One of the values of having GAO inspector general look at issues is that it sometimes encourages people to look at

what they're doing and say, are we meeting the standards and are we doing what we should do. We got into the whole issue of hepatitis C in a hearing we had, a monumental hearing on the safety of the blood supply. We learned that HHS was not using their review panel to come up with new recommendations as this Congress had mandated.

But instead of being critical of the agency, the Department, for not doing it, we just were grateful that they started. But in the process of looking at the safety of the blood supply, we invited hemophiliacs, 10,000 of whom had died during the infection of AIDS. We were told about this kind of silent killer, and it was called hepatitis C. It was new to us, and we learned that in the process of the taint of HIV, there was also hepatitis C.

And this really kind of opened up this understanding to the committee and I think also to the various departments that it needed to. It's just sad that we haven't made as much progress as I think we all have wanted to make. We're just trying to see that come to conclusion.

Let me ask you, is there any question you feel we should have asked?

Mr. Platts, welcome. I understand you may have questions for the next panel, but not this panel.

Is there any question you would like to ask yourself and then answer?

Ms. BASCETTA. No, but I don't think I answered the second part of your question, which is why aren't more facilities using the clinical reminder system. The answer is that, there's very complex software, actually that needs to be installed. And the computer systems at most of the facilities vary. So it's almost as though the reminder system needs to be customized, there has to be custom programming, which requires a high level of expertise to not only install it but have it produce reliable information.

There were some initial startup difficulties for both hardware and software. In some cases, if the hardware was inadequate, the entire CPRS system, the computerized patient records system, could be running slowly, which of course would frustrate providers and cause them not to use it. As well as, there's always a learning curve with any new technology and some initial resistance. Frankly, the managers in those facilities need to tell providers that this is a way that will dramatically improve quality of care in the long run, and that they need to get used to the new system.

But we think that one of the most important things that VA can do is get that clinical reminder system and the computerized records running everywhere.

Mr. SHAYS. Individuals who have other jobs but then have to deal with technology sometimes postpone. I have a computer that's been sitting on my desk for the last few weeks, and it is still a mystery to me, but it won't be hopefully for long.

Ms. BASCETTA. Once you get used to it, you'll never go back.

Mr. SHAYS. I know. But you've got to make that initial step. So I have to cancel a hearing so I can have the opportunity. [Laughter.]

Let me thank you. Is there any question, Mr. Reynolds, that you want to respond to? Anything we should have asked you that we didn't?

Ms. BASCETTA. I don't think so.

Mr. SHAYS. OK. Thank you very much.

I'll call our next panel. Let me invite our panel to come. We have Dr. Frances Murphy, Deputy Under Secretary for Health, Department of Veterans Affairs, accompanied by Dr. Lawrence Deyton, Chief Consultant for Public Health, Department of Veterans Affairs, Dr. Robert Lynch, Director of Veterans Integrated Service Network 16, Department of Veterans Affairs. Everyone is from the Department of Veterans Affairs. Ms. Mary Dowling, Director of the VA Medical Center, Northport, NY, and Mr. James Cody, Director, VA Medical Center, Syracuse, NY.

I was trying to read quickly so I could keep you standing, but if you would all rise and raise your right hands, please.

[Witnesses sworn.]

Mr. SHAYS. Note for the record that we have one statement which would be you, Dr. Murphy, but all will be invited, in fact, encouraged to respond. Let me ask unanimous consent to include in the record statements submitted for the record by Terry Baker, executive director, Veterans Aimed At Awareness. Without objection, so ordered. And Dr. Allen Brownstein, president of the American Liver Foundation. Their statements will be in the record.

[The prepared statements of Mr. Baker and Dr. Brownstein follow:]

STATEMENT OF

Terry Baker
Executive Director
Veterans Aimed Towards Awareness, Inc.

Committee on Government Reform
And Oversight

Subcommittee on National Security, Veterans Affairs
And International Relations

Hepatitis C
A review of the GAO Report of April 2000

14 June 2001

Dear Mr. Chairman, Members and Distinguished Guests of the Subcommittee:

On behalf of Veterans Aimed Toward Awareness, a support group for veterans with Hepatitis C and other chronic illnesses, and Vietnam Veterans of America Chapter 83, I am honored to be able to offer my testimony to the Committee in regards to the VA's handling of the Hepatitis C epidemic. I am also appreciative of the opportunity to respond to the first of what will likely be many reports by the General Accounting Office on the methods used by the Department of Veterans Affairs to provide health care and benefits to our nation's veterans, although I am not altogether happy with what the GAO has discovered.

Since last we met, I have been traveling around the country testing and talking to veterans, visiting VA hospitals and clinics, and corresponding with Dr. Laurence Deyton who now directs all hepatitis C activities of the Department of Veterans Affairs. The problem the Committee is addressing today is one that has been a great concern to me and many of my counterparts. Since I last gave testimony before this Committee in July 2000, the leadership at the VA as it relates to handling hepatitis C has changed. I would like to commend Dr. Garthwaite for his insight in appointing Dr. Deyton, a physician with experience in treating infectious diseases, to lead the VA HCV program. Dr. Deyton has proven to be a very good choice for the job because he has experience in dealing with epidemic diseases, having worked in AIDS care at both the VA and the National Institutes of Health. I believe there has been an improvement in the attention, communications and changes since Dr. Garthwaite appointed Dr. Deyton to this position.

However, I am very concerned that neither Dr. Garthwaite nor Dr. Deyton has much control over how well the VISNs do their jobs. Neither of these VA officials can force a VISN Director to put Hepatitis C on the list of priorities for that VISN. These esteemed doctors cannot force the VISN to keep track of how many veterans they have treated for hepatitis C. They cannot require that VISNs counsel veterans about their risk for hepatitis C. In fact, the Department has removed performance measures related to HCV from the Departmental Performance Plan for FY 2001 because they are not sure how to measure the activities of the VA as they relate to this disease. For the record, this is exactly the opposite of recommendations by the GAO to increase performance measures around HCV activities at the VA.

I am not sure how we will ever know if the changes being pushed by VA headquarters will produce better results if the VISNs are not held accountable, but I am hopeful and supportive of the direction the program is headed.

Members of the committee, we are here today because there are a lot of unanswered questions about the VA and their HCV activities. At the request of Congress, the GAO has reviewed these activities. Their findings confirm what I have long suspected—few in the VA have any knowledge of Congress' intent to address this disease in our nation's military veterans and fewer still have any idea that the Congress appropriated taxpayer money to help treat these veterans.

The General Accounting Office report released on April 25, 2000 examined the failure of the Department of Veterans Affairs (VA) to spend money Congress appropriated for Hepatitis C testing and treatment in FY2000 and FY2001; $195 million and $340 million respectively.

The GAO Report is helpful in focusing congressional attention on the VA's failure to adequately detect and treat hepatitis C in the veteran population, despite the availability of substantial dedicated resources. The GAO points to $145 million shortfall in expenditures in FY2000 – which is much larger than the VA's own estimate to Congress of a $95 million shortfall. In particular, the VA spent only $36 million -- one-fifth of the budgeted amount – on treatment in FY2000.

While the GAO repeats VA explanations that their estimates of demand for HCV treatment were based on untested assumptions and their actual service volume was underreported, the GAO emphasizes that management decisions also contributed to lower levels of screening and treatment than were appropriate. They particularly point to VA's failure to communicate to the VISNs and medical facilities the amount of money that was available for screening and treatment of hepatitis C. As a result, (and I quote from the GAO report) "...staff at local facilities we visited perceived that little or no funds had been appropriated to implement VA's Hepatitis C initiative. Providers at some of these facilities told us (the GAO) that this perceived funding shortage was a factor that ultimately could explain the unexpectedly low number of veterans treated."

The GAO Report confirms many of Veterans Aimed Toward Awareness' concerns about the problems in VA's implementation of their Hepatitis C initiative. VATA hopes that this report will help reinforce the commitment of veteran advocates in Congress to press the VA Central Office—and their local VA Medical Centers and Regional Offices--to step up treatment at the VISN and medical center levels.

According to the GAO report, the VA distributed the full $340 million requested for Hepatitis C to the 22 health care networks using the Veterans Equitable Resource Allocation (VERA) model. Although we traveled over 60,000 miles in the past 12 months visiting VA medical facilities, we could find no one who could confirm the distribution or provide us with a list of how much funding each VISN received. GAO reports similar findings, they conducted a series of site visits and audits of VISNs and individual VA hospitals and found that "Network and medical facility staff we interviewed were generally unaware that they had received $21 million [in that particular case] in funding that the VA had requested. Network budget officers, medical center managers and clinical staff told us that they thought VHA did not receive additional funding to support increased Hepatitis C activities. Those who thought funds were available were unsure of the amount."

GAO addresses our most significant concern when they addressed treatment for HCV. VA's budget assumed that nearly 17,000 veterans would be treated in FY 2000 and that 70 percent would complete a 12-month antiviral drug therapy regimen. VA reported, however, that 4,455 veterans received antiviral drug therapy and that most dropped out of treatment before 6 months. Through talking with veterans, Veterans Aimed Toward Awareness has found out that while some improvements have been made, Veterans are still being warned of the terrible side effects of HCV treatment. Instead of being counseled and encouraged to go on treatment, some facilities use these scare tactics to keep the numbers down.

Our recommendations are:

1. That Congress encourages the VA to hire more physicians and physician's assistants and nurses in order to open more HCV clinics for more hours.
2. That every VA Medical Center has at least one physician that is trained in treating hepatitis C.
3. That Congress encourages the VA to work with local veteran service organizations, such as VATA, to form and sponsor support groups for veterans with hepatitis C and for those who awaiting treatment and on treatment. This should improve treatment outcomes.

VATA's plan is to continue to work with the VA and Congress to push for greater accountability--sooner. This Congressional hearing and the GAO Report should help.

American Liver Foundation

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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
PRESIDENT AND CHIEF EXECUTIVE OFFICER
AMERICAN LIVER FOUNDATION

JUNE 14, 2001

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Member National Health Council, Inc.

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 provide testimony regarding the VA's response to hepatitis C in the veteran population.

ALF is a national voluntary health organization dedicated to the prevention, treatment and cure of hepatitis and other liver diseases through research, education and advocacy. ALF has 30 Chapters nationwide and provides information to more than 300,000 patients and families. 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 10,000 calls to our National Helpline requesting information about hepatitis and other liver diseases. Over 90% of those calls are about hepatitis.

ALF was founded 25 years ago by the American Association for the Study of Liver Diseases. In recent years, ALF has provided nearly $10 million to support hepatitis/liver disease research and over $10 million dollars to promote public awareness about hepatitis.

APPLAUDING THE COMMITTEE'S LEADERSHIP

On behalf of the American Liver Foundation, we applaud the continued leadership of this Committee to bring appropriate focus and attention to hepatitis C and liver disease problems that exist among the veteran population. Mr. Chairman, you and your Subcommittee have been dedicated to addressing this national issue for several years. As early as March of 1997, you brought public attention to the epidemic of hepatitis C and its impact on the veteran population with a hearing. In October of 1998 the Committee published a report titled *Hepatitis C: Silent Epidemic, Mute Public Health Response* further highlighting the daunting challenge hepatitis C poses to public health. In many ways, your Committee has led the nation's response to the hepatitis C problem that exists among the veteran population.

As you know, 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. It is important to recognize, however, that some populations are more vulnerable to chronic hepatitis C than others. Specifically, 6.6% of U.S. veterans are affected with the hepatitis C virus, most of which are from the Vietnam era. In fact, among Vietnam veterans, well over 10% are infected with the hepatitis C virus. This compares to the 1.8% of the overall U.S. population affected with the virus.

Clearly, hepatitis C is a well-documented major health challenge for the nation. 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 for a minority of infected patients it is potentially life-threatening condition and the leading cause of liver transplantation, underscores the importance of identifying those veterans who are infected. With your leadership, we believe that much progress has been made, but much more can still be done.

ALF'S VETERANS HEPATITIS C AND LIVER DISEASES COUNCIL

To mark our commitment to addressing the issue of hepatitis C in the veteran population we created the ALF Veterans Hepatitis C and Liver Disease Council. This Council brings together representation from Veteran Service Organizations, Veteran Health Administration officials, the nation's leading medical authorities on hepatitis C, and the ALF leadership to identify and implement the most expeditious means to increase the rate of testing and treatment for hepatitis C for at risk veterans. The ALF Veterans Council stands unified in its firm commitment to help meet the needs of veterans affected by the hepatitis C virus.

In December 2000 the ALF Veterans Council identified advocacy goals are being pursued in the 107th Congress. These goals include:

1. Support re-introduction (in both House and Senate) and passage of HR 5132, the Veteran's Hepatitis C Health Care Act.

2. Support increased funding for testing, treatment and counseling for hepatitis C within the Veteran's Health Administration.

3. Support appropriate administrative and/or legislative mechanisms to insure that funds requested and provided by the Congress for hepatitis C are actually spent on hepatitis C.

4. Support increased VA research funding for hepatitis C and increased cooperation between NIH research efforts and the Veterans Health Administration.

5. Support funding and congressional directives to establish a VA Hepatitis C Registry to provide data by VA hospitals on the prevalence and incidence of hepatitis C and the resources devoted to the prevention, education, outreach, testing, counseling and treatment of veterans with hepatitis C.

6. Support reviews and modifications (as necessary) of the VA VERA system of resource allocation to insure appropriate support for hepatitis C.

7. The Council should advocate for making home test kits available through the VHA as part of a formulary or other mechanism.

8. Support steps to provide service connection, where appropriate, for veterans with hepatitis C.

Furthermore, the ALF has developed a veterans hepatitis C information brochure (text attached) that will be accompanied with a letter from the VA's Deputy Undersecretary for Health and to be sent to the 4 million veterans that use the VA health system. This letter with the ALF brochure will help educate the veteran population on the importance of being tested and treated for hepatitis C.

ADDITIONAL RESEARCH PRIORITIES

Research is the foundation of our struggle against hepatitis C. It is estimated that in Fiscal Year (FY) 2002, the National Institutes of Health (NIH) will spend $88.9 million on hepatitis C research. This is 25.2% more than what was spent in FY 2000 and 11.9% more than what is estimated to be spent on hepatitis C research in FY 2001. ALF applauds the continued dedication of research to hepatitis C by the NIH, however, in spite of the progress much remains to be done.

As you recall, in March, 1997 the NIH convened a Hepatitis C Consensus Development Conference which assembled the best and brightest scientific minds from across the country to ascertain the best diagnostic and treatment protocols and to identify additional research most urgently needed to address the hepatitis C health threat. While the research recommendations are still valid, four years later, however, we find that the 1997 recommendations on treatment options are outdated. We therefore recommend that NIH convene a new Hepatitis C Consensus Conference in calendar year 2002 that would involve the broadest possible representation from other NIH institutes, the Veterans Health Administration, the Centers for Disease Control and Prevention, the Department of Defense, and representation from the research and medical community.

Mr. Chairman, the VA system of 173 hospitals and 771 clinics provides medical care for the full array of diseases and medical conditions to 4 million veterans. As such, ALF feels that the VA system is an ideal setting for large multi-center studies and clinical trials and that NIH should more aggressively utilize this resource to facilitate and accelerate research. It is requested that NIH explore with the VA ways to increase cooperative research efforts and develop an interagency Memorandum of Understanding to accomplish this purpose and report to the Committee on the projects initiated under this cooperative effort.

THE GAO REPORT: OBVERSATIONS ON VA'S ASSESSMENT OF HEPATITIS C BUDGETING AND FUNDING-ALF COMMENTS AND RECOMMENDATIONS

The American Liver Foundation expresses its appreciation to the General Accounting Office for the preparation and submission of the report that was requested by the House Appropriations Subcommittee for Veterans Affairs and Housing and Urban Development, and Independent Agencies in House Report 106-410. In the Appropriation Committee's report requesting the GAO study, the Committee included the following language:

> "The Committee has noted the alarming rise in the percentage of veterans infected with the hepatitis C virus, and is concerned about the Department's management of this epidemic. The Committee directs the GAO to report on the Department's activities related to hepatitis C four months after the date of enactment. The report should include, by VISN, the amount of fiscal year 2000 resources spent on hepatitis C testing and treatment, the number of veterans tested and treated for hepatitis C, the percentage of tested veterans who are infected with hepatitis C, and how fiscal year 2001 funds will be allocated for hepatitis C testing and treatment. Further the Committee directs the GAO to examine whether the Department's allocation methodology provides adequate funding

for VISN's with statistically higher percentages of veterans testing positive for hepatitis C.

In addition the Committee directs the Department to include hepatitis C as a new patient classification under the Complex Care Component and to calculate VISN resources using this new methodology."

In the Spring of 2000, the ALF Veterans Council advocated in support of the Appropriation Committee language calling for the GAO report. In ALF's opinion, the GAO report, submitted on April 25, 2001, offers an excellent summary of the current status of VA efforts to test and treat Veterans with hepatitis C and provides a strong blueprint for improvements that need to be made in the VA effort. We understand that GAO testimony presented at the June 14, 2001 hearing will be based on additional GAO work done at the request of the House Committee on Government Reform. As this new information will not be released until June 14, 2001, ALF's comments are necessarily based on the findings of the April 25 report and the expert observations of ALF members.

ALF's concern focuses on four areas discussed by the GAO report: 1) VA management decisions that lead to the low numbers of veterans who were screened in FY 2000 and a finding by GAO that these problems have not yet been remedied; 2) the large percentage of veterans who dropped out of VA hepatitis treatment protocols; 3) the slowness in adopting and implementing a registry and data tracking system to help manage the VA's hepatitis C initiative; and 4) the continued underfunding and underspending by the VA on the necessary testing and treating of Veterans with Hepatitis C. These concerns are discussed below:

1. **VA Management Decisions are slowing the response.** GAO reported that the VA failed to adequately report to the VISNs the amount of funding that had been allocated to them for Hepatitis C screening testing and treatment, and had failed to establish performance targets for the VISNs. If properly implemented, these management actions would result in a significant expansion in the number of veterans tested and treated. Therefore, ALF recommends that the Committee urge the VA to take these management steps immediately.

2. **4,455 veterans enrolled in treatment but "almost all dropped out".** The VA enrolled 4,455 veterans in treatment in FY 2000 compared to the prediction that 17,000 would be enrolled with 70% of these individuals completing a 12-month treatment regimen. While the 70% estimate may now be viewed as unrealistically high, the fact that "almost all dropped out of treatment before 6 months" suggests that the VA is not providing appropriate case management services to the veterans and their families. ALF recommends that the Committee urge the VA to support veterans and their families with case management services including mental health counseling so that a larger number of veterans who enter treatment can complete the standard 12-month treatment regimen.

3. **The Hepatitis C Registry continues to be delayed.** GAO reported that the implementation of the Hepatitis C Registry that will track veterans with hepatitis C and their treatment status has been delayed. The GAO reported that the Registry may not be operational until the 4th quarter of 2002, and may not be available for the support of budget formulation until the FY

2004 budget process. The information this Hepatitis C Registry would provide is critical to the management of appropriate treatment follow up for veterans who test positive and for the appropriate allocation of resources. In the spring of 2000, ALF was told that this system would be operational by the end of calendar year 2001. ALF recommends that the Committee urge the VA to implement the Registry in a more timely manner and in no case later than March, 2002.

4. **The VA continues to underspend hepatitis C budget estimates.** The VA requests for FY 2000 and FY 2001 were $195 and $340 million respectively but the actual spending will be $100 million and $151 million. The actual numbers are even less than reported as the VA now includes the "treatment of Hepatitis C related conditions" in the totals and this category totaled $50 million in FY 2000. In FY 2000, the VA spent $145 million less than the Congress provided for the testing and treatment of veterans with hepatitis C. In FY 2001, the VA now projects that it will spend $239 million less than what Congress provided for this purpose. The GAO identified several VA management actions (discussed above) that could be taken to help remedy this problem. ALF recommends that the Committee urge the VA to implement these management actions immediately in order to more fully and appropriately use the resources that have been made available. For FY 2002, the VA has requested $171 million, or just 50% of the amount requested for FY 2001. ALF urges Congress to increase the FY 2002 funding level to at least the FY 2001 level, and to urge the VA to renew its commitment to get the job done in a more aggressive manner consistent with the need.

CONCLUSION

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. The ALF Veterans Hepatitis C and Liver Disease Council represents the long term commitment and unification of government and advocacy groups to face this significant public health crisis of hepatitis C as an emerging infectious disease among veterans.

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

ASSESSING YOUR RISKS

ASSESSING THE ENEMY

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

For further information contact:

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Department of Veterans Affairs
Hepatitis C Centers of Excellence
http://www.va.gov/hepatitisc/

Centers for Disease Control
www.cdc.gov/ncidod/diseases/hepatitis

The information contained in this brochure is provided for information only. This information does not constitute medical advice and it should not be relied upon as such. The American Liver Foundation (ALF) does not engage in the practice of medicine. ALF, under no circumstances, recommends particular treatments for specific individuals, and in all cases recommends that you consult your physician before pursuing any course of treatment.

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VETERANS: THE WAR AGAINST HEPATITIS C

PHARMAGRAPHICS # ALF ALF 07609 ALF Veteran Guide
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The hepatitis C virus is a blood-borne disease that attacks the liver. In 85% of all cases, the infection will last a lifetime. This puts a person at risk for developing cirrhosis (scarring) of the liver, liver cancer, and even death.

Hepatitis C kills 8,000-10,000 Americans each year. Many people don't know they are infected because there are no symptoms at first. However, hepatitis C can slowly progress to cirrhosis over many years. Unfortunately, most of the 4 million Americans infected have not been diagnosed, and thus do not know that they have hepatitis C.

The major types of hepatitis are hepatitis A, B, and C. Safe and effective vaccines exist for hepatitis A and B, but there is no vaccine to prevent hepatitis C. Fortunately, new treatments for hepatitis C that succeed in many patients do exist. Research is continuing to find improved treatments for the years ahead.

KNOW YOUR RISKS

Hepatitis C is a virus that is spread by infected blood. Many ways of getting infected have been identified. Combat and even military training often bring soldiers into contact with blood. Exposures to bleeding wounds or transfusions are ways you may become infected. Tattoos, sexual contact, or injection or snorting of drugs are other possible risks.

Please take this easy quiz. It will help to tell if you may have been exposed to the hepatitis C virus. It is vital that you be honest with yourself in answering these questions. Even if you can't remember, or are in doubt, PLEASE GET TESTED.

ARE YOU AT RISK FOR HEPATITIS C?

1. In your military service, have you ever been in a situation in which you have had exposure to someone else's blood through contact with a bleeding wound, through needlestick injury, or in any other way?
2. Did you serve in Vietnam?
3. Did you have a blood transfusion or organ transplant before 1992?
4. Have you ever, EVEN ONCE, injected drugs?
5. Have you ever, EVEN ONCE, snorted or inhaled cocaine using a straw or bill?
6. Have you ever had unprotected sex with multiple partners?* Do you have a history of sexually transmitted disease?
7. Have you ever had a tattoo or part of your body pierced?
8. Have you ever had acupuncture?
9. Have you ever had hemodialysis?
10. Were you born to an HCV-infected mother?
11. Have you received, before 1987, blood products for clotting problems?
12. Have you ever had an abnormal liver function test?

If you answer YES to any of the questions, you need to get a simple blood test for hepatitis C. Visit your VA medical center or doctor immediately.

*Studies show the risk of getting hepatitis C through unprotected sex is low, if you don't have multiple sex partners or you don't have a sexually transmitted disease. You can't get or give hepatitis C through everyday contact like hugging or kissing.

PLANNING YOUR ATTACK IF YOU'RE INFECTED

If your blood test shows that you have hepatitis C, your doctor may recommend further testing, possibly including a liver biopsy. A biopsy shows how much damage (if any) the hepatitis C virus has done. Based on these results, your doctor will discuss treatment options that are increasingly effective.

If you are diagnosed with hepatitis C, it is important that you DO NOT drink alcoholic beverages. Research has shown that alcohol speeds up the advance of liver disease. It is also important that you get vaccinated for hepatitis A and B. These diseases are even more dangerous for someone with hepatitis C.

If you have hepatitis C, there are other things you can do for your health. There are also important things you can do to help prevent spreading hepatitis C to your loved ones and other individuals. Ask your doctor for more information on these topics. The sooner you know if you are infected, the sooner you can take steps to safeguard your health.

You protected your country. Now protect yourself if you have hepatitis C. If you have any questions, or want more information about hepatitis C, contact your health care professional, your VA medical center, or the American Liver Foundation.

Mr. SHAYS. I think what we'll do is we'll get your statement on the record and then I'll come back for questions.

STATEMENTS OF FRANCES M. MURPHY, M.D., M.P.H., DEPUTY UNDER SECRETARY FOR HEALTH, DEPARTMENT OF VETERANS AFFAIRS, ACCOMPANIED BY DR. LAWRENCE DEYTON, CHIEF CONSULTANT FOR PUBLIC HEALTH, DVA; DR. ROBERT LYNCH, DIRECTOR, VETERANS INTEGRATED SERVICE NETWORK 16, DVA; MARY DOWLING, DIRECTOR, VA MEDICAL CENTER, NORTHPORT, NY, DVA; AND JAMES CODY, DIRECTOR, VA MEDICAL CENTER, SYRACUSE, NY, DVA

Dr. MURPHY. Thank you, Mr. Chairman and members of the subcommittee. I appreciate this opportunity to discuss VA's hepatitis C screening, testing, treatment and prevention programs. With me today are Dr. Lawrence Deyton, Chief Consultant for Public Health, who coordinates VA's hepatitis C programs; Dr. Robert Lynch, who is the Network Director in Network 16, in the southern part of the United States; Mr. James Cody, the Director at the VA Medical Center in Syracuse, NY; and Ms. Mary Dowling, who's the Director at the Northport VA Medical Center in New York.

Hepatitis C, as you know, is a major public health program for the VA and the United States as a whole. VA has responded vigorously to the challenges by creating the largest hepatitis C screening testing and treatment program in the world.

Let me briefly mention just a few of our activities. VA has issued three directives for information letters outlining hepatitis C screening and testing guidelines. Over 800 front line clinicians have participated in VA national education programs for hepatitis C screening, testing and treatment.

In July 2000, the National Clinical Reminder System was initiated to alert clinicians about the need for hepatitis C screening at the time of each patient visit. Even though it is new, the clinical reminder system shows VA has screened over 734,000 veterans for hepatitis C infection during the last 2 fiscal years, plus the first quarter of this fiscal year, 2001.

We believe that is an underestimate. From fiscal year 1999 through the second quarter of fiscal year 2001, VA performed over 800,000 hepatitis C tests and identified over 77,000 veterans who currently are under care for hepatitis C.

As you previously acknowledged, I'm pleased to report to you today on hepatitis C specific aspects of our external performance review program that reported results to us for the first time last Friday. The EPRP reviewed nearly 18,000 medical records of veterans using VHA facilities. In that review, they found that 49 percent of those veterans had either been screened or tested for hepatitis C.

Since this is a random review of a very large number of records, this we believe is a more reliable number than other data that can currently be derived from our clinical reminder system, since it has not uniformly been implemented in every medical center, due to software and computer compatibility problems.

These data from our external peer review program demonstrate the VA providers have responded vigorously to screen and test veterans for hepatitis C. Nearly 2 million veterans have likely been

screened or tested for hepatitis C in the last 2 years. We are increasing our efforts to ensure that all VHA users are screened for hepatitis C. I believe these data also demonstrate that the problem we have is primarily with our data system and our recording of our efforts. We depended on these to report on screening and also for budget estimates. But it appears we have underestimated the screening activities that have already gone on.

However, despite our successes, we intend to do even more for hepatitis C screening and testing. We're improving the use of the clinical reminder system for hepatitis C screening to make it uniformly available and used across the VHA system. We've initiated an epidemiologic study, so that we can determine the actual prevalence of hepatitis C among VA health care users, and to identify the risk factors in this veteran population. This will allow us to better target veterans who are at greatest risks.

We have learned from front line providers and administrators that we can do a much better job of communicating our hepatitis C program priorities and the resources that are available. We have therefore initiated a number of activities that will improve communications with front line providers. The National Hepatitis C program office and VHA's chief information officer are working to establish a new national hepatitis C registry. This registry will assist us in accurately tracking veterans with hepatitis C and managing the resources that VA devotes to helping them.

VA's hepatitis C clinicians are among the most experienced and well trained in the world. We have hepatitis C lead clinicians at each VA facility where hepatitis C care takes place. These clinicians are extraordinarily capable and experienced in the treatment of this disease. They have averaged 14 years experience in the care of hepatitis C and chronic liver disease. These clinicians average 11 years serving in VA health care. Ninety-four percent of these physicians have specialty or sub-specialty board certification in gastroenterology, internal medicine, family practice or infectious disease. Sixty-two percent of these have academic affiliations at the level of full professor or associate professor of medicine, and 44 percent have treated over 500 patients with hepatitis C or chronic liver disease, and 84 percent have treated over 100 patients.

VA makes available all licensed drugs to treat hepatitis C. We've added to our national formulary the new form of alpha interferon and made that available as soon as it was licensed by FDA. Our National Hepatitis C program office informs all of our clinicians and pharmacists treating hepatitis C patients of the availability of new treatments upon licensure by the FDA.

The treatment for hepatitis C, as you know, changes rapidly as new drugs and new information is developed. Thus, the National Hepatitis C program office is now updating VA's hepatitis C treatment guidelines and will distribute them to the field shortly.

Before I close my statement, I would like to address issues that we have concerning VA's projections about the utilization of hepatitis C——

Mr. SHAYS. Maybe I need to ask you, how much time would that take?

Dr. MURPHY. Another minute.

Mr. SHAYS. I think we can do that. I don't want to rush you, I'm happy to come back, but if it's a minute, we'll do it now.

Dr. MURPHY. We recently submitted a report to Congress that articulates the reasons for the differences between our projections and VA's budget formulation requests. Hepatitis C is a new disease, the hepatitis C virus was only identified in 1988, the blood test in 1992 and the first treatments approved in 1997. The previous budget estimates were based on assumptions that were not informed by reliable data, because there was no experience on which to base these projections. Our estimates of the numbers tested, the prevalence and the treatment acceptance were larger than proved to be the actual case.

At the same time, our ability to accurately capture hepatitis C treatment related costs likely missed significant costs to the VA health care system. Today, based on actual experience in testing and treating hepatitis C, we feel we better understand where early assumptions were inaccurate, and intend to continue to improve the projections for the future.

Because of the magnitude of difference between previous models and our actual experience, VA revised its projections for hepatitis C expenditure in fiscal year 2002 to $171 million. The budget planning for 2003 will include use of improved data.

With that, also, the National Hepatitis C registry will allow much more accurate reporting and tracking. So we believe that we'll be able to perform better in the future.

Mr. Chairman, my colleagues and I will be happy to answer questions.

[The prepared statement of Dr. Murphy follows:]

STATEMENT OF
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DEPUTY UNDER SECRETARY FOR HEALTH
DEPARTMENT OF VETERANS AFFAIRS
BEFORE THE
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS AFFAIRS AND INTERNATIONAL RELATIONS
COMMITTEE ON GOVERNMENT REFORM
HOUSE OF REPRESENTATIVES

JUNE 14, 2001

Mr. Chairman and Members of the Subcommittee:

Thank you for the opportunity to discuss the Department of Veterans Affairs' (VA's) programs for hepatitis C screening, treatment, and prevention. Hepatitis C is a major public health problem in the United States and no less so for VA.

VA has recognized the importance of hepatitis C by establishing an impressive array of initiatives, programs, and activities that have created the largest hepatitis C screening, testing, and treatment program in the world. In recognition of the important and long-term aspects of VA's commitment to hepatitis C, last October the Under Secretary for Health established a new National Hepatitis C Program in VA's Office of Public Health and Environmental Hazards. The mission of this program is to address the needs of veterans with, or at risk for, hepatitis C from a public health perspective. The program includes the following elements:

- wide-spread education for veterans about the risk factors and the disease itself, and scientific and medical education for providers;
- a proactive hepatitis C screening and testing program;

- a treatment program to deliver the highest quality care to veterans with hepatitis C;
- a prevention program to identify veterans at risk and work to intervene; and
- a research program to find ways to improve hepatitis C treatment among veterans.

The Under Secretary also directed this office to create a new National Hepatitis C Registry in order to (1) more accurately track veterans with hepatitis C and their clinical course and outcomes and (2) to manage the resources VA devotes to helping veterans with hepatitis C.

Beginning in FY 2000, reimbursement for the care of veterans on drug therapy for hepatitis C has been at the complex level under the VERA model, equaling approximately $43,000 per year per patient. This level of funding will ensure that facilities receive sufficient resources for these hepatitis C initiatives.

I would now like to address briefly each element of our new National Hepatitis C Program, our accomplishments to date, where we are going in the near future, and the status of our program to screen all veterans for risk of hepatitis C.

Veterans Hepatitis C Education Program

Informing all veterans about known risk factors for hepatitis C is the first step in our overall public health approach for hepatitis C. Through VA's newly established Hepatitis C Field-Based Resource Centers Program (formerly the Hepatitis C Centers of Excellence Program), education material specifically targeted to veterans and their families has been developed and disseminated. VA medical centers (VAMCs), community-based outpatient clinics, substance abuse programs, and Vet Centers distribute information about hepatitis C. In addition, VA recognizes that veterans who do not access the Department's services also must be educated about hepatitis C. We have worked with several veterans service organizations (VSOs), such as the American Legion, Vietnam Veterans of America, and a Veterans-specific hepatitis C interest group, Veterans Armed Toward Awareness (VATA), to assist in education of their

members. The American Legion and VATA have recently distributed education posters about hepatitis C to over 14,000 American Legion chapters. The American Legion is also making available an additional 2000 of these posters for distribution to VAMCs and Vet Centers.

In order to inform veterans about the latest scientific advances in hepatitis C, we often update patient education materials on hepatitis C posted on the VA's hepatitis C information web site (www.va.gov/hepatitisc). We have patient-oriented information on 26 separate topics already available or in development on this web site. Currently, we are developing a hepatitis C video education series targeted at veterans and their families to be distributed throughout VA, VSOs, and other community and health organizations. These videos will feature as narrators internationally recognizable United States military, veteran, and government leaders. This video education series will allow the viewer to learn about hepatitis C, possible risk factors, how and why to get tested, and treatment options.

In addition, we will very shortly be distributing 3.4 million educational brochures on hepatitis C to VA users through a joint project of VA and the American Liver Foundation. We also will soon be testing the availability of hepatitis C information through VA Information Kiosks placed in public areas of VAMCs. One of four Hepatitis C Field-Based Resource Centers will specifically focus on Patient Education and Self-Management and will provide patient and family information on hepatitis C, its treatment, prevention, and other important topics.

VA Clinician Hepatitis C Education Program

Hepatitis C is a complex chronic disease for which epidemiology and treatment knowledge is changing rapidly. We have provided resources and opportunities to VA clinicians to learn about hepatitis C and to update their knowledge and skills in order to provide the highest quality hepatitis C care in the Nation. In FY 2000 alone, VA conducted three national hepatitis C update conferences on topics such as guidelines for screening, testing, counseling, and

diagnosis and clinical treatment updates. Over 800 front-line VA providers have attended these conferences. Clinical education materials on 18 separate topics are available or in development on the VA Hepatitis C web site mentioned earlier. An additional VA national videoconference on hepatitis C screening, testing, and counseling is scheduled for August 2001. Another national hepatitis C clinical update conference focusing on treatment and transplantation issues will be held in September 2001. In addition, one of the four Hepatitis C Field-Based Resource Centers will focus specifically on Clinician Education.

VA maintains the single largest training program for health care providers, such as medical students, interns, residents, and students in nursing, pharmacy, social work, and psychology In order to educate these clinicians-in-training about hepatitis C, VA will make available 150,000 "Trainee Pocket Cards" that will include information on hepatitis C risk and screening criteria for veterans and will be a resource for these trainees for additional medical information on hepatitis C.

Hepatitis C Screening and Testing Program

We define hepatitis C screening as the process of assessing whether a veteran has known risk factors for exposure to hepatitis C in order to determine if testing for the presence of the virus is warranted. We believe all veterans should be screened for risk factors for exposure to hepatitis C. Those found to have known risk factors should be referred for blood testing for evidence of hepatitis C infection. We do not believe that all veterans should have their blood tested for hepatitis C for three reasons. First, data from CDC and the National Health and Nutrition Evaluation Survey demonstrate that the prevalence of hepatitis C among those who identify as veterans in a sample of the U.S. population is the same as that of the public at large. Second, the false positive rate for the standard hepatitis C screening blood test is unacceptably high (up to 50 percent) when used in a low prevalence population. Third, widespread blood testing would lead to unnecessary additional testing, anxiety, and potential harm to the many veterans with false positive tests.

However, there is anecdotal evidence that the prevalence of hepatitis C among certain groups of veterans or certain groups of VA users may be higher than the national rate. Thus, we believe a two-step approach to identification of persons with hepatitis C is the best approach for VA. Those two steps are (1) screening (assessment of known risk factors to determine if blood tests are warranted); and (2) blood testing for evidence of hepatitis C infection, if risk is identified.

Using this approach, VA has mounted the largest single hepatitis C screening and testing program in the world. VA screened nearly 540,000 veterans for risk factors of hepatitis C and conducted over 650,000 blood tests in FY 1999 and FY 2000. An estimated 150,000 additional tests have been conducted in the first two quarters of FY 2001. This screening and testing has identified approximately 77,000 unique veterans with hepatitis C and referred all for medical evaluation. Because the electronic clinical reminder system from which these data have been derived has been in place only since July 2000 and continues to be implemented, it is important to recognize that VA has probably screened an even greater number of veterans for hepatitis C risk.

In order to continue to improve VA's hepatitis C screening and testing, we recently revised and reissued guidelines on hepatitis C screening, testing, and test counseling. Screening, testing, and counseling will also be the focus of a VA nationwide videoconference to be held in August. In addition, a significant component of VA's hepatitis C videotape series currently being produced will focus on screening and testing for hepatitis C.

Hepatitis C Treatment

VA has identified and treated more persons with hepatitis C than any health care organization in the world. Approximately 77,000 veterans are currently under care in VA facilities for hepatitis C. As you know from the information you recently requested, our Hepatitis C Lead Clinicians are extraordinarily capable and experienced in the treatment of this chronic liver disease. Overall, the providers who serve as lead clinicians for hepatitis C have

an average of 14 years experience in the care of hepatitis C and chronic liver diseases and an average of 11 years serving in VA health care. Of the physicians, 94 percent have specialty or subspecialty board certifications, 62 percent of which are in gastroenterology, 23 percent in internal medicine/family practice, and 15 percent in infectious diseases. Sixty-two percent of those with academic affiliations are ranked as full professors or associate professors of medicine. Collectively, our Hepatitis C Lead Clinicians have extraordinary clinical experience as well. Forty-four percent have treated over 500 patients with hepatitis C/chronic liver disease, and 84 percent have treated over 100 patients.

VA makes available all licensed drugs to treat hepatitis C and recently added to the national formulary a new form of alpha interferon as soon as it became licensed by the Food and Drug Administration (FDA). Our National Hepatitis C Program office informed all clinicians and pharmacists treating veterans with hepatitis C of the availability of this new treatment upon its licensure by the FDA. Treatment for hepatitis C changes rapidly. Thus, the VA National Hepatitis C Program office is now updating VA's hepatitis C treatment guidelines and shortly will disseminate the revised materials to all hepatitis C treating clinicians and pharmacists.

VA strongly believes that the best medical management of hepatitis C is far more comprehensive than the administration of drug therapy for persons infected with hepatitis C. Our experience is similar to that of many clinicians caring for persons with hepatitis C. In fact, drug therapy for hepatitis C represents a minority of the care and services needed for those with hepatitis C infection. VA defines hepatitis C treatment as the appropriate medical evaluation of all persons with documented hepatitis C infection, determination if and when drug treatment is warranted, all direct and associated care and services needed during drug treatment, watchful waiting and treatment of related conditions if treatment is deferred, and long-term follow-up care for all. Related conditions frequently include mental health problems, alcohol and substance abuse, liver transplantation, and complications of long-standing hepatitis C or the frequent toxicities of the drugs currently used to treat hepatitis C infection. Thus, the

resources needed to care appropriately for veterans with hepatitis C goes well beyond drug therapy. As mentioned earlier, to ensure adequate funding for hepatitis C care, starting in September 2000, VA's Veterans Integrated Service Networks (VISNs) began to receive annual reimbursement at the complex level under VERA for each patient who receives drug therapy for hepatitis C. I feel this is an appropriate reimbursement and a strong incentive to provide comprehensive medical and supportive care to veterans with hepatitis C.

Hepatitis C Prevention

The Centers for Disease Control and Prevention estimates that there are 40,000 new hepatitis C infections each year in the United States. Undoubtedly, many of these new infections occur in veterans. Our comprehensive public health approach to VA's hepatitis C program includes development of proactive programs both in primary and secondary prevention. Primary prevention will identify veterans at risk of hepatitis C infection who receive care and services throughout VA and implement interventions to reduce their risk. Secondary prevention will address veterans already infected with hepatitis C to keep them healthier and free of hepatitis C-related medical complications. Secondary prevention involves decreasing alcohol intake and other lifestyle or medical interventions to protect liver health, such as vaccination for hepatitis A and B. One of the four Hepatitis C Field-Based Resource Centers will focus specifically on hepatitis C prevention.

Research on Hepatitis C

Excellence in clinical care goes hand in hand with excellence in research. Thus, VA endorses a proactive hepatitis C research program. VA researchers are conducting 134 research projects on hepatitis C. This represents an investment of nearly $7.3M in FY 2001. In addition, VA currently supports two Medical Research Hepatitis C Program Projects located at the Portland and Palo Alto VAMCs. The total funding for these projects is approximately $2.6M over five years.

One important research project is being conducted at 24 VA sites in collaboration with the Schering-Plough company and is teaching us much about the treatment of hepatitis C among VA users. Early results from this study show that of the 5,000 patients with hepatitis C who were evaluated for treatment, over 900 (about 18 percent) were enrolled for treatment. The reason for non-enrollment tells us much about how to improve treatment candidacy and why those who elect to be treated or who defer treatment do so. Specifically, we have learned that approximately two-thirds of VA patients with hepatitis C do not meet standard hepatitis C treatment criteria; for example, they have significant non-liver diagnoses, ongoing substance abuse, psychiatric conditions, or a combination of these factors. This study is also confirming what our wider VA treatment data have shown. For those who do meet standard hepatitis C treatment criteria, nearly one-half elect not to be treated because of concern over side effects or the desire to defer treatment to a later date.

I am pleased to announce that VA has begun a national hepatitis C prevalence study that will address several questions important to both veterans and VA. This study will determine the prevalence of hepatitis C among users of the VA system. It will also help determine the risk of hepatitis C associated with several known and putative risk factors, such as era of service, military service in Vietnam, the use of air gun inoculation devices, and alcohol and drug use behaviors. The study will involve 4,000 veterans across the country. The results of this study will greatly improve our understanding of how best to identify veterans at greatest risk of hepatitis C and the magnitude of the care and services that VA will need to supply.

In order to ensure that VA hepatitis C scientists and clinicians are at the forefront of research to improve hepatitis C care, VA's Hepatitis C Program office will sponsor a Hepatitis C Research Symposium in October 2001. This symposium will bring together VA hepatitis C researchers, researchers from other government agencies (NIH, CDC, and DOD), and potential collaborators from the pharmaceutical and biotechnology industries. The goal of this

symposium will be to catalyze collaborations between VA and other potential partners in hepatitis C research.

Hepatitis C National Registry

The Under Secretary for Health has instructed the National Hepatitis C Program office and the VHA Chief Information Officer to establish a National Hepatitis C Registry. This registry, which will be internal to VA and without public access, will become a pivotal tool for both VA clinicians and managers in assessing and improving our overall hepatitis C effort. The registry will enroll every veteran with hepatitis C and track each veteran's clinical status, use of VA services including pharmaceuticals, laboratory tests, and general health care utilization. Tracking these parameters will allow local clinicians to best manage individual patients through the course of their hepatitis C infection. The registry will also allow our program managers at the local, VISN, and national level to appropriately track and manage the resources needed to care for all veterans with hepatitis C. The computer programming required for this registry is currently being created. Initial testing will start this fall, and the registry will be in place to assist in development of budget projections beginning in FY 2003.

Lessons from the Field – Screening and Communication:

Mr. Chairman, when the Under Secretary established the new National Hepatitis C Program Office in October 2000, he asked the staff to learn immediately from our front-line providers how we were doing in hepatitis C screening, testing, and treatment. In January and February of this year, that office convened a series of four field-based "Think Tanks on Hepatitis C" that involved over 150 front-line providers from all types and sizes of VA facilities. The lessons learned from these meetings have begun to be acted upon.

One of the most important messages we received is that many front-line providers and administrators understood the importance of initiating and increasing screening and testing activities for hepatitis C, but did not understand that resources had been specifically requested to assist them in those efforts. In

short, many front-line providers and administrators felt that the increased activities in hepatitis C screening and treatment were an "unfunded mandate." In order to improve communications with front-line hepatitis C care givers and their administrative staff, the National Hepatitis C Program Office initiated the following activities.

- In February 2001, a VA Directive was issued requiring each facility to identify a Hepatitis C Lead Clinician to serve as the principal point of contact between that facility and the National Hepatitis C Program Office.
- In March 2001, the National Hepatitis C Program Office initiated an e-mail list of over 800 VA providers involved in hepatitis C care. The purpose of this e-mail list is to communicate directly to the field about hepatitis C programs, priorities, policies, issues, and clinical and research updates.
- In April 2001, the National Hepatitis C Program Office held the first meeting of the newly formed Hepatitis C Technical Advisory Group (TAG). This group is made up of 25 VA field and administrative staff. The purpose of this TAG is to advise the National Office about programs, priorities, and problems with hepatitis C activities.
- In May 2001, the National Hepatitis C Program Office initiated a newsletter sent to VISN Leadership, all Hepatitis C Lead Clinicians, and the e-mail list of 800 providers. This newsletter summarizes VA priorities, programs, and initiatives, and highlights the goals of VA's Hepatitis C Program.
- In June 2001, the National Hepatitis C Program Office updated and reissued Guidelines on Hepatitis C Testing and Counseling to all VA providers and administrative staff.
- In June 2001, the National Hepatitis C Program Office will issue a Request for Applications to the Hepatitis C Field-Based Resource Centers Program. These four Centers will be funded in FY 2002 and will be required to provide high quality products and programs for front line providers in the areas of Hepatitis C Patient Education, Hepatitis C Provider Education and Skills Building, Hepatitis C Prevention and Risk Reduction, and Hepatitis C Models of Care Delivery and Best Practices.

Differences Between VA Hepatitis C Projections and Actual Utilization:

Before I close my statement, I would like to address issues that have come to light concerning VA's projections about utilization of hepatitis C medical care services. We recently submitted a report to Congress that articulates the reasons for differences between the projections used to formulate budget requests for VA hepatitis C care and what we were able to document as having been actually spent on that care.

It is important to point out that since we began tracking hepatitis C-specific utilization and expenditures, VA has significantly increased the number of patients screened, tested, and treated every year. In addition, VA expenditures for hepatitis C have also increased every year, thus reflecting this increased activity. Hepatitis C expenditures have increased by over $70 million over the past two years.

Hepatitis C is a new disease. The virus that causes the disease was first identified in 1988. The blood test for it was developed only in 1992, and the first treatments were approved in 1997. For these reasons, VA's previous budget estimates were based on assumptions that could not be informed by reliable data on Hepatitis C screening, testing, and treatment. On the basis of VA's actual experience in testing and treating veterans with hepatitis C, we are now better able to understand where those early assumptions were inaccurate.

Specifically, areas of large discrepancy between the earlier estimates and our actual experience involve (1) the number of patients who agreed to be tested for hepatitis C (fewer agreed to be tested than we had projected); (2) the actual number of people who test positive (prevalence – fewer tested positive than we had projected); and (3) the number who agree to treatment for hepatitis C (many fewer agreed to begin therapy than we had projected). It is important to point out that there is continued medical uncertainty about some aspects of hepatitis C treatment, including, for many patients with minimal clinical disease, the value of treatment versus the risk of side effects from treatment. Since hepatitis C infection may persist for decades without clinical symptoms or signs of liver

damage, some asymptomatic patients and their providers opt to defer therapy until more effective and better-tolerated therapies are available, or until the infection begins to cause liver damage.

In addition, we have learned that methods used to track disease-specific costs in VA are not well equipped to quantify accurately the actual expenditures on any particular disease. Thus, our analyses show that there is likely a systematic under-reporting of costs related to hepatitis C throughout VA.

In sum, our projections were based on estimates of the numbers tested, prevalence, and treatment acceptance that were larger than they have proven to be in reality. At the same time, VA's ability to accurately capture all hepatitis C treatment-related costs likely misses significant costs.

The magnitude of difference between previous models and actual experience justifies a reexamination of the models and assumptions currently used to project hepatitis C expenditures. As a preliminary step in this direction, VA has revised the projections for FY 2002 to $171 million. The budget planning process for FY 2003 will include a more comprehensive revision of the hepatitis C model. In addition, the creation and use of the National VA Hepatitis C Registry will greatly facilitate both VA's ability to capture all hepatitis C treatment-related costs and our overall planning and management of resources for the care of veterans with hepatitis C.

Mr. Chairman, thank you for the opportunity to discuss VA's hepatitis C program. I will now be happy to answer any questions that you or other members of the Subcommittee might have.

Mr. SHAYS. Let me just say, if you felt a little rushed, we can have you make any other statement you want. I'll come back. I have two votes, so it may take a while. We stand in recess.

[Recess.]

Mr. SHAYS. We were in recess, and we are back in session. I just want to make sure, just to make sure we get back into this, if there's any comment that any of you want to make before we start the questions.

Let me start the process by asking you, we have GAO coming in and obviously doing a sample study, and then you have a peer review study. Tell me why you think the numbers differ, and tell me what you think the peer review study really tells us.

Dr. MURPHY. The peer review study was done on a random selection of charts during a 2-month period in VA. It's part of our routine peer review quality assessment program. With the larger number of charts over a broader range of medical centers, we believe that the data is more accurate than doing a small number of charts.

That's not a criticism of the GAO methodology. It's simply a difference in the screening technique that was used and the depth of the analysis that was done by EPRP.

Mr. SHAYS. What is the timeframe used in that study?

Dr. MURPHY. The charts were pulled from patients who were seen during March and April. But the analysis was actually whether risk factor screening was done during the 2-year period prior to that.

Mr. SHAYS. How was it conducted?

Dr. MURPHY. By actual medical record review. So the way the information was gathered was that a random number of charts were selected, 18,000 medical records were reviewed, and in those medical records, the health care provider would have had to record risk factor screening for hepatitis C or a positive test for that chart to be included in the 49 percent positive for screen.

Dr. DEYTON. Positive or negative test, juste any testing.

Mr. SHAYS. I'm sorry?

Dr. DEYTON. The review looked for risk factor screening or a test for hepatitis C. So the test could be either positive or negative.

Mr. SHAYS. OK. By the way, I welcome anyone else jumping in here. We'll get out into the field and just question. Tell me how the sample was drawn?

Dr. MURPHY. We have a standard sampling methodology that EPRP uses. What they do is they randomly select from among the veterans charts who are seen at our facilities nationwide over a 1-month period. The EPRP reviewers will send a list of charts to the medical center just prior to their visit to pull, so that they can be reviewed for a number of quality measures.

Mr. SHAYS. I was going to ask, and am going to ask, but I get the inference that it wasn't just one network, it was all the networks?

Dr. MURPHY. Yes.

Mr. SHAYS. It was random throughout the system. And what is the margin of error when we do this?

Dr. DEYTON. I believe I heard yesterday when we were discussing this with GAO, I think I recall the EPRP programs testing, the

margin of error is very small, like 97 to 98 percent accuracy. And I should point out, sir, that this is performed by an external contractor group. They're professionals in going in and monitoring medical records. So this is a contract that VA has external to us to review the quality of the work we're doing in specific areas.

Dr. LYNCH. It's in fact a State peer review organization that does Medicare work for the State of West Virginia. So they're already an existing group in the State of West Virginia that does Medicare peer review. And we contracted so we kept it outside of VA. The sample sizes are designed to be statistically significant at the network level, so they make sure they extract enough charts.

Mr. SHAYS. And how is it determined that a veteran had been screened and tested for hepatitis C? How did they determine that?

Dr. MURPHY. They actually looked at the medical records, went back through the progress notes for a 2-year period. And in one of those progress notes or in a discharge summary, there needed to be evidence that the veteran was screened for hepatitis C, and specifically screening for the risk factors that are on your chart, or that there was a test for hepatitis C ordered.

Dr. DEYTON. I'd be glad to provide to your or your staff, sir, the specific questions that the reviewers do go and look in the charts for over the last 2 years. Because they're very specific instructions, and the reviewers are certified on doing this in a very accurate way.

Dr. LYNCH. They're in fact required to be medical record technicians or registered record technicians. This is their job.

Mr. HALLORAN. And hepatitis C questions were just added t the external review process?

Dr. DEYTON. Yes, sir. Back in I think it was February or March, when the EPRP staff were developing the questions to go out in the latest cycle, we were able to insert six specific questions about hepatitis C for the reviewers to go and look at.

Mr. HALLORAN. How often is this done?

Dr. DEYTON. Constantly.

Mr. HALLORAN. The EPRP process?

Dr. DEYTON. It's a constant, ongoing process. There are new questions added every cycle.

Mr. HALLORAN. A cycle being—my question is, when can we expect to see another set of data with hepatitis C questions in it?

Dr. DEYTON. We don't have a set time plan, obviously. When Dr. Garthwaite gave us responsibility for this program, we wanted to immediately insert in the EPRP some of these questions to just get a baseline. So obviously we will be going back to EPRP in the near future to followup on some of these and other issues that we'll need to for better management of the program. But I don't have a specific time date in mind.

Mr. HALLORAN. Let's go down the data and get from it what we can, and I know it's preliminary and there will be subsequent analysis. But just to decode some of the data elements here, the 49 percent is derived from the sample six, the 17,994, that's the charts reviewed, right?

Dr. DEYTON. Yes.

Mr. HALLORAN. And they found in those 17,994 charts 8,846 showed indications of screening and/or a test, is that correct?

Dr. DEYTON. Yes, sir.

Mr. HALLORAN. Positive or negative. Moving down the rest of the data, tell me what they represent, if you would.

Dr. DEYTON. What I get from these data, and again, we just got these data the other day, and staff hasn't even had a chance to do all the analysis and the final sort of summary of it. But what I get from these data, the important messages, that first message that of the nearly 18,000 charts that were reviewed, there was evidence of screening for hepatitis C or a test in a 49 percent.

The other very important factor to me is that of those who tested, or who had a risk factor, only 49 percent of those people actually went on to get a hepatitis C blood test. So there's another 50 percent that had identifiable risk factors and were not tested for some reason. I don't know what those reasons are.

Mr. HALLORAN. That's the differential the GAO was talking about?

Dr. DEYTON. That's exactly what GAO found as well, yes. So I think that's a very important lesson here, that there's risk being identified in the screening, and there is about half who are not going on to get a blood test for some reason.

Mr. HALLORAN. What are the possible reasons? I mean, maybe a veteran says no?

Dr. DEYTON. Yes, the veteran says no, or it may be a situation where the veteran is at incredibly low risk for a problem, that is, a 90 year old veteran who is in the hospital with dementia, you might not want to get tested there. Other reasons may be that the screening itself may be again, I think GAO found some evidence of this, screening may be going on in a way where it's happening in a clinic, a waiting room setting or something like that where the information actually doesn't get to the doctor or nurse to order the test.

So those are all issues which we need to identify and figure out how to correct that problem, so that in fact, testing of all 100 percent who do have a risk factor does happen.

Ms. DOWLING. I would add something to that, just to share my experience. In the way we rolled out the program, we started in our primary care area, one team, and then rolled it out across the team. Over a 12 month period, if you look at our average of patients who were tested, those who had a risk factor and were tested, it was 48 percent.

But if you look at how it was rolled out in the beginning, it was 23 percent, and at the end, it was 90 percent. So it's really progressed remarkably well in terms of improvement.

Mr. HALLORAN. I'm glad you raised that. My next question was to ask the other facility directors here if this data comports with your experience in the field. Is there any other surprise besides the 49 percent?

Mr. CODY. I'm from Syracuse. I wasn't surprised at the data. I thought we were screening much more than the 20 percent than was being quoted before. I was surprised at that figure. And at Syracuse, I could show that 20 percent was not the figure. It's in excess of at least 30 percent that I know have been screened and given the blood test, at this point, just over the last year.

What I am finding though, I am a little bit surprised that of the one that we do the actual questioning or screening on, most of them are getting the blood test at our place. I'm not finding that half of them are not getting it. I can't explain that.

Mr. HALLORAN. So most who have an identified risk factor——

Mr. CODY. Right, just to throw out some numbers, just in the last 6 months, 6,011 were screened, 41 percent of them presented some risks. And of those, 98 percent of them got the blood test.

Mr. SHAYS. And then what happened?

Mr. CODY. Out of those, then about 15 percent came out positive.

Mr. SHAYS. Fifteen of the 41 percent?

Mr. CODY. Yes. Excuse me, 15 percent of the people had the blood test, which is essentially all the 41 percent that you just mentioned. So about 15 percent were positive, then they have the confirmatory test. Of those, it varied between 25 and 40 percent were again positive.

So the numbers diminish very quickly as to who should go on for treatment. Then I have numbers after that who have actually gone on for treatment. But that varies significantly. A lot of people don't go on for treatment for very many reasons.

Mr. HALLORAN. Right. But that raises the question I think GAO came across, I think it was your facility or one of them here, that there was a concern at the provider level about the implications of the screening and testing, that care was expensive, or that, why would we test somebody who may be, the risk factors are so pronounced that they're likely to be ineligible or not tolerate the care? Is that——

Mr. CODY. I'm not finding that at Syracuse, if I understand the question. From the whole process, we start with a process of the patient filling out the screening. That is done in private with a nurse. The nurse presents it to the provider at the time in the primary care visit. The provider and the patient then discuss the results of it. There is a decision made as to whether the patient wants to get a subsequent blood test on that.

Once the blood test results come back, then there is specific counseling with people trained to do the counseling to tell them what the implications are, what the possible treatments are, there are contraindications for getting the treatments. But those are discussed, a decision is made between provider and the patient to go on or not. And some patients don't come back.

Mr. HALLORAN. What is or was your understanding of the fiscal implications of this program in terms of the facilities, resources to undertake the screening and testing?

Mr. CODY. The preliminary indications were that this was going to be very, very expensive. As we've slowly, continuously progressed and we're actually seeing and actually having to treat those figures are not coming out as high as we thought they were going to be. It's still very significant. But I think originally it was 18 percent of the veteran population was going to need to treatment at $10,000 apiece. Well, that's not going to happen, because we're not finding that's going on. Is that your question?

Mr. HALLORAN. Yes, exactly.

Dr. LYNCH. I think you asked two questions. The first is on the issue of why this 49 percent is not getting, why we have this large

group of patients who are screened, appear to have these factors and don't get tested. I don't have the perfect answer for that, either, but we do have data on people who have a positive hepatitis C blood test who don't get treated. We've been able to analyze why they don't get treated, and I suspect some of that also speaks to this group, why they don't get tested.

For example, we can go in and look at codes for things that are objectively codeable that, or laboratory tests, for example, that would exclude patients from treatment, a low blood count, which is a contraindication to treatment. We find that about two-thirds of the patients who have a positive blood test have a codeable contraindication to treatment.

And I suspect that's also true in this screening group. Because I suspect, as Dr. Deyton pointed out, we have non-physicians doing some of the screening, then when it gets to the physician, they apply a little cognitive input and they can discriminate and make a decision that probably would not agree with, but that's probably what's happening.

Mr. HALLORAN. A codeable diagnosis or condition that would exclude somebody from treatment is not an exclusionary factor from testing, is it?

Dr. LYNCH. I think in some cases you're right. I think Dr. Deyton pointed out a case where we'd say it is exclusionary. For example, I don't think there's much benefit to testing someone, say, who's institutionalized with advanced dementia. They won't change their behaviors and we won't change ours. Somebody who is still functional and has a lot of years to live, we want them to modify their risk factors, and that person we should test. So it depends who you're asking the question about.

The issue of resources, in our network, when the Under Secretary pulled money out of the reserve to fund, we sent a specific disbursement agreement through a methodology we used in the network to our facilities. In fact, I think that was shared with the GAO site visitors when they visited in Gulfport and Biloxi. Since that time, we've made it very clear to our managers how our budget is generated in terms of how hepatitis C has gone to the that formulation.

Our policies, we've had a policy since March 1999 which is developed by a committee that consists of our associate directors, chiefs of staff and nurse executives. That policy is confirmed and voted on by our PLC, which is our directors, which basically has to do with how we're going to do these things. So there should be no ignorance in our facilities about where the moneys come from, that it's out there and what our expectations are.

Now, when you get down to the end clinician, I will be the first to admit we don't always get the perfect information out to them and a lot of stuff is being thrown out there and things get confused and there's a lot of competing agendas.

Mr. SHAYS. I have a few interests. One obviously is that we have a study that says approximately 20 percent are being tested, and another study that we received last night, yesterday, 49 percent. When did you get the results of that study?

Dr. DEYTON. We heard about the results of the EPRP, first news that we might be able to get an analysis out was Friday night. I

actually was able to see the data and talk to staff about it Monday morning, this week. We took Monday to understand it more and shared it immediately then with GAO and your staff.

Mr. SHAYS. And immediately is when?

Dr. DEYTON. I sent an e-mail to GAO Tuesday, and we talked Wednesday morning.

Mr. SHAYS. When did we get this study?

Dr. DEYTON. Yesterday.

Mr. SHAYS. So why do you use the word immediately? Today is Thursday. And you got the study Friday of last week, and now you wanted to analyze it before you shared it with the committee?

Dr. DEYTON. I actually was able to talk to staff about the data Monday morning.

Mr. SHAYS. Our staff?

Dr. DEYTON. No, the staff at the EPRP program at VA.

Mr. SHAYS. So you knew about the study last Friday, you had the information on Monday?

Dr. DEYTON. Yes.

Mr. SHAYS. With all due respect, why would we get it Wednesday afternoon?

Dr. DEYTON. I needed to understand if it was real. I was not as familiar with the EPRP program on Monday morning as I am now. It was really just a, this has been my education about that program.

Mr. SHAYS. Well, I'll tell you how I would have, you had a study, it's relevant, even whatever it says, there's something relevant to it. We appreciate getting it before the hearing, but last night is not very helpful, because then we have a difficult time making our assessment. So your team immediately, I just want to take issue with, you didn't do it immediately.

Dr. MURPHY. Congressman Shays, I apologize for that. And we won't let it happen again. We really, at the time that Dr. Deyton got this information on Monday, needed to verify in fact what it meant.

Mr. SHAYS. No, I understand, but I'm just saying to you, and given the way we interact with each other and the long term relationship we have, you could have said, by the way, we got this on Friday, we started to ask questions about it on Monday, we don't know if it will help or hurt our understanding, but we want you to be aware it's there, and here's what we know, and we haven't figured out what it actually says yet, and we'll invite you to do some questions yourself. I think it would have been helpful.

Dr. MURPHY. It was an error in judgment on our part, and we'll work more closely with your staff in the future.

Mr. SHAYS. Yes, there's no reason not to.

When I look at the questions, what I wanted to say is that whether it's 29 percent or 20 percent or 49 percent, I'm struck with the fact that it's been over a decade since we've known about hepatitis C. Now, there's not a cure, and there wasn't always a way to always identify it. But we knew there was a problem there. One of the things that we've had a problem with HHS and with VA is that we weren't getting the word out to people that they may in fact have hepatitis C.

Now, what I'm struck with is, we're debating 20 or 49 percent, and you gave us a statistic that says 41 percent of the people who came in were at risk, and of the 41 percent, 15 percent. So we're talking about at least 5 percent of the total population. If it was 15 of the 41, not 15 of your total. So we're talking approximately 5 percent.

That's a huge number of people if I projected it out to 4 million. Did you want to say something?

Dr. MURPHY. I believe it's 5 percent of those who have risk factors.

Mr. SHAYS. Right, and the risk factor was 41 percent. No, it was 15 percent, I thought you said?

Mr. HALLORAN. That were positive.

Mr. SHAYS. What were the numbers, Dr. Lynch? I wrote them down. I wrote 15, if I wrote incorrectly and I even asked you.

Mr. CODY. I believe you're talking about numbers that I was providing——

Mr. SHAYS. I'm sorry, Mr. Cody, you said 41, then said 15 percent of those proved positive.

Mr. CODY. Over the last 16 months, yes.

Mr. SHAYS. Of the 41, yes. So of the 100 percent, 41 percent were at risk, and you had almost 41 percent take the test. And of that, 15 percent showed positive, correct?

Mr. CODY. Yes, and then there's one more going down from that. Of the 15 percent, then you do a confirmatory test, and about 25 percent of those were confirmed.

Mr. SHAYS. OK, so 15 percent said, we need to do another test, in other words. I just want to make sure we agree on these numbers, my question still stands.

Dr. LYNCH. I apologize for the confusion, I think I understand it now. But I have similar numbers, and it does make a somewhat different point. We've seen the prevalence, this is the number of tests, the number of positive tests as a percentage of patients tested. This is the first time a patient has been tested, not repeat testing, decline significantly since we've tracked this now for the last 4½ years, while the number of tests have gone up significantly.

For example, this year we're on track to do about four times as many hepatitis C screening and blood tests as we did in fiscal year 1996, 1997.

Mr. SHAYS. You're telling me a point you want me to know, but I at least want to get an answer to the point I've asked. Is that all right?

Dr. LYNCH. Sure.

Mr. SHAYS. We had 41 percent who basically showed up as risks. We had 15 percent of those who, in the initial test, said we'd better test further to nail it down. Of that 15 percent, 25 percent of the 15 percent proved to have hepatitis C, correct?

Dr. LYNCH. That's correct.

Dr. MURPHY. Yes.

Mr. SHAYS. Which is basically one quarter of the 15 percent?

Dr. LYNCH. It's a prevalence rate of about 3 to 4 percent.

Mr. SHAYS. Yes. Now, 3 to 4 percent of 4 million people is a large number.

Dr. MURPHY. Note those numbers are from one medical center with a different population and shouldn't be translated to the national——

Mr. SHAYS. Fair enough. It could be larger or it could be smaller.

Dr. MURPHY. Right.

Mr. SHAYS. But those are the numbers we've got, and I appreciate your qualifying that, because we're going to qualify the 49 percent, too.

Dr. LYNCH. The point I was trying to make was relevant to that, I didn't mean to interrupt.

Mr. SHAYS. OK. I just want to nail down that number. We're making one point, now you make your point.

Dr. LYNCH. Well, it's just that these figure change through time. And I think it has to do with the fact that when you go and you screen by risk factors, you're trying to narrow down on a population that has a higher prevalence than the general population. If you go toward the highest risk factors, you'll obviously find more patients positive than if you go to a low risk population. In fact, when we tested in 1997, 27 percent of the people who had a blood test were positive. This year it's only 9.84 percent, and it's fallen every year.

In other words, what we're finding is, since we've started aggressively screening, using risk factors as a screening——

Mr. SHAYS. But that tells me we should speed up the process.

Dr. LYNCH. Well, I'm not disagreeing with that——

Mr. SHAYS. No, numbers, let's leave that as the point.

Dr. LYNCH. It's just that the prevalence is going to decline, or the positive are going to decline——

Mr. SHAYS. The more we test and the more we identify, the more the numbers are going to decline. So let's get on with it. The one, I think, problem I have with the VA, almost more than anything else, and it's a culture that exists, I feel like I could ask my interns over to the left of me to design a system that would ensure that every veteran was asked this question, and they don't have the mind set that we have in the VA, they wouldn't think that they're allowed a margin of error. I mean, if I had traffic controllers here, they wouldn't tell me, it's 20 percent or its 49 percent, they don't have those margins of errors.

We're talking about people's lives, and I don't want to sound like I'm talking and preaching to you, but we are. And I need to know this question. I need to know why a simple, now, I'm looking at the questions you ask, or recommend, this is Center of Excellence in Hepatitis C Research and Education. That is VA?

Dr. LYNCH. Yes.

Mr. SHAYS. Now, some of these questions, why did you come to be tested for hepatitis C, have you ever been tested for hepatitis C, have you ever received a blood transfusion, have you ever injected drugs, gets a little more sensitive, if yes, do you currently inject drugs, have you ever snorted cocaine, people are probably going to respond not as honestly. Asks about condoms, it asks about, have you ever been tested for HIV, how many sex partners have you had, it gets on, have you ever been tattooed, have you ever had a body piecing, have you ever been in drug treatment, have you ever felt that you should cut down on your drinking, have

people annoyed you by criticizing your drinking, have you ever felt bad or guilty about your drinking.

So these get a little more sensitive with people, but we're still talking about their lives. And I want to know why every health care provider isn't required to ask these questions of the veterans who come in. I need to know why there would be one person, why even one would escape these questions. I just need to know. It's like, it's almost like, I'll just make this point to you, it's like, my gosh, if it's not 20, it's 49, case closed, let's get on with it. Tell me why there should even be one person that comes to a VA facility who is not asked this. And tell me why it wouldn't be the mandate and directive of the Director of the VA, the Secretary of the VA, to basically say, this will be done.

Dr. DEYTON. Mr. Chairman, we certainly agree that these are questions that the hepatitis C screening needs to happen much more. We've got many veterans that need to be screened. There are occasional examples where it's not appropriate. I have a clinic at the VA medical center here. And if I have a patient who comes in with a 104 fever and evidence of bacteria running through his or her system, I think it's more appropriate for me to handle that medical situation that's an emergency and then get to the hepatitis C question later.

Mr. SHAYS. Right, OK, later means before they leave the hospital?

Dr. DEYTON. Probably, yes.

Mr. SHAYS. My dad, at one time I told my dad I forgot something. He said, if I gave you $1 million, would you have forgotten? I wouldn't have. It just wasn't important to me. And the question, I almost find it irrelevant what you said to me, with no disrespect, you're making a point you wouldn't ask them in the beginning, but now let me ask you why you wouldn't ask them before they leave.

Dr. DEYTON. I would.

Mr. SHAYS. OK, then why aren't 100 people, why isn't it 100 percent?

Dr. MURPHY. Our hepatitis C policy is in directive. And we have put a clinical reminder system in place in the computerized patient records system. This year we will require that clinical reminder system be loaded in every medical center around the country.

That will allow us to not only require the screening, but also remind our clinicians on an ongoing basis that if a patient has not been screened, that they will be.

In addition to that, we've done a number of things to try to ensure that all of our clinicians are informed about hepatitis C and the need for screening in the veteran population. We're going to be doing more education of clinicians. We've set up a system so that there is a lead hepatitis C clinician at every facility that does the screening and testing for hepatitis C.

Mr. SHAYS. Explain that one. I was going to ask earlier, we have 11,000 facilities, but that can just be even a small, intake, outpatient facility. But you say in a place that does, you said screening? Why wouldn't every place that a veteran comes in, why wouldn't we be asking these questions?

Dr. MURPHY. We should be asking the questions. In some cases, the lead clinician may be at the parent VA medical center, rather

than out in the contract VA facility. We believe that if we have a point of contact, so that we can constantly and continuously feed information to that clinician, and continue to share information about changes in treatments and policy, that they can then work within their system to get the information out to every front line health care provider.

Mr. SHAYS. Why haven't performance targets been developed yet?

Dr. MURPHY. Performance targets are under development for fiscal year 2002. They will be in place during the next fiscal year.

Mr. SHAYS. We're in fiscal year 2001. So why wouldn't they be ready for fiscal year 2002? Why not get it ready now? I don't understand.

Dr. MURPHY. They will be in place in October 1st at the beginning of the next fiscal year.

Mr. SHAYS. And then what does that mean?

Dr. MURPHY. That means that starting in that fiscal year, on October 1st, we will begin monitoring the performance of every facility and every network based on the measures that have been agreed upon.

Mr. SHAYS. In all facilities?

Dr. MURPHY. Yes.

Mr. SHAYS. OK, so why do we say 2003? That's 2002.

Dr. MURPHY. GAO reported to you that it was 2003, sir, but in fact, we will have them in place in 2002.

Mr. SHAYS. OK, and that's a certainty, no reason not to?

Dr. MURPHY. No reason not to.

Mr. SHAYS. Technically, there's no reason, tell me why they couldn't be done in a month? There has to be a reason, I just don't understand why.

Dr. MURPHY. By July, we'll have them developed and then we'll negotiate the performance agreements for every network director and they'll be in place——

Mr. SHAYS. Do they need to be negotiated?

Dr. LYNCH. I don't think negotiation is the issue, it's that our performance contracts run on the fiscal year basis. We also need to have a system in place to measure the performance. That's one of the most challenging aspects of this, how do you tell whether I did what you asked me to do.

Dr. MURPHY. That's the reason, in fact, that they're not in place currently. Because without the clinical reminder system in place, so that we can track the performance at the facility level and at the network level, it's difficult for us to set a measure that was objective and reasonable. The only way to do that is to have a data system in place to collect the information and to track it over time.

Mr. SHAYS. So right now, there is not an incentive for the managers to be moving forward with asking these questions, at least in terms of an evaluation. But they're not evaluated based on their success in this area?

Dr. DEYTON. Right now, that's correct. And that will be in place as Dr. Murphy has said, immediately, and negotiated in the contracts of the network managers.

Mr. SHAYS. I'm showing my ignorance here, obviously, but I guess, it again still sounds a little bureaucratic. It's saying to me that because of a contract with our managers, we're not going to

do something that would be beneficial to our veterans. I'm wondering, if you were a competitive business, whether we would think that way.

Dr. MURPHY. No, I think that we've been very clear what our expectation is of our managers, in terms of implementing the screening, testing and treatment of hepatitis C in the veteran populations. We've also improved our prevention and education efforts. The program has been very aggressive.

What we haven't been able to do is to develop an objective performance measure to put in the contract, because of the lack of an adequate data base.

Mr. SHAYS. See, when you say very aggressive, I'm reacting the same way that I reacted when you said you gave us the material immediately, which you didn't. Very aggressive would mean 100 percent. Why is it very aggressive? We have two people who are from the district, out in the district who, when GAO met with them, they did not have aggressive programs. And they had different reasons for that.

I mean, Mr. Cody, would it be fair to say, Ms. Dowling, that you have aggressive programs in your facilities?

Ms. DOWLING. Through this time period, I would say at this point I'm working toward that. I would not say that when the GAO came that I had an aggressive program.

Mr. SHAYS. OK. And it's not to throw stones, because I'm sure that your facility does some great things in other areas. But this is an area that needs improvement. And you could come to my office and you could point out areas in my own office that we need improvement.

But let me ask you, why was this an area that was not getting as much attention as some of the other things that you were handling?

Ms. DOWLING. I think the program was far more complicated than I initially understood. It took a great deal of time, for example, to make sure that the education took place across all of, not just the physicians, but our nurses, we have an interdisciplinary team in the areas. We had to plan how we would roll it out. Perhaps this approach other people would not agree with, but most of our patients go through our primary care area.

It took some time to plan how we would phase in and test and make sure things were working and then roll it out across all of the primary care areas. We're continuing to build on that. As we measure how we're doing in the progress, we are improving. But clearly, we're not where you and I think where we need to be in terms of the 100 percent screening.

Mr. SHAYS. Is there any reason why on your level you couldn't make it 100 percent, forget what they did elsewhere, but in your own facility?

Ms. DOWLING. At this point, I absolutely can make it 100 percent.

Mr. SHAYS. And it shouldn't have to wait until 2 years from now?

Ms. DOWLING. Oh, no, it will not take 2 years.

Mr. SHAYS. Mr. Cody.

Mr. CODY. To add to what Mary is saying, at Syracuse, we developed this progressively as well. There was a lot of things that need-

ed to occur, education, setting it up, tracking it, making it happen, using the clinical reminders and then actually gaining the experience from the original estimates of how significant it was going to be to how it looks like it's something that is more manageable in that sense.

On July 1st, we're going to be at 100 percent, all our primary care clinics will be screening the patients in all our community based outpatient clinics at the medical center, 100 percent is going to be happening just in a couple of weeks.

Mr. SHAYS. In your facilities?

Mr. CODY. Yes.

Mr. SHAYS. How is that going to happen?

Mr. CODY. By the use of the clinical reminder system, when the patient comes in, it comes up actually on the screen. There's a lot of other things in there, other than hep C, but that will be up there and the provider will know that the screening tool needs to be used at that time, and our whole process will start from there. That will generate need for blood tests.

Mr. SHAYS. How much additional time does this add? Is this a factor in discouraging, in other words, you are understaffed, I make that assumption, probably pretty accurate, so you're understaffed, you have people waiting in line, so that discourages asking a lot more questions. How much time does this add?

Mr. CODY. I don't treat the patients, so I don't know how many minutes it's going to take. But it's part of a lot of other things that we do that have been showing, because of our preventive approach to care, we've been making a tremendous difference in the veterans that are coming to us. Hep C is one of them, but diabetes screening, which helps in reduction in the number of amputations, pneumonia vaccination. We have studies showing a number of patients that were caught because of what we're doing on a preventive nature. These are a lot of things. Yes, they do take time. I couldn't tell you what exactly.

Mr. SHAYS. Mr. Deyton.

Dr. DEYTON. Mr. Chairman, in my experience with my patients, this is not a simple procedure at all. You see the kinds of questions we have to get into. So on an average, depending on the patient's receptivity, it probably adds 15 minutes to half an hour to every visit.

Mr. SHAYS. Why would it have to add 15 minutes?

Dr. DEYTON. Oh, Mr. Chairman, you don't just launch into these questions if you want to get an honest response. You need to explain, I need to ask you some questions about a blood-borne infection called hepatitis C. And talk about what that is and why that might be important to them. You are a Vietnam-era vet, therefore you might have been exposed to this virus, and what it means. So I talk to them about the disease, that the liver——

Mr. SHAYS. So if I started out and said to you, Dr. Deyton, we are extraordinarily grateful for your service, but we are very concerned about the health of you and your colleagues because of this incredible silent killer called hepatitis C, I need to ask you some questions that could help extend your life, and some of them may be very intrusive, but I need to ask them and you need to give me honest answers in order for us to make sure that we are doing ev-

erything we can for you. You're a Vietnam veteran, did you have a blood transfusion, and go through this. I would think that fairly quickly you could ask it.

Dr. DEYTON. Maybe I'm a slow clinician, but I find that when I ask these questions patients bring up other issues that are medically germane.

Mr. SHAYS. Fair enough. So is this a factor in discouraging these tests? Aside from the fact that you all weren't aware that some of the money was available out in the field, is there, we did not appropriate money for the extended—this is a mandate, in a sense. We require more work to process. Did the money we appropriate go in part for this? It did?

Dr. DEYTON. Yes, it did. And I think GAO found in their other investigation that there certainly has been sufficient money to support this screening, testing and treatment.

Mr. SHAYS. Let me do this. It's 12 o'clock, and this is an ongoing process. I welcome any of you—did you have a question?

Mr. HALLORAN. Yes. Two quick ones.

Mr. SHAYS. Dr. Murphy, I'm very content to have you and Dr. Deyton leave, with no problem at all. We'll just finish up, Dr. Lynch and Mr. Cody and Ms. Dowling, if you could stay. We'll let you get on your way.

Dr. MURPHY. We'll be happy to stay until we're finished, sir.

Mr. SHAYS. We'll just be a little longer, but I'm happy to have you leave, no problem.

Dr. MURPHY. Thank you.

Mr. HALLORAN. I just want to ask two quick questions, and one I asked GAO, which is, and for the facility directors, have you come across evidence of other outreach or lookback efforts that your facilities feel the impact of? Has a local blood center or hospital done anything, or the Liver Foundation done some letter writing or advertising, have you seen the effects of other attempts to identify potential hepatitis C infection?

Dr. LYNCH. There's a couple things. One is a national lookback at the blood supply, which every entity that gives blood participated in. Obviously we did that as a system, and there were a fair number there. We've seen a number of independent outreach groups in places like Houston and what have you. I cannot quantify what that's meant, but yes, it's been in——

Mr. HALLORAN. You felt some impact of it?

Dr. LYNCH. Yes.

Mr. CODY. I'm not aware of any specific impact on the Syracuse area. I couldn't comment on that.

Ms. DOWLING. There was, to my knowledge, the same as Jim Cody, I'm not aware of specific efforts of these external groups that you mentioned.

Dr. DEYTON. Could I add to that? I think there have been some really extraordinary efforts made by several organizations and as some in collaboration with us. For example, as you may know, we're working in collaboration with the American Liver Foundation to distribute 3.4 million brochures to veterans who use the VHA system, just education brochures on hepatitis C. Because we recognize that not everybody accesses the system all the time, and they may have risk factors.

Also the American Legion and Veterans Aimed Toward Awareness, which is a hepatitis C specific veterans group, have put together really, I think, helpful education programs for veterans and their members to learn about hepatitis C that we are totally supportive of, and glad to see is happening. Because getting the word out there is how we're going to get these folks to get screened.

Mr. CODY. As Dr. Deyton just added that, I have to qualify or add something to my answer before. Through the efforts of some of the service organizations, like DAV and American Legion, yes, they have been educating their members. People do come into our clinics saying, I've read this, I'd like to hear about it.

Ms. DOWLING. I would agree with that, too, Vietnam Veterans of America.

Mr. HALLORAN. There was, you mentioned the availability of the screening of primary care facilities. There was some indication that GAO worked that in specialty care facilities, is this more of a challenge there? In a heart clinic or a diabetes clinic, I presume you have them, other more specialized care facilities, is this a tougher sell there?

Dr. LYNCH. I would answer definitely. Not sell. I think it's much harder to do it there for a couple of reasons. As you are probably aware, we do have performance measures we're trying to improve, the time it takes for a veteran to get into certain clinics, you named some of them. And I would be loathe to put an additional burden on those if I felt I could do it someplace else.

Mr. HALLORAN. Might those not be some of the only entrance points for a veteran in the VA system?

Dr. LYNCH. That is becoming less and less the case. We are approaching rather high percentage, at least in our network, I don't have a figure at hand, of all of our patients who see us on an ongoing basis who are now enrolled in primary care. Our goal is to have anybody who's enrolled on an ongoing basis in primary care.

But also, if you listened to what Dr. Deyton had to say, I'm less confident that some of these subspecialists would spend the amount of time necessary and would have the background and the interest to do what we've asked them to do. In addition, we've got tight timeframes where we are asking them to do it.

Dr. DEYTON. And in those specific situations, there are multiple approaches that we can take and that some VAs are already doing, to do the proper screening in a way that will be successful and not, say, take a super-subspecialist's time and energy away. For example, we have great examples of teams of providers, a nurse, nurse practitioner, somebody even trained in the testing and counseling area, who can service those areas to in fact do the screening in all clinics.

So one of the things that we're learning are some of the best practices that have been put in place in many facilities and beginning to promulgate those throughout the rest of the system.

Mr. HALLORAN. And finally, among the things you gave us yesterday was a copy of the solicitation for applications for additional, not centers of excellence, I forget what you called them, they were field resource centers or something. Why?

Dr. DEYTON. Why?

Mr. HALLORAN. Yes, why?

Dr. DEYTON. Why do we need them?

Mr. HALLORAN. Yes. What's the point? Why are we identifying more kind of nodes of——

Dr. DEYTON. Because what we've learned in talking to the front line providers in various settings is that they have a need for some specific products and resources to in fact do this job. So we are investing in four hepatitis C field based resource centers to in fact develop those materials to be used across the system. Those resource centers will focus in four different areas. One is in patient and patient's family education, so that we get the proper kinds of materials together to educate the patient, who's either in screening, or has tested positive.

The second area is in clinician education and preparedness. The third area is in prevention and risk reduction, particularly for those veterans who test positive. What can they do to modify their lifestyle to keep their livers as healthy as possible. And the fourth area is in what we were just talking about, models of care and best practices, and how to promulgate those across the system.

We believe that these four centers will serve the whole VA, so that we can have the best practices possible.

Mr. HALLORAN. And the relationship of these centers to the existing centers of excellence?

Dr. DEYTON. It's the same program. It's just being redefined and recompeted.

Mr. HALLORAN. OK.

Dr. DEYTON. I'm pleased to say that even as the early word has leaked out to the VA that these resources will be available, the competition is going to be very stiff. There's a lot of interest that has been developed around the hepatitis C treatment areas by all the work that you've heard has happened. So we're going to have some excellent centers.

Mr. HALLORAN. And I didn't notice any particular application or qualifying criteria to be one of these centers that you actually treat or have been successful so far in screening. One hopes that these lessons learned would be derived from places that have been doing it.

Dr. DEYTON. That is certainly the criteria, so I'm sorry you missed that. But in the application process, the criteria that each applicant will be judged on is what experience do they have in the area that they want to work, what successes have they had, what resources are they going to put to it.

Mr. SHAYS. I think Mr. Halloran may have asked this question. Before I go, I want to be clear on this, because I'm intrigued by the comment that it could take a half hour. I have 15 minute meetings and sometimes they go to 20 or 30, and they may be interesting, but I then know everything is backed up and I get anxious and it discourages me from asking questions. But Mr. Rapallo was asking the same question as well, on minority staff.

Why can't you, first off, I assume most of our veterans know how to read. But if they didn't, we could just ask them orally. Why can't you just give them the questions, say, do any of the above apply, without having to say which ones?

Dr. DEYTON. That certainly is an approach which some places do, and I think it's one of the best practices that we want to promulgate around the system.

Mr. SHAYS. It wouldn't have to take 15 or 20 minutes. After they say yes, it might. And it puts a little bit of risk on their part. It may be that if you asked more questions directly and looked into their eyes, are you sure you're right, you could, but at least this way you could start to cover more quickly.

Dr. DEYTON. I think there's certainly benefit in that. Let me tell you the risk of it, too. In many years of experience of handing out questionnaires to patients in waiting rooms, they sometimes don't fill those out either or don't fill them out——

Mr. SHAYS. Even if you tell them they could die if they don't?

Dr. DEYTON. Congressman, I think people are worried about putting something down on paper. And some of these behaviors are behaviors which have great ramifications to their eligibility for certain care. And that was drilled into them in the service. So that gets translated to us as well.

In the HIV arena, sir, I have certainly found that people don't want to put down on any piece of paper what risk factor they might have, because they're afraid——

Mr. SHAYS. Am I reading that if one was a little more so-called innocent, they wouldn't want to say yes, because someone might assume it's something worse?

Dr. DEYTON. Yes.

Mr. SHAYS. Well, let me say this. You all are coming back next year to deal with the treatment side. We are going to ask you questions about what we asked here. We're going to make an assumption that you're going to be screening everyone, and that when we meet next year, we're going to see that it's in place and that you're screening everyone. Is that a false assumption?

Dr. MURPHY. Our goal will be to screen everyone, or at least offer the opportunity for the screening questionnaire. I think in any public health program, it is very difficult to reach 90 percent or 95 percent. So I would have to say honestly, sir, that I don't think we're going to be able to come back and tell you that we've screened 100 percent of patients, no matter how hard we try. We're going to make every effort to.

Mr. SHAYS. We're going to be able to know that the evaluation process will be in place, and I would like to think it will, maybe the process will be in place, even if you don't evaluate until the start of the next fiscal year, but you can give your managers some practice with it. That will be 100 percent. And then you're telling me there are going to be some that fall through the cracks. But I would like to think that it would be a very small percent.

Is there any comment that anyone wants to make, particularly those of you that are out in the field doing this work?

We'll let you get on your way. Thank you for your time, and this time when I say the hearing is adjourned—no, it's not adjourned yet. We have a statement from Jacqueline Garrick, who is the Deputy Director of Health Care for the American Legion. I ask unanimous consent that it be submitted into the record, and it will be.

[The prepared statement of Ms. Garrick follows:]

STATEMENT OF
JACQUELINE GARRICK, ACSW, CSW, CTS
DEPUTY DIRECTOR, HEALTH CARE
THE AMERICAN LEGION
TO THE
SUBCOMMITTEE ON NATIONAL SECURITY, VETERANS' AFFAIRS AND INTERNATIONAL RELATIONS
COMMITTEE ON GOVERNMENT REFORM
U.S. HOUSE OF REPRESENTATIVES
ON
ISSUES RELATED TO HEPATITIS C VIRUS

JUNE 14, 2001

Mr. Chairman and Members of the Subcommittee:

The American Legion appreciates the opportunity to submit this statement on behalf of veterans suffering from hepatitis C. Hepatitis C infection is a major public health problem with enormous and growing consequences. With a large number of veterans infected with hepatitis C, the Veterans Health Administration (VHA) claims to have given the highest priority to addressing this public health problem. Unfortunately, the exact prevalence of hepatitis C infection in the veterans' population is questionable, but based on limited survey data, VHA estimates a probability of 6.6 percent. Recently, VHA reported that over 70,000 veterans currently enrolled in VA medical facilities are known to have tested positive for hepatitis C. VHA is the largest single source of integrated health care services in the world for persons with hepatitis C.

The Hepatitis C Virus (HCV) was first identified in 1989, more than ten years after most Vietnam veterans would have been potentially exposed. HCV is a blood-borne pathogen that can go undetected for years because of its lack of symptoms. , Since so many combatants, medical corps service members and those receiving transfusion and hemodialysis were at risk for exposure, hepatitis C continues to be a major issue for the Department of Veterans Affairs (VA). Many other veterans are also at risk for hepatitis C because of the informal military traditions relating to tattooing and alcohol consumption. Individuals with HCV may experience very few symptoms, which makes it is a difficult disease to identify and treat.

VA continues to do more outreach to veterans to educate them about hepatitis C. Likewise, The American Legion is conducting its own outreach efforts. Recently, The American Legion mailed hepatitis C educational posters to 14,574 posts located in local communities across the country. These educational posters were also mailed to all the infectious disease clinic coordinators within the VHA and Vet Centers. Hopefully, these efforts will assist in encouraging veterans to be screened and tested for the HCV. However, The American Legion questions if VA is doing enough to provide all veterans, who are at risk, with appropriate access to screening and treatment.

In FY 2000, VA estimated that it would cost $195 million to screen and treat HCV and its co-morbid conditions. However, it only spent $100 million on these activities, leaving a large discrepancy in its expenditures. The American Legion believes there were several contributing factors to this difference. Some contributing factors are outlined in the General Accounting Office (GAO) report, *Observations on VA's Assessment of Hepatitis C Budgeting and Funding* from April 25, 2001.

GAO reported that VA's FY 2000 budget had assumed that nearly 17,000 veterans would be treated for HCV and that 70 percent would complete a one-year antiviral drug therapy regimen. However, only 4,455 veterans received the antiviral drug therapy. Regrettably, most dropped out of the treatment program before six months. The American Legion finds this unacceptable and very concerning. It is estimated that 6.6 percent of the veterans' population are at risk for being hepatitis C positive. The fact that less than 5,000 veterans even began treatment and hardly any finished is a glaring deficit in the number of veterans receiving and being able to comply with appropriate treatment.

The American Legion recognizes that the treatment protocol available for HCV is a difficult one for patients and produces many adverse side effects. These side effects are usually more unbearable than the virus symptoms the patient had in the first place. In a population that is already medically complex, adding the burden of a strenuous course of treatment does increase the risk of non-compliance and treatment failure. However, with proper case management and a strong multidisciplinary approach, concomitant symptoms, and side effects could be better managed.

GAO reports that local managers were cautious in their approach regarding who to screen and when. The American Legion is aware of cases in which veterans were requesting to be screened, but experienced difficulty getting tested. In some cases, veterans were trying to get screened through primary care and would have to wait several months for a non-emergent appointment to get a lab consult. This process would become elongated when VHA would cancel appointments. Then veterans had to wait several more months for the next available appointment, often becoming frustrated and disinterested. In other cases, veterans seeking HCV screening were told that if they were not Vietnam veterans, they could not be screened. World War II and Korean War veterans in VISN 11 contacted The American Legion and reported that they could not get HCV testing. Veterans have reported cases like this around the country from other eras and non-combatants.

In looking at the networks, The American Legion notes that there is clearly a disparity in the outreach activities throughout VHA. The American Legion identified 30 VHA medical facilities aggressively identifying and treating veterans for hepatitis C. This disparity not only varies from VISN to VISN, but from medical facility to medical facility. For example, the Seattle, Washington VHA medical facility is very proactive in screening and treating veterans for HCV, but in the same network, the Portland, Oregon VA medical facility has hardly treated anyone.

The most obvious cause for this variance that The American Legion can identify is the staffing shortage at some VA medical facilities. Nationally, there is an overall nursing shortage that adversely affects all elements of the health care industry and VHA has not been exempt. This lack of staffing is effecting VHA's infectious disease clinics as well. There is also a shortage of infectious disease specialists in some areas of the country, making it difficult to recruit and retain physicians and nurses in this unique sub-specialty. As previously recommended, The American Legion believes HCV treatment compliance would improve if VHA provided a stronger multidisciplinary approach and provides appropriate staffing to accomplish this critical mission. Staffing is a key element to antiviral drug therapy compliance. When patients are experiencing discomfort and adverse side effects, they need immediate access to the discipline that can help them address those problems. If a patient is experiencing depression and the next available appointment in the mental health clinic is 90 days away, the patient will probably not be able to tolerate the regimen and will stop taking prescribed medication.

For the staff members in these clinics, training and education on the latest research and pharmaceutical advances is imperative. In the past few years, VHA has orchestrated several informative and detailed conferences that address the multitude of issues surrounding hepatitis C. These conferences proved to be extremely helpful to the staff covering infectious disease, mental health and primary care clinics most likely encounter hepatitis C patients and their families. The American Legion attended several of these conferences. A symposium in March 2000 focused on providing an update on hepatitis C with emphasis on pre-test and post-test counseling for nurses, pharmacists and counselors. Another symposium in August 2000 emphasized psychiatric evaluation of patients and treatment of complex patients. Another symposium in December 2000 focused on psychosocial needs of the patient with hepatitis C and his or her family.

VHA, especially for its Center of Excellence, should be commended for the efforts in providing quality educational forums to its staff. These conferences were well attended over the last few years. But, as staff changes are made and new hires occur, this level of education and training must be continue. Efforts should also be made to access whether or not all the appropriate staff are getting the training and not just a select few from a medical center.

GAO also cited VHA's lack of basic data on the number of veterans screened as impeding efforts to track performance and expenditures. According to GAO, *To be counted, VHA requires providers to include Hepatitis C code in its computerized records system.* GAO goes on to note, *This problem persists system-wide, despite VHA's efforts over the past 2 years to encourage... accurate coding by providers.* GAO concludes that these problems could be addressed if VHA would create a registry to document demographic and clinical data on all its hepatitis C patients. The American Legion understands that VHA plans to develop software to interface with the current electronic medical record system, but that is expected to take over a year to activate.

In the President budget request for FY 2002, VHA is aware of the need to establish and monitor goals for the quality of care in hepatitis C. At the beginning of

2001, responsibility for coordinating the hepatitis C programs was transferred to the Office of Public Health and Environmental Hazards. The hepatitis C program staff is responsible for implementing a plan:

- to meet all needs required to provide hepatitis C testing to any veteran who may be at risk;
- to provide medical evaluation, appropriate treatment, and follow-up to any veteran who test positive; and
- to develop an appropriate hepatitis C risk prevention program.

Two critical steps in meeting these goals:

- a comprehensive review of data sources and identification of areas for improving data collection and management; and
- a proposal to create a new nationwide electronic registry to improve data management.

The American Legion agrees with GAO that VHA's ability to code is a primary contributing factor to its inability to capture accurate data on this specific patient population or any other for that matter. The American Legion is concerned that the responsibility for this issue is being placed in the hands of the same area of operations that has not been able to efficiently do billing and collections. It is the same coding issue that is keeping VHA from effectively collecting reimbursements from third-party insurers. Currently, it takes VHA approximately 180 days to collect on a bill, whereas it takes the private sector 7 to 9 days. This lag time is due primarily to the inaccuracies in VHA's coding ability. The American Legion does not feel GAO has sufficiently explored this issue with VHA and that much more needs to be done to improve its overall software system. The American Legion finds this unacceptable, especially since the current plan calls for a lag time of over a year and is not predicted to provide accurate data on hepatitis C patients until FY 2004.

In conclusion, The American Legion supports the efforts made by VHA to screen, test, and treat veterans with hepatitis C and those of the GAO in providing oversight. However, The American Legion does not feel that either entity has gone far enough to improve VHA's hepatitis C effort. Veterans, who are infected with HCV and have not even been identified, need to still hear that message. The American Legion is committed to assisting in these outreach efforts and will continue spreading information on HCV throughout the veterans' community through its educational poster project, articles in **The American Legion Magazine**, articles in **The American Legion Dispatch**, and through announcement on its web site (www.legion.org).

However, VHA must improve its ability to track and identify veterans infected with hepatitis C. It should not have to take a year to better code records to get more of an accurate picture of veterans' needs. The American Legion understands that VHA has been aware of this coding problem for several years, yet there is no hard evidence that this problem will be resolved next year.

The American Legion recommends that VHA focus on its staffing issues and ensuring that HCV is a priority in ***every*** VHA medical facility. This can be done without waiting to see if the coding problem can be fixed first. Veterans need to be screened, tested and treated now.

In the President's budget request, VA requested $171 million in FY 2002 for treatment of HCV. VHA also requested an increase of 180 FTE. The American Legion strongly recommends that a staffing survey be conducted to ensure that veterans have access to an entire multidisciplinary approach and that there is enough clinic availability (for appointments) at any VHA medical facility in which veterans choose to enroll.

Mr. Chairman and Members of this Subcommittee, The American Legion sincerely appreciates the opportunity to submit testimony and looks forward to working you and your colleagues on this critical issue. Thank you for your continued leadership on behalf of America's veterans and their families.

Mr. SHAYS. We are not recessed, we are in fact adjourned, and you can get on your way. Thank you very much.

[Whereupon, at 12:12 p.m., the subcommittee was adjourned, to reconvene at the call of the Chair.]

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