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HEPATITIS C: SILENT EPIDEMIC, MUTE PUBLIC HEALTH RESPONSE

SEVENTH REPORT

BY THE

COMMITTEE ON GOVERNMENT REFORM AND OVERSIGHT

OCTOBER 15, 1998.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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LETTER OF TRANSMITTAL

HOUSE OF REPRESENTATIVES,
Washington, DC, October 15, 1998.

Hon. NEWT GINGRICH,
Speaker of the House of Representatives,
Washington, DC.

DEAR MR. SPEAKER: By direction of the Committee on Government Reform and Oversight, I submit herewith the committee's seventh report to the 105th Congress. The committee's report is based on a study conducted by its Subcommittee on Human Resources.

DAN BURTON,
Chairman.

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105TH CONGRESS, 2d Session } HOUSE OF REPRESENTATIVES { REPORT 105–820

HEPATITIS C: SILENT EPIDEMIC, MUTE PUBLIC HEALTH RESPONSE

OCTOBER 15, 1998.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. BURTON, from the Committee on Government Reform and Oversight, submitted the following

SEVENTH REPORT

On October 8, 1998, the Committee on Government Reform and Oversight approved and adopted a report entitled, "Hepatitis C: Silent Epidemic, Mute Public Health Response." The chairman was directed to transmit a copy to the Speaker of the House.

I. SUMMARY

Called "the silent epidemic," the spread of Hepatitis C Virus [HCV] infection has evoked a Federal public health response almost as mute.

Hepatitis C poses a daunting challenge to public health. Chronic infection can linger without symptoms for more than 20 years, then produce profound health consequences, including liver failure and cancer. There is no preventive vaccine or universally effective treatment. Up to 10,000 will die this year from the disease. That number could triple in the next two decades, according to the Centers for Disease Control and Prevention [CDC].[1]

HCV has now spread to an estimated 4 million Americans. Eighty-five percent of those infected develop chronic liver disease and about 10 to 20 percent develop cirrhosis of the liver about 20 years after the onset of infection.[2] HHS estimates the total societal cost of Hepatitis C at more than $600 million per year.[3] More than

[1] NIH Consensus Development Statement "Management of Hepatitis C," Mar. 24–26, 1997 (in subcommittee files).

[2] *Public Health 2000: Hepatitis C—The Silent Epidemic,* 105th Cong., 2d sess., p. 6 (subcommittee hearing, Mar. 5, 1998) (prepared statement of Surgeon General David Satcher).

[3] Ibid, p. 6.

a million persons received HCV infected blood and blood products.[4] Most are unaware of their infection.

They need to be told. They need to be tested. Many will need treatment, and many will need to learn how to prevent further spread of the disease to their spouses, sexual partners, and household members.

But HHS plans to "look back" for people infected through blood have sputtered, and little has been accomplished. Disease reporting and surveillance is uneven. Research into HCV is uncoordinated. Education on prevention and treatment has been undertaken primarily by private sector organizations.

Unless confronted more boldly, more directly, and more loudly by the Department of Health and Human Services [HHS], the threat posed by Hepatitis C will only grow more ominous. As we learned when the Human Immunodeficiency Virus [HIV] breached our public health defenses, scientific uncertainty, cultural biases and bureaucratic inertia can thwart the actions needed to repel an elusive viral invader.

In a 1996 oversight report, this Committee recommended HHS take steps to notify the 300,000 or more Americans known to have been infected with Hepatitis C through blood before 1990.[5] To date, that has not been done. The time for pondering the appropriate, pro-active public health response to Hepatitis C is past. The time for aggressive implementation is at hand.

Findings in brief:

1. The Federal response to the Hepatitis C epidemic has lacked focus and energy.
2. The proposed HCV "look back" is too limited.
3. Private organizations, with some Federal assistance, have taken the lead in HCV public education efforts.

Recommendations in brief:

1. a. The Secretary of Health and Human Services should take the lead in coordinating the Federal public health response to the Hepatitis C epidemic, including implementation of a research plan.

b. The Department of Defense should test recruits, active duty personnel and those about to be discharged for Hepatitis C infection.

c. The Department of Veterans Affairs should conduct additional studies of the prevalence of HCV in veterans populations.

2. The Hepatitis C look back plan should be expanded.
3. Federal educational campaigns on HCV infection should be launched immediately.

II. Background

The Centers for Disease Control [CDC] estimate that at least 4 million Americans are infected with the Hepatitis C Virus [HCV], which was formerly known as "non-A, non-B hepatitis." HCV is a liver disease agent found in the blood of infected persons. Infection

[4] Ibid, p. 6.

[5] *Protecting the Nation's Blood Supply from Infectious Agents: The Need for New Standards to Meet New Threats,* 10th Report by the Committee on Government Reform and Oversight, Aug. 2, 1996.

may occur through intranasal exposure (cocaine use), injection of street drugs, accidental needle stick injuries to health care workers, transfusion of infected blood and plasma products, transplantation of solid organs (such as kidney, liver, heart), kidney dialysis, maternal to fetal transmission and through exchange of bodily fluids.

Secondary transmission to spouses and maternal transmission to fetuses in utero has been documented, but the extent of transmissibility is not known. In addition, more than 40 percent of infected persons do not have histories of risk factors, suggesting a possible unknown route of transmission. There is no vaccine to prevent the disease and NIH estimates that vaccine development will take at least a decade.

CDC estimates that 28,000–180,000 new HCV infections occur each year. Only 25–30 percent of infections are symptomatic. Many HCV infected individuals are not aware of their infection until signs of liver failure appear, often decades after infection. This has prompted some to call HCV, the "silent epidemic."

Hepatitis C is responsible for an estimated 8,000–10,000 deaths annually in the United States. According to current estimates, more people will die of HCV in the year 2000 than will die of AIDS.

An estimated 1 million Americans received blood from a donor who subsequently tested positive for Hepatitis C.[6] Of these people, CDC estimates 700,000 may have tested positive with the first generation anti-HV test which was introduced in 1990. The first generation test had a higher false positive rate than later generation tests and there was little confirmatory testing performed in this group of tested donors.[7] A more precise "second generation" HCV screening test became available in 1992.

CDC concedes,

> it is not possible to estimate the TOTAL number of living persons with transfusion associated HCV infection from the look back estimates, since these estimates do not extend before 1990. CDC has estimated that approximately 300,000 of the 4 million living anti-HCV positive persons acquired their infection from blood transfusion.
>
> CDC arrived at this estimate using the National Health and Nutrition Examination Survey [NHANES] data and Sentinel Counties surveillance data concerning the proportion of HCV infections that were transfusion associated at various time periods.[8]

Treatment of HCV is usually with interferon and approximately 12–15 percent of individuals will clear the infection with the first treatment. There is some evidence that individuals with HCV who do not respond to the first treatment may be able to clear the infection with a second round of treatment, or with higher dosages of interferon or combinations of drugs. Many infected persons do not develop symptoms. Others, however, will develop severe cirrhosis of the liver, which will require a liver transplant or be fatal. Cirrhosis

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[6] Written communication from Centers for Disease Control to subcommittee staff, Sept. 15, 1998 (in subcommittee files).

[7] Ibid.

[8] Ibid.

caused by HCV infection is the primary reason for liver transplants in the United States.

In the 104th Congress, the Committee issued a report entitled, "Protecting the Nation's Blood Supply from Infectious Agents: The Need for New Standards to Meet New Threats," (House Report 104–746) which contained several recommendations including one to require the Department of Health and Human Services to ensure that the estimated 300,000 living recipients of blood and blood products who may have been infected with Hepatitis C Virus before 1990 are notified of their potential infection so they might seek diagnosis and treatment.

III. FINDINGS

1. The Federal response to the Hepatitis C epidemic has lacked energy and focus

Since 1989, when the Hepatitis C Virus [HCV] was first unmasked, federal public health agencies have often pondered, but never implemented, a comprehensive response to this insidious infectious agent.

The FDA's Blood Products Advisory Committee [BPAC] considered whether patients who received the HCV infected units should be notified of their exposure (a.k.a. "look back") on all of the following dates: October 31, 1989; January 17–18, 1991; September 26–27, 1991; March 12–13, 1992; March 25–26, 1993; December 2–3, 1993; and December 15–16, 1994. However, the BPAC did not take action on this issue, even though treatment options were available to infected persons if they had been told of their infection.

The FDA's July 19, 1996, Guidance Memorandum [9] recommended quarantine and disposition of certain prior collections of blood and blood components from donors who tested repeatedly reactive to HCV antibodies. At that time, FDA did not recommend notification of recipients of blood from donors who subsequently test positive for anti-HCV, because "no clear consensus on the public health benefit of such action had emerged." [10]

In testimony before the Human Resources [HR] Subcommittee on October 12, 1995, HHS Secretary Donna Shalala committed that the HCV look back notification would be the first issue considered by the new HHS Advisory Committee on Blood Safety and Availability [NACBSA]. NACBSA reviewed the notification issue at its meetings 2 years later, in April and August 1997.

At the August 12, 1997, meeting, a look back was recommended by the Committee for individuals who had received blood which had tested positive for HCV on the second generation screening test implemented in 1992. Some members of the NACBSA [11] wanted a more extensive look back, feeling that a less comprehensive approach was unethical because many infected individuals would not be contacted by a look back triggered only by HCV donors de-

[9] July 19, 1996, memorandum from Director, Center for Biologics Evaluation and Research to All Registered Blood and Plasma Establishments (in subcommittee files).

[10] "Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)," background section, Mar. 20, 1998.

[11] Dr. John Penner, Dr. Arthur Caplan, Dr. Dana Kuhn, Dr. Ronald Gilcher, and Ms. Tricia O'Connor.

tected after 1992.[12] CDC did not provide an estimate of how many of the 1.1 million Americans who received potentially HCV-infected blood did so before 1992. However, CDC concludes the possibility of transmission was much higher before the 1992 introduction of more effective screening and testing.

The NACBSA recommendation was reviewed by the Public Health Service [PHS] operating divisions (FDA, CDC, NIH, et cetera) prior to its presentation to the Blood Safety Committee on November 4, 1997, and December 3, 1997. The recommendation was communicated to Secretary Shalala on December 22, 1997.

The recommendation was discussed with HHS Deputy Secretary Kevin Thurm on January 13, 1998, and with the Secretary on January 22, 1998. Secretary Shalala communicated her decision to accept the recommendation to NACBSA Chairman Arthur Caplan on January 28, 1998.

On March 5, 1998, HHS Surgeon General David Satcher announced the HCV look back and education plan in testimony at a Human Resources [HR] Subcommittee hearing. He testified that HHS has "established a comprehensive plan to address this significant public health problem. It is our intention to reach effectively as many people at risk as we can."[13]

On February 11, 1998, Dr. John Eisenberg, HHS Acting Assistant Secretary for Health and acting chairman of the Blood Safety Committee, requested specific responses with time lines from the FDA, CDC, and the Agency for Health Care Policy and Research [AHCPR] on the status of the agencies' HCV notification and education plans.

The FDA response was the publication of a Guidance to Industry on March 20, 1998, in the *Federal Register.*[14] The guidance recommended that blood banks identify past donors of blood who have tested positive for HCV antibodies on the 1992 second generation test and notify the hospital blood banks and transfusion services that units taken from those donors may be infected. The hospital should then notify either at-risk patients or their doctors directly by September 20, 1998.

The CDC and AHCPR responses were received by HHS on April 10, 1998, and further discussed at the June 18, 1998 Blood Safety Committee meeting. HHS pledged to undertake additional public education campaigns to notify additional persons who may have received HCV-infected transfusions. HHS pledged to evaluate the success of the direct notification efforts and committed to take additional, unspecified steps to identify other at risk groups for HCV infection.

Surgeon General Satcher, who had been asked by the Secretary to lead the notification and look back efforts,[15] stated in a letter to Chairman Shays that,

> responses from the public, notably from America's Blood Centers (ABC), the American Association of Blood Banks

[12] Aug. 31, 1997, letter from NACBSA member John Penner M.D., to NACBSA Chairman Arthur Caplan, Ph.D., (in subcommittee files).

[13] Testimony of Dr. David Satcher, HR Subcommittee hearing, Mar. 5, 1998, p. 7.

[14] "Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)," *Federal Register,* Mar. 20, 1998.

[15] Testimony of Dr. David Satcher, HR Subcommittee hearing, Mar. 5, 1998, p. 6.

(AABB), and the American Red Cross (ARC) were received on May 19 and 20, 1998. I met with the leadership of the American Association of Blood Banks, as representatives of these other organizations, on May 24, 1998. In response to these and other communications, FDA announced plans to revise its Guidance to Industry at the Blood Products Advisory Committee meeting on June 18, 1998, specifically in the areas of additional testing of donor samples and implementation time frames.[16]

CDC organized a Consultant's Conference to plan implementation of the HCV education initiative on July 15–17, 1998. A follow-up workshop for industry, cosponsored by ABC, AABB, and ARC was held on August 25–26, 1998, and suggestions arising at this workshop were communicated to the Department on September 9, 1998. On October 16, 1998, CDC will publish "Recommendation for the Prevention and Control of Hepatitis C Virus [HCV] Infection and HCV-Related Chronic Disease" in Morbidity and Mortality Weekly Report.

On September 8, 1998, FDA withdrew the March 20, 1998, "Guidance for Industry: Supplemental Testing and the Notification of Consignees of Donor Test Results for Antibody to Hepatitis C Virus (Anti-HCV)."[17] Unexpectedly, no other guidance was issued in place of the first guidance and the agency did not commit itself to a date certain for re-issuance. The agency's action removed FDA's recommendation that blood establishments should begin notifying consignees within 6 months of the date of publication of guidance (i.e. by September 20, 1998) concerning results of donations tested prior to the date of implementation of the guidance.

At the HR Subcommittee's September 9, 1998 hearing, Chairman Shays asked FDA Acting Commissioner Michael Friedman for a status report on the HCV look back and education campaign. Dr. Friedman responded, ". . . the commitment given by Dr. Satcher, not just on the part of FDA but on the part of the entire Health and Human Services, indicated a serious organization-wide commitment and look-back campaign."[18]

FDA's Office of Blood Research and Review Director Jay Epstein, M.D., stated, in response to a question from Chairman Shays about the status of hospital identification of HCV infected transfusion patients, that, "FDA published a guidance in March of this year which directed the blood organization to identify the units where the donor subsequently was learned to . . . [seroconvert] to Hepatitis C. The process of tracing those records, we believe, has been ongoing since that time . . ."[19]

At no point during the hearing did any FDA witness volunteer that the March 20, 1998, Guidance to Industry on HCV look back had been withdrawn the day before. Blood collection organizations were notified by FDA of the impending withdrawal of the guidance

[16] Sept. 18, 1998, letter from Surgeon General David Satcher to Chairman Shays (in subcommittee files).

[17] FDA web site announcement (www.fda.gov/cber/whatsnew/htm), Sept. 9, 1998.

[18] *Blood Safety: Minimizing Plasma Product Risks,* 105th Cong., 2d sess., p. 22 of original transcript (1998) (testimony of Dr. Michael Friedman).

[19] Testimony of Dr. Jay Epstein, HR Subcommittee hearing, Sept. 9, 1998, p. 24 of original transcript.

by telephone call on August 28, 1998.[20] Consumer groups such as the American Liver Foundation and the Hep C Connection were not notified of FDA's action in advance.[21] No written notices were sent by FDA of the agency's instructions to blood banking organizations and no written records were kept of these exchanges.[22]

Dr. Epstein also testified that, while the blood banks had told the agency that letters to recipients had been sent, FDA had no independent verification that this had occurred and was simply relying on the industry's verbal assurances that identification of suspected HCV-infected units had been achieved. Dr. Friedman acknowledged that no recipient of HCV-infected blood products has yet received a letter informing him or her of possible infection.

On September 23, 1998, FDA issued a revised "Guidance for Industry: Current Good Manufacturing Practice for Blood and Blood Components: (1) Quarantine and Disposition of Units from Prior Collections from Donors with Repeatedly Reactive Screening Tests for Antibody to Hepatitis C Virus (Anti-HCV); (2) Supplemental Testing, and the Notification of Consignees and Blood Recipients of Donor Test Results for Anti-HCV." The revised guidance grants blood establishments another 6 months from the date of issuance of the guidance to begin notifying consignees (i.e. March 23, 1999). FDA recommends that this notification be completed within 18 months of the date of publication of the guidance. This guidance suggests, but does not require, that individuals who received potentially HCV-infected blood and blood products should be notified by March 23, 2000.

In testimony at the June 18, 1998, FDA Blood Products Advisory Committee [BPAC], Dr. Hal Margolis, Director of CDC's Hepatitis Branch described HHS' view of the HCV look back.

> Basically it has been our perception and our assumption that, in fact, the targeted look back is something that is primarily going to be conducted by the blood industry, both by the blood collection agency as well as the transfusion services. In fact, as far as public sector programs, that is something that PHS, other than the guidance and much of the supporting educational material, has not put together a major effort or plans for conducting.[23]

The National Institutes of Health [NIH] have conducted an equally sluggish and fragmented approach to research on HCV. Basic research on Hepatitis C is conducted at NIH by seven different Institutes: the National Cancer Institute [NCI], National Heart, Lung and Blood Institute [NHLBI], National Institute of Diabetes, Digestive and Kidney Diseases [NIDDK], National Institute of Allergy and Infectious Diseases [NIAID], National Institute of Drug Abuse [NIDA], National Institute of Alcoholism and Alcohol

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[20] AABB Weekly Report, "HCV Look back Update," American Association of Blood Banks newsletter, Sept. 4, 1998, Bethesda, MD, vol. 4, No. 34, p. 1.

[21] HR Subcommittee staff telephone conference call with Allan Brownstein, executive director, American Liver Foundation, Sept. 10, 1998, and with Ann Jesse, executive director, Hep C Connection, on Sept. 14, 1998.

[22] HR Subcommittee staff conversation with Melinda Plaisier, Deputy Associate Commissioner for Legislative Affairs, Sept. 10, 1998.

[23] Transcript of June 18, 1998, Blood Products Advisory Committee meeting, p. 21 (in subcommittee files).

Abuse [NIAAA], and the National Center for Research Resources [NCRR].

Research moneys have increased during the last 3 fiscal years from $25,300,00 in fiscal year 1997, to an estimated $29,835,000 in fiscal year 1998, to an estimated $34,405,000 in fiscal year 1999. These figures include both intramural and extramural funding. NIH did not keep Hepatitis C funding figures prior to 1997, according to the NIH Budget Office.[24]

In contrast, one pharmaceutical company alone spent $25 million in 1996 on HCV research.[25] Dr. Teresa Wright, medical advisor to the American Liver Foundation and director of the Liver Clinic at the San Francisco VA Hospital, told subcommittee staff that HCV research is largely "pharmaceutical company driven" due to the large potential market for HCV therapies.

Consumer groups such as the American Liver Foundation have criticized the allocation of resources to hepatitis programs by HHS. They feel hepatitis transmission and treatment research funding is not commensurate to the threat the disease presents to public health.[26]

On July 22, 1997, the House Committee on Appropriations included report language to accompany the NIH appropriations bill which noted that "the March 1997 Hepatitis C [HCV] consensus conference made significant new research recommendations that affect several NIH Institutes and, therefore, requests that the Office of the Director play a role in coordinating this research in order to most effectively respond to the HCV epidemic."[27]

NIH established the coordinating committee on February 12, 1998. Dr. Anthony Fauci, Director of NIAID, chairs the committee.

NIAID is attempting to develop an HCV preventative vaccine. However, NIAID researchers told HR Subcommittee staff that a vaccine is at least 10 years away due to the variety (21) in genomic types of the HCV virus.

NIAID has proposed a strategic plan for Hepatitis C research to guide NIAID programs in this area. NIAID recently established 4 Hepatitis C Cooperative Research Centers at Stanford, University of Texas Medical Center at Galveston, University of Southern California and the University of Washington. In 1997, the NIDDK developed a long range strategic plan for liver disease research, which includes Hepatitis C. The Strategic Plan for Liver Disease Research was transmitted to Congress prior to submission of the fiscal year 1999 budget, as requested by the House and Senate Appropriations Committees.[28]

It is noteworthy that the National Institute on Drug Abuse [NIDA] spent the most NIH resources and continues to spend the most resources on HCV research, which may reflect an institutional bias within HHS that HCV is a disease of injection drug

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[24] Feb. 26, 1998, correspondence from NIH Congressional Affairs Office to HR Subcommittee staff (in subcommittee files).

[25] Sept. 18, 1998, letter from Audrey Wright Spolarich, Health Policy Analysts, to Subcommittee staff (in subcommittee files).

[26] Statement of Dr. Teresa Wright, American Liver Foundation, HR Subcommittee hearing Mar. 5, 1998, p. 65–73.

[27] House Report 105–205, "Departments of Labor, Health and Human Services, and Education, and Related Appropriation Bill, 1998," p. 100.

[28] Department of Health and Human Services, National Institutes of Health, "Liver and Biliary Diseases Strategic Plan," March 1998 (in subcommittee files).

users. This bias may have worked against early recognition of HCV as a broader public health problem.

The Centers for Disease Control and Prevention [CDC] have developed a comprehensive, nationally-focused plan for the prevention and control of HCV infection, entitled "A Prevention and Control Plan for Hepatitis C Virus Infection." Components of the plan include counseling and testing, professional and public education, surveillance, epidemiology and laboratory investigation, and evaluation. CDC estimates that the plan will cost $48 million. The plan was submitted to HHS on April 14, 1998, but was not discussed by the HHS Blood Safety Committee due to HHS refusal to commit the requested funds to this CDC program.[29]

To date, CDC conducted an educational satellite teleconference for primary care physicians on November 22, 1997, with subsequent distribution of a conference audiotape to 200,000 medical professionals in the summer of 1998. CDC has assisted private organizations such as the American Liver Foundation, Hepatitis Foundation International and the National Association of County and City Health Officers in the development, evaluation and dissemination of educational materials for populations at risk of HCV infection.

VA spent $11,546,423 on HCV from fiscal years 1988–1997, primarily on drug trials. In addition,

> the VA Cooperative Studies program is currently planning a large-scale treatment trial to determine whether interferon can prevent progressive liver disease in veterans infected with Hepatitis C Virus. The study will include more than 500 veterans at 17 VA medical facilities nationwide. Enrollment of patients is expected to take 3 years, and each veteran enrolled will be treated for 4 years. The total duration of the study is expected to be 7 years. Final approval of the study is pending. In addition, VA, in collaboration with the Department of Defense, is planning to issue an RFP [request for proposals] for studies on emerging pathogens including Hepatitis C. This initiative is supported by funding in the DOD budget for VA/DOD collaborative research.[30]

VA researcher Dr. Gary Roselle published the first large study of HCV infection in VA patients in November 1997. In a mandatory survey of VA health care facilities, the number of HCV antibody positive patients increased as follows:

6,612 in 1991
8,365 in 1992
14,097 in 1993
18,854 in 1994 (the last year with published data).

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[29] HR Subcommittee staff conversations with Dr. Eric Goosby, HHS Office of HIV/AIDS and with Marc Smolonsky, Office of the Assistant Secretary for Legislation, Sept. 18, 1998 (notes in subcommittee files). Note: Total CDC spending on HCV Public Education Activities for fiscal year 1998 was $716,894 (in subcommittee files).

[30] Feb. 27, 1998, fax from VA to HR Subcommittee staff (in subcommittee files).

He concluded, "This represents an increase of more than 285% during the 4 year period." [31]

Since most veterans are not treated in VA medical facilities, the actual incidence of HCV infected veterans is undoubtedly much greater. VA has not conducted widespread surveillance to ascertain the number of infected veterans.

There is much speculation that Vietnam era veterans, now in their 40's and 50's, are at much greater risk of HCV infection due to heavy transfusion activity during the Vietnam war. Dr. Roselle concluded, "Of particular interest to the VHA [Veterans Health Administration] is the possible relationship of HCV disease with service in Southeast Asia during the Vietnam era. Although HCV strain differences may not be useful for determining specific sources of infection, amplification of this blood-borne pathogen (e.g. transfusions) among the troops is a conceivable explanation for a number of HCV infected persons identified in this study. Further epidemiologic data will be required before this issue and that of service connection can be resolved." [32]

Former Surgeon General C. Everett Koop is among physicians who have called for an HCV screening program for all U.S. military personnel. In May 1997, Senator Richard Shelby (R–AL) asked the Pentagon to look further into the possibility that immune globulins may have spread HCV. The Pentagon did not agree to study the issue and Senator Shelby inserted the following report language in the 1998 Department of Defense Appropriations bill: "The Department of Defense shall determine rates of hepatitis C infection among personnel who served in deployments overseas or who received blood plasma products from individuals infected with hepatitis C and provide counseling and access to treatment for personnel as needed." [33]

DOD provides an exit physical for retiring and discharged service personnel. Diagnosis of a medical condition is a basis for eligibility for lifetime treatment in military hospitals and for a service-connected disability for treatment in VA facilities.

DOD does not routinely include a test for HCV infection in the blood series done at the exit physical or during annual physicals, although new recruits are tested for HCV infection if they report a history of hepatitis or are symptomatic of the infection.

The omission of the HCV test ensures that military personnel with undiagnosed chronic HCV miss the opportunity for early detection and treatment of the disease. Also, DOD does not have an accurate estimate of the prevalence of HCV in the military. As a result, veterans cannot establish a service connection for HCV infection contracted in military service and are therefore not entitled to treatment for HCV or related liver disease in VA facilities.

DOD stated in a fact sheet produced in July 1997 that, "HCV infections among military service members mirror those observed in the United States civilian population . . ." New recruits, like other young people, have lower than average HCV infection rates. DOD

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[31] Gary A. Roselle, Linda H. Danko, Charles L. Mendenhall "A Four-Year Review of Patients with Hepatitis C Antibody in Department of Veterans Affairs Facilities," Military Medicine, 162, 711–714, 1997.

[32] Ibid.

[33] Senate Report 105–45, Committee on Appropriations, Department of Defense Appropriation Bill, 1998.

policy is to screen or treat when clinically indicated, despite the fact that Hepatitis C rarely manifests acute symptoms.

Military service does involve exposure to some known risk factors for transmission of HCV such as: contact with HCV infected blood in training, in combat and through transfusions; medical and surgical care; service in regions with high rates of HCV infection such as Asia and North Africa; tattoos and IV and non-IV drug use.

DOD cites studies in which military members did not have increased incidence of HCV infection. Those studies found no evidence that foreign travel or other geographic risk factors placed military members at greater rates of infection than non-military personnel.

Veterans who are seeking now to establish a service connection for their HCV and liver disease are being rejected by the Board of Veterans Appeals because they cannot show competent evidence of a nexus between any disease in service and their current HCV. Of 1,599 chronic hepatitis cases before the panel between 1994 and 1996, only 37 were approved, according to recent analysis of case data collected by the Board and made publicly available on CD–ROM. The Board's decisions were based largely on the conclusion that episodes of acute hepatitis during service were "healed" prior to discharged, a conclusion that could be refuted with a blood test at the time of discharge.

2. The HCV "look back" is too limited

HHS estimates that 1,183,537 persons received potentially HCV-infected blood or blood products. Of that number, only 302,199, or 25 percent, would be directly informed with the look back program instituted by HHS.[34] The remaining 75 percent of individuals who had received potentially HCV-infected blood would not be directly notified and would need to be informed of their HCV risk through indirect, public notification programs.

The reason given by HHS for not requiring look back for individuals who received transfusions prior to 1992 was that the first generation test had a high false-positive rate. However, the first generation test was sensitive enough to be relied upon to detect infection, and many of those who tested positive were in fact infected and present a risk to recipients of their blood.

The sensitivity of the first generation test was 84–89 percent, while the sensitivity of the second generation test was 92–95 percent.[35] The specificity of the first generation test was 22 percent, while the specificity of the second generation test was 30 percent.[36] To reduce the rate of false positives, the second generation test was conducted using a confirmatory test for the positive results. A confirmatory test was not available for the first generation test.

HHS estimates that only 27,500 individuals, of the 1.1 million Americans who received potentially HCV infected blood and blood

[34] Nov. 17, 1997, memorandum from Drs. Eric Goosby and Stephen Nightingale, Office of HIV/AIDS Policy, to Dr. John Eisenberg, Acting Assistant Secretary for Health, p. 4–5 (in subcommittee files).

[35] Ibid., p. 2–3. Note: "Sensitivity" is defined as the ratio of true positives over true positives plus false negatives. "Specificity" is defined as the ratio of true negatives over true negatives plus false positives.

[36] S. Kleinman, et al., "Increased detection of hepatitis C virus (HCV)-infected blood donors by a multiple antigen HCV enzyme immunoassay," *Transfusion,* vol. 32, No. 9, p. 807, 1992.

products, received units from an individual with a false-positive test.[37] Therefore, HHS' decision against a broader look back is based on the fact that 2.75 percent of identified persons would not be truly positive. HHS believes that direct notification of these additional 27,500 persons will result in an estimated cost of $45.9 million to blood banks and hospital transfusion services.

The look back as proposed by HHS is not consistent with the concept of a patient's right to know critical medical information, such as HCV infection. HHS drew an arbitrary line between those who will be notified and those who will not simply by virtue of the fact that they were infected before 1992. This critical, public health decision was determined by the costs to the blood banks and transfusion services of identifying and contacting 2.75 percent of the cohort.

3. Private organizations, with some Federal assistance, have taken the lead in HCV public education efforts

Within 2 weeks of the issuance of the Committee on Government Reform and Oversight's August 1996 oversight report, "Protecting the Nation's Blood Supply from Infectious Agents: The Need for New Standards to Meet New Threats," the American Liver Foundation ran ads in USA Today and other publications advising recipients of blood transfusions prior to 1990 to seek HCV testing.

Since 1996, the American Liver Foundation has spent an estimated $7.5 million on its Hepatitis C public awareness and education program called "T.H.I.N.K. Hepatitis" which stands for "The Hepatitis Information You Need to Know." The program is targeted to the general public, patients and health professionals. CDC provided $150,000 of support for this program through a cooperative agreement.[38]

The Association of State and City Health Officials [ASCHO] received $50,000 from CDC in fiscal year 1998 to administer focus groups to help CDC develop CDC materials for providers and at-risk populations. ASCHO has been approved by CDC for another $75,000 in fiscal year 1999 for development of additional materials for at-risk populations.[39]

The Hepatitis Foundation International [HFI] received $50,000 in fiscal year 1998 to develop an educational video on Hepatitis B and Hepatitis C prevention. HFI received verbal notification that CDC will provide $178,000 in fiscal year 1999 to assist in video distribution efforts. HFI participated jointly with CDC in a November 1997 satellite teleconference for physicians.

Several prominent researchers, physicians, and consumers believe that the lack of a public health campaign has fueled the perception in the medical community that HCV was strictly an IV drug abusers' disease and has delayed medical and public recognition of the extent of its spread throughout all levels of society.

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[37] "Briefing Document on Public Health Service Options for the Identification of Hepatitis C Virus Infection Among Prior Transfusion Recipients," Mar. 28, 1996 (revised for Sept. 22, 1997, Resolution from the Advisory Committee on Blood Safety and Availability-ACTION memorandum by John M. Eisenberg to members of the Blood Safety Committee) (in subcommittee files).

[38] Sept. 11, 1998, letter from American Liver Foundation President Alan P. Brownstein to Chairman Shays (in subcommittee files).

[39] HR Subcommittee staff conference call with Donna Grossman, Association of State and City Health Officials, Oct. 1, 1998 (notes in subcommittee files).

Ann Jesse, now executive director of the Hep C Connection, described in testimony at the March 5, 1998, hearing how it took over 20 years for her HCV infection to be diagnosed following a blood transfusion in 1973, due in part to the perception of her doctors that a 62 year old, Caucasian grandmother didn't fit the usual profile of an HCV patient.[40]

Dr. Carroll M. Leevy, director of the Sammy Davis Jr. Liver Institute in Newark, NJ, described in testimony at the HR Subcommittee's March 5, 1998 hearing that 30 percent of his patients from suburban New Jersey who are coming in for HCV treatment are without identifiable risk factors for the disease.

Dr. Leevy also discussed the disproportionate impact that HCV is having on minority communities, where 3.2 percent of African Americans and 2 percent of Hispanics are affected in comparison to 1.2 percent of Caucasians. He recommended a public education campaign with a variety of educational models to inform at risk individuals of HCV, enable them to be screened, and provide appropriate support to ensure therapeutic compliance.

IV. Recommendations

1. a. The Secretary of Health and Human Services should take the lead in coordinating the Federal public health response to the Hepatitis C epidemic, including implementation of a research plan.

b. The Department of Defense should test recruits, active duty personnel and those about to be discharged for Hepatitis C infection.

c. The Department of Veterans Affairs should conduct additional studies of prevalence of HCV in veterans populations.

HHS,[41] DOD and VA should undertake a coordinated research campaign to educate and reduce the incidence of Hepatitis C. Basic research on epidemiology, surveillance, modes of transmission, vaccine development and therapeutic interventions is overdue, poorly planned, and involves several cabinet departments and numerous Federal agencies. The Federal response is inadequate to an infection that threatens every American and has already infected 1 of every 50 adult citizens.

Dr. C. Everett Koop, former Surgeon General, testified at the March 5, 1998, hearing:

> We need a coordinated Federal effort that reaches across the relevant agencies and identifies activities that can be significant in training physicians, raising public awareness, and seeking out target populations for screening and treatment. I believe we have a 5-year window to identify and treat a significant proportion of the infected popu-

[40] Statement of Ann Jesse, HR Subcommittee hearing Mar. 5, 1998, p. 83–85.

[41] HHS public health agencies include: the Food and Drug Administration [FDA], the Centers for Disease Control and Preventions [CDC], the National Institutes of Health [NIH] and the Health Care Financing Administration [HCFA].

> lation if we are to head off the huge increase of liver disease I believe is ahead.[42]

A comprehensive, interagency HCV research plan should be developed by HHS, VA and DOD to identify gaps in HCV knowledge and ensure that the millions of public health research dollars are directed to best meet public health goals.

At the March 5, 1998, HR Subcommittee hearing, Dr. Koop announced his "Prescription for Action on Hepatitis C" which included screening and treatment recommendations for DOD personnel and veterans. He testified, "It is my understanding that there has been a lack of attention to this disease in the Department of Defense or in the Department of Veterans Affairs where rates of infection are likely to be high and where screening and treatment can have a positive impact."[43]

He added:

> In some studies of veterans entering the Department of Veterans Affairs health facilities, half of the veterans have tested positive for HCV. Some of these veterans may have left the military with HCV infection, while others may have developed it after their military service. In any event, we need to detect and treat HCV infection if we are to head off very high rates of liver disease and liver transplant in VA facilities over the next decade. I believe this effort should include HCV testing as part of the discharge physical, and entrance screening for veterans entering the VA health system.[44]

A coordinated approach to combating HCV in the military requires DOD testing of all recruits upon entrance, all active duty personnel and those about to be discharged. VA, in turn, must initiate additional studies of prevalence of HCV in veterans populations to detect those patients most likely to benefit from new therapies and to avoid increased demand for costlier liver transplants.

2. The Hepatitis C look back plan should be expanded.

HHS should immediately take steps to ensure notification of all recipients of blood from donors who have tested positive on any HCV screening test, regardless of date. Infected individuals have a right to know of their infection. HHS should not draw an arbitrary line between those who will be notified of their infection after 1992, and those who were unfortunate enough to be infected prior to 1992.

The vast majority of the 1 million Americans infected by transfusion were infected prior to 1992. They deserve no less ethical consideration than those infected after 1992.

3. Federal educational campaigns on HCV infection should be launched immediately.

In testimony before the Human Resources Subcommittee on October 12, 1995, Health and Human Services [HHS] Secretary

[42] Statement of Dr. C. Everett Koop, HR Subcommittee hearing, Mar. 5, 1998, p. 58.
[43] Ibid, p. 56.
[44] Ibid.

Donna Shalala committed that Hepatitis C would be a top priority for the Department's new blood safety committees.

In the spring of 1998, the CDC presented the HHS Blood Safety Council with a comprehensive public education plan entitled, "Plan to Prevent HCV Infection and Its Chronic Disease Consequences." HHS declined to include the plan in the fiscal year 1999 HHS Budget Request. HHS also decided against seeking a supplemental appropriation to fund the plan in the summer of 1998.

To date, 200,000 physicians have received HCV practice information kits. HHS should immediately implement broader HCV public education plan and seek the funding necessary to accomplish it.

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