Public Hearing

before

ASSEMBLY HEALTH COMMITTEE

"Testimony about hepatitis C and its public health implications"

LOCATION: Bergen County
Administration Building
Hackensack, New Jersey

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2:00 p.m.

MEMBERS OF COMMITTEE PRESENT:

Assemblywoman Charlotte Vandervalk, Chairwoman
Assemblyman Nicholas R. Felice, Vice-Chairman
Assemblyman Francis J. Blee
Assemblywoman Loretta Weinberg

ALSO PRESENT:

Assemblyman David C. Russo
District 40

Assemblyman John E. Rooney
District 39

David Price
Office of Legislative Services
Committee Aide

Natalie Collins
Assembly Majority
Committee Aide

Dana Burley
Assembly Democratic
Committee Aide

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ASSEMBLYWOMAN CHARLOTTE VANDERVALK (Chairwoman): Good afternoon. I want to welcome everyone here today. I think you'll find the testimony very enlightening.

We'll hear information about an emerging public health issue: hepatitis C. This is a chronic, often symptomless, blood-borne virus which is implicated in 40 percent to 60 percent of all liver disease. It is currently estimated that about 4 million to 5 million Americans are infected with the virus, which, if left untreated, can result in serious and sometimes fatal liver disease.

This year there has been a heightened national focus on hepatitis. In March, the National Institutes of Health convened a Consensus Development Conference on hepatitis C and brought the issue to the forefront in the medical community. The NIH panel concluded that such a large group of infected individuals poses a risk of transmission to others and that there should be continued monitoring of the epidemiology of acute and chronic hepatitis C.

In August, a Federal Advisory Committee on Blood Safety recommended that anyone who received a blood transfusion prior to 1992 be tested for hepatitis C. Also in August, the Council of State and Territorial Epidemiologists passed a resolution calling for emphasis on collecting data on chronic hepatitis C in order to better understand the prevalence and the transmission issues as the root of transmission is unknown in as many as 40 percent of hepatitis C cases. Unknown, the root of transmission -- I wanted to repeat that. I think that is of critical importance.

I believe that the distinguished parties who will address the Committee today will address these issues and others. As the recognition of hepatitis C's public health implications has increased, there has been an increased media attention and public education campaigns about hepatitis C.

In speaking with the various parties who will address this Committee today, I have learned two things: First, this is an emerging public health problem that must be taken seriously in order to reduce the prospect of future liver disease in people infected with hepatitis C; however, there is no need for panic. Second, unlike the AIDS epidemic, we have been given early warning and have the chance to minimize hepatitis C's impact on our population through proactive public policies which addresses research, education, screening, and appropriate treatment.

This hearing is the first of what I believe will be many held in other states around the country. It is an important first step in the process of educating the members of the Committee, the Legislature, and the appropriate health care professionals and officials about the epidemiology of this disease and its impact upon the citizens of New Jersey.

We are very honored this afternoon to have Dr. C. Everett Koop with us, and I'm particularly pleased. He has a very extensive resume and we just might be here until 4:00 if I read the entire resume, but I think we all know he is the Former Surgeon General for the United States. Just one line here struck me, he has been awarded, among other things, 37 honorary doctorates -- very impressive -- and these are from all over the world.

Dr. Koop, please, if you would join us at the table here, we thank you in advance. Before you start, Doctor, let me just introduce the members of the Committee with us this afternoon.

This is the Assembly Health Committee. On my left is Assemblyman Frank Blee and Assemblyman John Rooney; Assemblyman Nick Felice; David Price, who is with the Office of Legislative Services; Dana Burley, who is also with the Office of Legislative Services, and we may have a few other members of the Committee who will be coming late, schedules are tight.

Thank you, Dr. Koop.

C. EVERETT KOOP, M.D.: Well, thank you, Madam Chairman. I do appreciate the opportunity to give you a public health perspective, if you will, on the epidemic of hepatitis C. I will give you as many facts as I can, and we will answer questions, if that is your wish, later on.

Hepatitis C is caused by one of six hepatitis viruses. As you have already said, between 4 million and 5 million Americans are afflicted. It is noteworthy that is more commonly found in minorities, with Afro-Americans being afflicted about twice as often as non-Hispanic white people. There are about 30,000 acute, first-time infections per year in this country, and only about one-quarter of these are diagnosed. Hepatitis C, therefore, accounts for about 20 percent of all hepatitis. Between 8000 and 10,000 Americans die each year, and without some change in the way this epidemic is progressing, that number could triple in between 10 and 20 years.

Hepatitis C is transmitted parenterally. One of the most common ways is through drug use, not only the abuse of drugs intravenously, but also through the paraphernalia that is used sometimes for snorting cocaine. It also

is not uncommon in folks who had transfusions before 1990 or perhaps had an organ transplantation in that same period of time. The present incidence, however, of the transmission of hepatitis C by those routes is negligible because of the pretransfusion tests of blood donors.

The virus is not easily destroyed in the human body by the body's own immune system and, therefore, the infection persists in about 85 percent of those patients who contract the virus and this results, as you might expect, in progressive liver disease of a chronic nature and this, in the long run, manifests itself as cirrhosis, liver failure, even hepatocellular cancer, but it usually takes between 10 and 20 years for that to occur.

There is, unfortunately, no vaccine to prevent infection, nor is there one on the horizon. This is one of the many problems associated with the ability of this virus to produce heterogeneous genotypes and subtypes, or in other words, to mutate very frequently. Hepatitis C is a reportable, acute disease, but the chronic liver disease which follows it -- chronic hepatitis -- is not reportable.

The most effective treatment is with alpha interferon, and there also is a promising adjunct to interferon therapy with ribavirin, which is an orally taken antiviral medication. Hepatitis C, at the present time, is the most common reason why liver transplantation is carried out in this country.

Let me return to the transfusion problem for a moment. I refer again to the fact that it's only transfusions before 1990, but it is important to remember that patients, many of them, don't know that they were transfused when they had a surgical procedure in a hospital and most who were are

unaware of the danger associated with that transfusion in reference to chronic liver disease.

There are two special categories that we must be concerned about who are at special risk: women who had cesarian sections before 1990 and individuals who were born prematurely before 1990. Many women who had cesarian sections were given transfusions. In fact, for a long period of time, it was almost routine to do that, but many times in the excitement of giving birth to a new baby, one of the things they did not take home from the hospital was the knowledge that they had been transfused, and the same is true of the parents of premature babies.

Premature babies have very many blood studies and sometimes they are almost bled out by testing them and transfusion is routinely given to repair that blood loss, and, again, because it happens, many times, when the parents are not around, they are not always notified about that possibility.

The Subcommittee that advises HHS on blood safety and availability has recommended a look-back protocol in reference to these two categories of patients, and I have urged the Secretary of HHS, Dr. Donna Shalala, to follow through with regulations supporting those recommendations.

The natural history of chronic hepatitis is that of a persistent, intermittent viremia. Two-thirds of the patients have elevated liver enzymes, which can be detected by a simple blood test. Antibodies to hepatitis C and circulating viral RNA can also be detected in almost all patients, and early detection is important because the greatest number of treatment options are then available. The likelihood of success from those treatments is enhanced

and also the quality of life is improved. With no treatment at all, there is an increased incidence of cirrhosis.

As I said, the disease is insidious. It has early-on nonspecific symptoms. In some, the first symptoms are those of advanced liver disease that occurs perhaps 10 years after the first infection; 20 percent of folks go on to cirrhosis with 20 years or less; cancer of the liver is much less an incidence -- it's between 1 percent and 5 percent -- and usually over a longer period of time, more than 20 years; but there also are a variety of nonliver diseases that afflict these folks. Most common among those are arthritis and kidney disease.

There are some very special points that I think you as legislative officials should be aware of. Hepatitis C has a very high incidence in corrective institutions -- in some places as high as 70 percent -- and many of these inmates also have concomitant infections of HIV. And perhaps as many as 50 percent of the population of veterans' hospitals also test positively for hepatitis C.

The challenges and the obligations are many. First of all, I think we have to make chronic hepatitis a reportable disease. I think we need education about hepatitis C in the broadest possible sense: the public, of course, and especially high-risk groups, which I'll mention in a moment, but also the professions who are not as up-to-date on hepatitis C as they are perhaps on hepatitis A and B. And I would think that the people most involved in this would be primary care physicians, internists, and obstetricians and gynecologists.

There also are some very special challenges in reference to screening and treatment. I've already mentioned correctional institutions. The

Department of Defense is another area, and I've already mentioned the Veterans' Administration, and we need special and repeated education for those people who work in health care settings where an accidental needle stick might be the cause of transmission of the virus.

There are, therefore, a large group in this country who are capable of transmitting hepatitis C to other people by drug abuse, and it is now known that between 50 percent and 80 percent of new drug abusers are positive for hepatitis C within six months. I'm referring now to IV drug abusers and that may account for as many as 50 percent of the chronic infections with hepatitis. The majority of the rest of the people had transfusions before 1990.

There also can be occupation exposure. I've mentioned blood in passing, and health workers are of the highest risk but also people you might not originally think about, and they are those who work with hemodialysis units. Noninjectable drug use has already been implicated. I mentioned it in passing. For example, the intranasal use of cocaine and the paraphernalia used then is shared with individuals and can transmit the virus.

Transmission by sexual contact is not clear. It does appear to occur. The rate is low, and it certainly is higher if other sexually transmitted diseases are present but especially HIV. The perinatal transmission is down to only about 6 percent -- again, it's higher if HIV is present in the mother -- and there is no evidence of passage of the virus by breast feeding.

So in conclusion, Madam Chairman, as far as state governments are concerned, I think they have an obligation in three particular areas: education in its broadest possible sense, the screening and treatment of high-risk groups, and the encouragement of research wherever that is possible.

Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you very much. You've shed a lot of light on it but also raised a lot of questions.

Are there any members of the Committee who wish to ask Dr. Koop a question?

Assemblyman Felice.

ASSEMBLYMAN FELICE: Thank you, Madam Chairman.

One particular thing, of course, with the rate of our growth in our prisons-- You mentioned that 50 percent or close to that or -- how many was that?

DR. KOOP: I'd say in some correctional institutions as many as 70 percent test positively.

ASSEMBLYMAN FELICE: Seventy percent, and fifty percent in veterans' hospitals; but that high in our correction facilities, is it because of, you feel, drug use taking place? How would the prisons have--

DR. KOOP: Because of drug use. We know that men who engage in sex with men have twice the incidence of those who do not, and also prisons are, many times, the place of amateur tattooing using needles or pieces of glass and some pigments that they can get here and there. So all three of those are possible routes of infection.

ASSEMBLYMAN FELICE: The other question, of course, I was concerned about is, again, 50 percent of our veterans' hospital-- There is a high incidence. There again, would that be also-- It can't be blood transfusions anymore because that's been pretty much corrected. What are the other methods in a veterans' hospital?

DR. KOOP: But you can recognize, sir, that many of the people who are in veterans' hospitals today did have transfusions before 1990. And, as your Chairman already pointed out, one of the difficult things about this disease is that we do not always know the method of transmission, and it will take some research to know more about that, and that's why I mentioned that as one of the obligations I think the State has.

ASSEMBLYMAN FELICE: Doctor, many of us in our districts help veterans to enter the veterans' facilities. And I know just recently they're quite strict in their physical and background medical checks. Do you feel that this should be a mandatory check for veterans coming in, that they are questioned if they ever had a blood transfusion, that they should at least be checked for hepatitis C?

DR. KOOP: Well, I certainly think that part of any medical history of an incoming patient should be whether or not they have had transfusions in the past and that being a high-risk group in reference to what we're talking about, they certainly should be screened. But I also think it is not unreasonable, with the high incidence of veterans who are hepatitis C positive, that it could be a universal screening.

ASSEMBLYMAN FELICE: Thank you, Doctor.

ASSEMBLYWOMAN VANDERVALK: Is there anyone else on the Committee? (no response)

Thank you, Doctor. We certainly appreciate your input, and you'll be hearing more from us. Thank you.

DR. KOOP: Thank you.

ASSEMBLYWOMAN VANDERVALK: We have a number of speakers, some other medical people, and also, later on, a patient. Next on the agenda is Dr. Elin Gursky, the Senior Assistant Commissioner of Epidemiology and Public Health Laboratories for the Department of Health and Senior Services for the State of New Jersey, and that is a mouthful. (laughter)

Dr. Gursky, thank you.

ASST. COMMISSIONER ELIN A. GURSKY, Sc.D.: Thank you, Madam Chairwoman, and distinguished Committee. It is a pleasure and a privilege to be here today in my capacity as Senior Assistant Commissioner and representing the New Jersey Department of Health and Senior Services.

It is a particular honor to participate in this event with Dr. C. Everett Koop, someone who for many years has served as a role model for me and many other public health practitioners in the United States. During Dr. Koop's tenure as Surgeon General, this country addressed many important public health issues, perhaps the most significant being smoking-related illness and the human immunodeficiency virus which causes AIDS.

It was not just Dr. Koop's professional acumen which we remember and respect, but more importantly, it was his clarion call to the nation that resulted in a greater awareness by citizens, medical professionals, and policy makers that issues which threaten the public's health must be addressed proactively rather than reactively. This is a fitting example for our presence here today.

The concern of this assemblage is our growing recognition of a blood-borne infection caused by the hepatitis C virus. We are concerned for

those who may be or have been vulnerable targets for this infections: persons who were transfused prior to 1990, injecting drug users, persons exposed through tattooing and body piercing, and those occupationally exposed. We are concerned because those who are infected create a pool from which additional disease transmission will continue to take place.

Our current knowledge of this disease and morbidity rates in this country indicated that perhaps almost 4 million Americans may be chronically infected, many more than those infected with the HIV virus. As many as 85 percent of those acutely infected will proceed to chronic infection. Persons chronically infected are a source of infection to others and are themselves at risk for additional negative health sequelae, including cirrhosis, hepatic carcinoma, and death. The natural history of this disease is such that persons acutely infected may be asymptomatic and therefore unable to seek medical intervention for this disease until serious illness is presented.

Given our nation's limited knowledge regarding prevention, intervention, and therapeutic measures, it is suggested that the number of those infected with this virus will increase more than 200 percent during the next 20 years. However, gaps in knowledge are not deterrents to protecting the public's health. Public health practitioners can take actions now based on existing epidemiologic information and using basic tenets of disease containment. Therefore, the following actions should be considered:

First, New Jersey must coalesce its medical and public health practice associations to build sound policies for its citizens. Such steps have already begun, especially through the work of the New Jersey Liver Institute, which I know will be further elucidated here today. To assist these efforts I

have written to Dr. David Satcher, Director of the Centers for Disease Control and Prevention, to request the CDC's guidance and direction in crafting such policies, such as reportability of both acute and chronic disease status.

Second, we must engage in aggressive education regarding this disease to populations at risk and to the medical provider community. The ultimate goal of such education would be to reduce at-risk behaviors, to assist individuals in making better choices for their health and the health of others, to inform medical providers about the need to screen at-risk patients. Education is a powerful tool to prevent new infections and to break the chain of existing infection.

Third, we should initiate protocols to determine infectivity rates in populations to better understand, prepare for, and intervene upon hepatitis C disease trends in this State. Such baseline information is essential if we are to evaluate the success of our interventions and to prevent the spread of disease to susceptible populations. We also need additional epidemiologic information regarding the infectivity of hepatitis C on other potentially susceptible populations, such as Dr. Koop has already discussed.

Fourth, we need to focus efforts on research regarding the diagnostics and treatment of hepatitis C. We must develop good laboratory tools, assure such tools are readily accessible, and assure the physician community is alerted to the efficacy and availability of appropriate treatment regimens.

We want to congratulate Chairwoman Vandervalk and the Assembly Health Committee for convening this hearing and making National Liver Awareness Month meaningful in this State. You have facilitated an

opportunity to share information which is vital to impacting upon and improving the health of New Jersey's citizens. The Department sincerely thanks you.

ASSEMBLYWOMAN VANDERVALK: Thank you, Dr. Gursky. There seems to be a concern as to collecting data on how many people are infected and from that then we learn other things. How is it transmitted, and how are you going to treat it and cure it, and so forth, and prevent the spread? So a lot of it seems to hinge on collecting the data in the first place, and I'm led to believe that only the acute flare-ups are reported and not the chronic cases. How difficult would it be on the part of the State to change that policy and say, "We want to become notified whenever there is a patient infected with this disease"? That seems rather simple. Is it that simple, or what-- Would you expand on that?

ASSISTANT COMMISSIONER GURSKY: I believe what you are suggesting may indeed become a strategy that the State will follow. To promulgate such rules, we would first need to clearly define what it is we would want physicians to report and assure consistency of such reporting. I think it is an appropriate and probably first order of business that we begin to address.

ASSEMBLYWOMAN VANDERVALK: Just to be sure I understand this correctly, if someone does go for a screening and they discover they have hepatitis C, they feel fine, but nevertheless the blood test shows that hepatitis C is present, that is not reported then. Is that correct?

ASSISTANT COMMISSIONER GURSKY: That's true. Actually there is some reporting that is done and some of that is very much practitioner associated. There are some physicians who do report whether or not reportable

disease states exist, but at this point, the State does not have a good idea of the burden of this disease and assumes there is significant underreporting and underestimates of morbidity.

ASSEMBLYWOMAN VANDERVALK: And if there were a requirement that all of these cases would have to be reported, I would assume that there would be some data that you would want to go along with that, some questions related to how long -- if there were any clues as to how the patient was infected. I'm not sure it-- In other words, how can you get this all in a nice, neat, tidy form? Is that possible, or does it get to be a problem?

ASSISTANT COMMISSIONER GURSKY: We would certainly work on a reporting mechanism with the medical community to assure that it's not onerous, burdensome, and is something that physicians can easily participate in. Obviously, the information that you were suggesting, the epidemiologic information, is important data to the State for us to be able to determine trends.

ASSEMBLYWOMAN VANDERVALK: Yes, I would agree. Well, I think we have to head in that direction.

ASSISTANT COMMISSIONER GURSKY: I agree. We have, as I indicated, asked Dr. Satcher for some Federal advice and guidance in developing such policies. I look forward to hearing from him, and certainly the support you indicated from the Council of State and Territorial Epidemiologists will be of assistance to the State, as well.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

And Jim McGarry (phonetic spelling), you're sitting there with Dr. Gursky. Is there something you wish to add? (negative response)

Oh, I'm sorry, Assemblywoman Weinberg.

ASSEMBLYWOMAN WEINBERG: Thank you.

How does the State Health Department decide that a disease becomes reportable or not?

ASSISTANT COMMISSIONER GURSKY: Well, the State certainly does not do this in a vacuum, and we do count on the medical practice community to help us in determining the appropriateness and direction of developing policies for reporting. We of course do use whatever data we have to try to determine the significance of impending health problems, but it's very much a participatory activity.

ASSEMBLYWOMAN WEINBERG: So, if I may--

ASSEMBLYWOMAN VANDERVALK: Certainly.

ASSEMBLYWOMAN WEINBERG: Given the testimony that we've heard thus far this afternoon and what I assume we'll be hearing, how long would it take the State Health Department to actually implement procedures to make hepatitis C a reportable illness?

ASSISTANT COMMISSIONER GURSKY: Assemblywoman, I don't know how to best answer that other than to tell you that the State is working with the New Jersey Liver Foundation and others on this very issue. It is something that is as important to us as it is, clearly, to this group today. And we will work on it with the greatest speed possible.

ASSEMBLYWOMAN WEINBERG: Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

ASSISTANT COMMISSIONER GURSKY: Thank you.

ASSEMBLYWOMAN VANDERVALK: The next speaker would be Alan Brownstein, the President and Executive Officer of the American Liver Foundation.

Thank you.

I just want to remind people if they do wish to testify and I'm not aware of it, if you could fill out one of these forms. (indicating) We will be hearing from anyone who wishes to testify.

A L A N P. B R O W N S T E I N: Well, thank you very much.

ASSEMBLYWOMAN VANDERVALK: Certainly.

MR. BROWNSTEIN: I am Alan Brownstein. I am the President and the CEO of the American Liver Foundation. I would like to thank you for holding this hearing during National Hepatitis Awareness Week and for the opportunity of letting us speak with you today.

I am here with Mary Licetti, and she is a person who is living with hepatitis C and is a member of our Board of our American Liver Foundation Chapter.

The American Liver Foundation was founded in New Jersey in 1976, and looking at the speakers that you have today, it seems that New Jersey is the epicenter of liver research in not just America, but the world. The ALF is a chapter- and membership-based national organization that is dedicated to the prevention, treatment, and cure of hepatitis and other liver diseases through research and education. As you've already heard, there are nearly 4 million Americans who are infected with hepatitis C, and we hope that this hearing will be part of a wake-up call for people in New Jersey but also for America about the seriousness of this infection.

This infection is more common in minority populations, with 3.2 percent of African-Americans infected with chronic hepatitis C, in contrast with 1.5 percent of non-Hispanic whites. Currently, hepatitis C is responsible for an estimated 8000 to 12,000 deaths annually, and without effective intervention, that number is projected to triple in the next 10 to 20 years, and this is documented by the CDC, and I'll be leaving this behind for you to review. (indicating) In a few years, you've heard from Dr. Koop, these numbers will exceed those who are already dying tragically from AIDS.

Hepatitis C is also the leading cause for liver transplantation in the United States. The epidemic growth of this infection has led it to being officially designated as an emerging infectious disease by both NIH and the Centers for Disease Control. In fact, it is so serious that NIH convened a Consensus Conference on Hepatitis C in March of 1997, just a few month ago.

The Consensus statement itself, as well as the American Liver Foundation's recommendations for follow up, are included in the packet that I have left for you here today.

In New Jersey, using the national average, we can estimate that there are at least 144,000 with hepatitis C in New Jersey and that would mean that there are about 450 deaths each year in New Jersey.

ASSEMBLYWOMAN VANDERVALK: Four hundred fifty, did you say?

MR. BROWNSTEIN: Yes, 450.

The American Liver Foundation's hot line receives 150,000 calls per year, with about 7500 from patients and family members, as well as physicians, right here in New Jersey. If you were holding this hearing just a

few years ago, very little could have been said because the hepatitis C virus was first discovered in 1988. Before then you might have heard of non-A, non-B hepatitis.

But today, a lot could be said about preventing, treating, and curing hepatitis C. The biggest problem, by far, is that the vast majority of the 4 million Americans and the 144,000 people in New Jersey who have chronic hepatitis C don't have a clue that they've got it. So it is very important that we find ways of making sure that primary care physicians also have the latest information about hepatitis C.

Many of you have seen our campaign advertising. In fact, we have samples of it right over there (indicating) where we have "Get Hip, Get Tested, Get Treated," in our "Get Hip to Hepatitis" campaign. What we found is that many people became aware of this and an increased number of phone calls we received and the overall awareness about hepatitis C increased tremendously. But then, the first round of phone calls that we received we referred people to physicians, but they went to their own physicians. Then they called us back, and they told us that their physicians told them not to worry about it. So the point is, is that from our failure, hopefully, we can all learn. We failed in not making sure that we didn't have a concomitant commitment to educating physicians along with the patients. So I'm just sharing that with you so that we can all do a better job at it.

ALF has begun what we call our "fake hepatitis" strategy, and that is, THINK, which stands for The Hepatitis Information you Need to Know. The "you" in this case is you, the general public. The general public needs to know for two reasons. Number one is that here we have an opportunity for

prevention. Number two is that here we have an opportunity to alert people who may have already contracted hepatitis C to seek care and to find out if, indeed, they actually have the disease.

We also need to make sure that patients -- people who are patients today, people who have been told they have hepatitis C and then told "Don't worry about, you'll die from something else in the next 30 years," that they, too, become aware of what the treatment options are today. A few years ago, there were no treatment options. But, as you've heard from Dr. Koop, these treatment options are improving, so we really do have some good news about the potential that can be realized through the emerging treatments.

The American Liver Foundation has formed an alliance with the American Digestive Health Foundation, which is made up of the major gastroenterology societies, including the American Association for the Study of Liver Diseases, to carry out a three-year viral hepatitis education campaign targeting the general public, patients, and primary care physicians.

It is important that the general public be included so that -- for the reasons I mentioned before. People need to understand how hepatitis is transmitted. You've heard that there is blood-to-blood contact, and that is done -- that you can contract hepatitis C through IV drug use, as well as intranasal cocaine use. Also today, we know that young people today have found new ways of expressing their individual identities through body piercing and tattooing. I have a teenage son and a young adolescent son, and I know that I can't wave my fingers at them and tell them what they can do and not do, but we sure as heck--

And I notice that some of you have teenage sons, too, by your reactions.

But clearly, I think that we can share with them the public health risks so that we can just tell them, "Please, if you're going to proceed in this way, make sure that the instruments that are used are sterilized so you're not putting yourself at risk." So that at least their health, which is the primary concern, is protected. And we have to-- I think I'm sharing with this because I think that in New Jersey and the private sector that we represent, we need to work together to figure out ways of better communicating.

So, for example, we have put out the *Red-Blooded Blues*, a recording where we partnered with PolyGram Records. (displays tape) It ended up being Number 11 on the Rhythm and Blues Charts, and we ended up making some money. But most important of all is that there are important messages about hepatitis and how to avoid it and symptoms of it. So what we are doing is we are using the lifestyle context of the people who may be more exposed to hepatitis by using this method of finding new ways of communicating to people. We have to go beyond traditional public health techniques.

I mentioned before that certain minority populations are more vulnerable. Well then, we need to find better ways of communicating to the groups that we wish to target. So we have retained special communications firms to help us communicate to the African-American community, to the Asian community, and to the Hispanic community, and I think that this, too, is extremely important in any strategy that must be worked out.

But it is also important, while we talk about the public health risks and the vulnerabilities to hepatitis C, that we also point out that a great deal

is not known about how it is being transmitted, that there are a number of people who don't know how they contracted hepatitis C, or they don't connect to the behaviors that are associated with its transmission. And some of those people, who don't connect to those behaviors, are people who have never had those behaviors but in some way or another, at some point in their life, had blood-to-blood contact.

So we need to let it be known that, other than the known risks, there are others who get it through any form of blood-to-blood contact. Also, there are many people where they might have experimented 20 years ago or 30 years ago with IV drugs, and they did it once or twice. Well, there, too, we need to find a place for people to go and to get tested. It is extremely important that we not just talk about the risk factors, which is important for prevention and for people to be alert to potential exposure, but that we also talk about the number of people where we do not know how they've contracted hepatitis C.

I will, in the interest of time, move to some concrete recommendations. Number one is that in order to think effectively about hepatitis, you do have to think about reaching the general public and using all methods possible, and to the extent that New Jersey -- the legislative and the public health leadership of New Jersey -- can come up with approaches to educating the public, we think that would be great.

And I'm going to say something else, because we are launching a campaign in January that will be starting off with a national summit, where we're going to be pulling together national organizations from all over America that have local affiliates in different states and cities around America -- that

includes New Jersey. Well, this is the first state that has already demonstrated some leadership by having this hearing here today.

I pledge, on behalf of the American Liver Foundation, to use whatever resources we may have to assist. So to the extent that our small, private support dollars can do certain things to help stimulate education, we're prepared to roll up our sleeves with you in helping to get that job done. We are also putting aside a budget where we are prepared to provide to community-based organizations some support funds for them to have community education hearings, community education sessions at community-based organizations about hepatitis C.

Secondly, there really needs to be an education initiative directed at primary care physicians. As new information emerges, they need to know. If they don't know, then the patients who are affected by hepatitis C will not get the information that they need to know to empower them to make their own decisions -- in consultation with their physicians -- about their own health. So we really need to do that, and there are a number of physicians who are working with the American Liver Foundation in New Jersey who would be very pleased to work with public health officials and to try to provide assistance toward the development of those programs.

Lastly is that while there are national prevalence data, we believe that it is extremely important that there be local data accumulated here in New Jersey so that you can better target your resources in ways that can produce the best results possible.

There is a lot more to be said, but I will not go on because what's very important is that the direct testimony of a person who is living with hepatitis C is very important today, and I'd like to introduce Mary to you.

Thank you.

M A R Y L I C E T T I: Thank you. Alan, I liked the way you introduced me now better than the--

Alan and I talked over the weekend. I had seen my name listed on one of the outlines for this meeting as the hepatitis C-afflicted individual, and my heart sort of sank and I felt like I was going to back out because I have never viewed myself as a hepatitis C-afflicted individual. I view myself as someone who is really no different than most of the people in this room. So, as I thought about it, I decided that's exactly why I need to be here, so that everyone here can realize that hepatitis C is not just something that scientists and doctors talk about; it is something that can and does affect everyday individuals who really are no different from you or me.

I'd like to mention that I am a volunteer for the American Liver Foundation. I work with Alan and the American Liver Foundation. I am a Director for the Greater New York Chapter and also work with the American Liver Foundation on some of the national-type projects.

My involvement with the American Liver Foundation began about six or seven years ago as a personal one in an attempt for me to gain more information about liver disease and to end the many years of turmoil that I went through trying to understand the cause of my own physical symptoms, symptoms that went undiagnosed and misdiagnosed for many years.

Serious attempts to determine the cause of my illness began only after I came across an article in a medical journal that listed the symptoms of hepatitis and recognized those symptoms as my own. Then, in a visit with my gynecologist, I mentioned my concern, and my gynecologist did, indeed, say that "Yes, you appear to have symptoms of liver disease." I didn't know at the time that her mother was dying of liver disease. She then took it upon herself to contact my primary care physician and strongly urge that additional follow-up be done.

I later learned that blood tests that I had received during each of my prior annual physicals with my primary care physicians had, indeed, showed signs of liver malfunction or something wrong. Those signs were increased liver enzyme levels and significantly cholesterol levels, which are indicative of liver disease. On one blood test the word "alcohol" had been written with a question mark. Apparently, my primary care physician assumed I had been drinking. No one thought to ask me. I hadn't been drinking. The blood test results were not brought to my attention and never connected with the physical symptoms that I had been explaining to my physician for many years.

Surprisingly enough, even after visiting my primary care physician on one occasion, mentioning that I thought I had symptoms of hepatitis, I was informed that someone would not have gotten over hepatitis in a day or two and that most likely I didn't have hepatitis, and this was probably 20 years ago, and therefore, a hepatitis panel was not done. No additional follow-up was done, and I continued to go with undiagnosed symptoms for many years.

During the next several years, my efforts shifted from getting someone to pay attention to me to trying to get the proper diagnosis. During a two- or three-year time frame, I received a diagnosis of autoimmune hepatitis, possibly attributed to some type of medication or triggered by some type of medication I had taken, a possible diagnosis of hemochromatosis, or iron-overload disease, as a result of a genetic anemia that I have. But by far the most devastating diagnosis I received was that of primary biliary cirrhosis, a disease where there is no cure. And the good news, my gastroenterologist told me, was that he had one patient who had lived for 10 years after receiving the same diagnosis. That was in 1991.

I later learned from a hepatologist, whose name I got from the American Liver Foundation, that the diagnosis of primary biliary cirrhosis was incorrect as a result of an unfortunate combination of a fragmented liver biopsy, as well as blood test results, that had gotten mixed up with someone else's results. The hepatologist explained to me it was readily apparent to him, upon looking at the blood test results, because my blood test results were not entirely consistent with a diagnosis of primary biliary cirrhosis.

For those people in the medical community, I had one test that was elevated, but all the rest of the markers that would have been elevated in primary biliary cirrhosis were not elevated. Nevertheless, I did receive that diagnosis.

The process that I went through to determine the cause of my illness was one that I would not wish on anyone. When I finally received the diagnosis of hepatitis C, my reaction was a mixed one, part anger at what I had gone through for more than 10 years trying to figure out what the cause of my

illness was and part relief that finally and at last I could focus my efforts on getting the proper medical treatment and what I needed to do to stay healthy rather than getting someone to diagnosis the cause of my illness.

When I look back, I can honestly tell you that the experience of obtaining a diagnosis for me was more difficult and more painful than any physical symptoms I have experienced from my illness. There were times when I wished that I had been diagnosed with something like cancer, that perhaps doctors might have been better able or quicker able to diagnose, that could potentially have been cut out and treated, and a disease that could be talked about where the first question that might come to someone's mind is "How are you feeling" rather than the all-too-familiar "How did you get that," which is what I hear from people when I do tell them I have chronic hepatitis.

Although I've been told that I am in remission-- And I do want to mention that because I saw an article that someone had before mentioning that hepatitis C was incurable or not curable and I don't believe that's true. There are treatments that are available, and people need to know that because that's part of the reason why we want people to be diagnosed. But although I have been told I'm in remission, I do continue to tell anyone in the medical community who may come into contact with my blood that I may have hepatitis, and that's because I feel I have a personal responsibility, as does every individual with hepatitis, to make sure that the disease that I unknowingly contracted is not passed along to someone else.

At times, the insensitive treatment I've received, however, makes me question my desire to be open to protect other individuals. And that is the stigma that is associated with hepatitis that we need to change so that more

individuals will be tested and be diagnosed. No one, regardless of how they contracted hepatitis or whether or not they have risk factors, deserves to live the experience of having hepatitis.

I will be forever grateful to the American Liver Foundation for having provided me with referrals and much-needed patient information to keep me abreast of recent developments and to make sure that I had the knowledge to question my physicians when necessary. Even while I was receiving treatment for the chronic hepatitis, I had medication prescribed by a primary care physician that I should not have taken and could have interfered with the treatment.

It is my sincere hope that with the help of this entire group and the leadership of individuals such as Alan and Dr. Koop that we will be able to encourage the recognition that hepatitis is a disease that can afflict anyone and ensure that confidential hepatitis testing is readily available in all communities, similar to the types of testing that are available for AIDS testing. When someone comes in for an AIDS test, why not have them have an AIDS test and a hepatitis C test at the same time? Reduce the stigma associated with the diagnosis of hepatitis so that individuals who think they may have contracted hepatitis will seek diagnosis and treatment.

Most importantly for me, ensure that primary care physicians receive the proper training and education in how to diagnosis and recognize the symptoms of hepatitis; provide individuals who do have hepatitis with access to specialists who will know the treatments that are available and can potentially treat their illnesses; lastly, and most importantly, so that by all of this we can reduce the spread of this devastating disease so that fewer and

fewer people will ever know what it is like to have or have lived the experience of having hepatitis.

Thank you.

ASSEMBLYWOMAN VANDERVALK: I certainly want to thank you for sharing that with us. It's extremely helpful to be able to hear an individual story, and I thank you for that.

Assemblyman Felice.

ASSEMBLYMAN FELICE: Yes, thank you, Madam Chairperson.

ASSEMBLYWOMAN VANDERVALK: Excuse me, before I do, a few people came in since I last made introductions. Assemblyman David Russo and Assemblywoman Loretta Weinberg.

ASSEMBLYMAN FELICE: Thank you.

Mr. Brownstein, if I may, the ideal situation would naturally be to say that everyone who's had a blood transfusion before 1990, everyone who's had tattooing or any kind of drug use -- it would be ideally the right direction to go to have them tested. Now, let's say that was possible, what do we consider an accurate test? What would it cost for an accurate test to check for hepatitis C? Do you have any idea, financially, what it would be?

MR. BROWNSTEIN: Yes.

ASSEMBLYMAN FELICE: All right. Can you tell us that, please?

MR. BROWNSTEIN: Yes, and it's a very good question because there is an enormous range, so people need to know what's out there.

So, for example, the American Liver Foundation is recommending that for anyone who either has any risk behaviors or any symptoms or if they are in doubt that they should get tested with a hepatitis B antibody test. There

are several types of antibody tests. It's primarily the second generation or beyond test, but that's all that is being used now and that could be gotten for as low as $15. But sometimes that test could be over $100 depending on how it's charged, so that when you do your -- when budgets are constructed, you really need to shop and figure out what you can get. So $15 for the hepatitis B antibody test.

What others are doing for more broad testing is they are using what is known as the ALT test, and that test is far less expensive and it can typically be between $1.50 or $3.00, but some people will charge you $50 for it. But between $1.50 and $3.00 is typically what you could easily get it for, if not less, and it's often part of the usual blood testing that is done, so it's not an add-on.

So the problem with that is that test is a little-- The data show that it misses between 10 percent and 40 percent of those known to have hepatitis C, so it can potentially miss some of the people we're trying to screen for.

ASSEMBLYMAN FELICE: This very Committee heard, not too many years back, a similar situation -- that's when we were studying the very rapid growth of Lyme disease, very similar -- that the testing was not accurate enough. It had to be done in a certain way. We've learned an awful lot since then, but I think when the medical profession, more doctors were aware of the different testing that was there and the different circumstances, it put us on a better understanding on how to treat and how to prevent Lyme disease but on a smaller scale.

On this scale, this is something that is growing, as we can tell, by leaps and bounds and is similar to other diseases that sometimes you don't even know, as we understand here -- that the patient doesn't know that they have this serious illness.

It's gratifying to hear, Mary, that there is treatment for this, and I think that's important to let people know that if they do take the testing that it doesn't mean that they're completely out of the picture or there is no help for them. That's very gratifying, because so many people who have certain diseases are afraid to get tested because they're afraid what those results will be. I think it's important that the message go out with the testing that there is help and the technology is growing day by day.

So I think your coming here is very, very important because if we're saying the answer is to get testing and all those groups that we talked about -- from tattooing to blood transfusion, or whatever -- that they know that there is help because so many people are afraid to get the testing because they're afraid of the results.

I thank you personally for coming here.

MS. LICETTI: Thank you.

ASSEMBLYWOMAN VANDERVALK: Mary, you mentioned that there were elevated cholesterol levels, is that--

MS. LICETTI: Decreased cholesterol levels.

ASSEMBLYWOMAN WEINBERG: Lower levels.

ASSEMBLYWOMAN VANDERVALK: What was that?

ASSEMBLYMAN ROONEY: Decreased.

MS. LICETTI: Decreased cholesterol levels.

ASSEMBLYWOMAN VANDERVALK: Decreased cholesterol levels?

MS. LICETTI: Yes, very low cholesterol levels, to the dangerous level. Most people don't realize your cholesterol can get too low.

ASSEMBLYWOMAN VANDERVALK: Is this the HDL or the LDL or the overall, the combined?

MS. LICETTI: It's the combined.

ASSEMBLYWOMAN VANDERVALK: It's the combined. Okay. All right. I'm particularly concerned with-- I think we have an enormous amount of women who have had cesareans. They have no idea that this is really a silent epidemic. I mean, if for $15 they can get a test, that's a small price to pay. I really think it's important. I recognize not everything is that simple. From what you've told us, certainly there can be and are complications, but--

Thank you.

ASSEMBLYMAN ROONEY: Charlotte?

ASSEMBLYWOMAN VANDERVALK: Yes.

ASSEMBLYMAN ROONEY: With this lower cholesterol level, I just remembered-- You triggered something, I guess. Just within the last month or two, there was a study that came out that said that in studies of cholesterol they found that low cholesterol levels led to kidney disease. Now, I guess, you've put all of the parts of the puzzle together. People with the low cholesterol level probably had hepatitis C, but they never said that. I'm sure when they come out with these surveys saying that "Well, we've done a study and people with" -- I think, it was -- "cholesterol levels below 160" -- that there

were very high incidences of kidney disease or whatever, and now that you're saying this--

MS. LICETTI: I wouldn't tell you what mine was. (laughter)

MR. BROWNSTEIN: Half that.

ASSEMBLYMAN ROONEY: What was it? What was it, out of curiosity?

MS. LICETTI: It was very low.

ASSEMBLYMAN ROONEY: Very low. Lower than 160. But they were saying that levels below 160 had extremely high incidences of kidney disease, particularly. I'm wondering why these studies aren't being put together, and somebody else is saying, "Well, here's the situation, we know hepatitis C causes low cholesterol, and here's another study that says in these instances you get high kidney disease," and why aren't people starting to say, "Let's find out how many people under that study had hepatitis C"? It just doesn't make sense.

MR. BROWNSTEIN: That's very interesting. I don't know. We don't know either.

ASSEMBLYMAN ROONEY: The study was out within the last month or two. Somebody in the audience, I think, might have an answer to that.

ASSEMBLYWOMAN VANDERVALK: Yes, I see a hand.

On this point, sir?

D O R I A N J. W I L S O N, M.D.: (speaking from audience) The symptom-- Dorian Wilson, from the Sharing Network. The symptom complex that you're describing in hepatitis C is related to a vasculitis, which

has to do with antibodies that are produced in the hepatitis C virus that cause complexes that then destroy the kidney. It's a glomerulonephritis that we see. It is hepatitis C related, and that's primarily the reason for renal disfunction that we see in the hepatitis C virus.

ASSEMBLYMAN ROONEY: Well, you proved my point, then, is that when these things go out, people think that low cholesterol levels are good, and probably when people are seeing low cholesterol levels, they're saying, "Oh, this is great." The only problem is they should say, "Wait a minute. Red flag, let me go get my blood tested for hepatitis C." So I think we've got-- There is a whole education program waiting to happen just at that level, I believe.

ASSEMBLYMAN FELICE: John, are you trying to justify your high level? (laughter)

ASSEMBLYMAN ROONEY: No, to be honest with you, my cholesterol level is not that high. (laughter) It's not to the point where it's that bad.

ASSEMBLYWOMAN WEINBERG: I figured John must have had a hamburger and a milk shake for lunch. (laughter)

ASSEMBLYWOMAN VANDERVALK: Could we get a frame of reference as to-- Since I would hate to have the message go out that if you have low cholesterol, now everything is a problem, could you shed some clarification as to what are we talking about? Some range with low that may trigger a correlation here?

MS. LICETTI: For myself, personally, my level was way below 100. So certainly someone who-- I'm not a physician or anything, but you're

right, I don't think we want everyone thinking that if they have a low level that they're at serious risk. Mine was dangerously low. It was low to the level where it was beyond normal on the blood test. If it's out of that normal range, then I think that's the issue.

ASSEMBLYWOMAN VANDERVALK: And I think all of this just goes to the complexity of the problem.

MR. BROWNSTEIN: And if the Committee wishes, I would be pleased to provide a written comment on that to the Committee after this.

ASSEMBLYWOMAN VANDERVALK: That would be helpful.

MR. BROWNSTEIN: So that--

ASSEMBLYWOMAN VANDERVALK: Certainly, that would be helpful.

Thank you very much.

ASSEMBLYMAN FELICE: Thank you.

MR. BROWNSTEIN: Thank you for the opportunity.

ASSEMBLYWOMAN VANDERVALK: Dr. Carroll Leevy. Dr. Leevy is Chairman of the Department of Hepatology at UMDNJ-University Hospital.

ASSEMBLYMAN FELICE: (addressing unidentified audience member tapping on microphones) No, those are recording microphones. The center one is the--

ASSEMBLYMAN ROONEY: The one in the center is the one that-- There you go--

UNIDENTIFIED SPEAKER FROM AUDIENCE: So they need to share, then.

ASSEMBLYWOMAN VANDERVALK: That's right.

ASSEMBLYMAN FELICE: You have to share or speak very loudly.

UNIDENTIFIED SPEAKER FROM AUDIENCE: Well, if there is only one person--

C A R R O L L M. L E E V Y, M.D.: Just one person.

Ms. Chairman, ladies and gentlemen, New Jersey has long been in the frontier of education, basic care, and research in liver and biliary tract disease through the medical schools, pharmaceutical industry, Sammy Davis Jr. National Liver Institute, and foundations.

It is of particular interest that 25 years ago, if an individual had liver disease that person was put on the side because liver disease was related and associated with alcoholism, and individuals who had liver disease were, therefore, not allowed to do those things and seek out the kinds of treatment necessary, and Sammy Davis Jr. was one of those persons.

He decided, after he was in UCLA, that he would build an institute. He was offered several positions and several areas. He came to Newark and felt that this should be the area where this should be started. At that time, people came from all over the world, including one of our favorite sons, Frank Sinatra, and liver disease moved along.

However, we still did not receive the kind of attention that heart disease, cancer, or a variety of other organ changes received until hepatitis C came forth. You've heard already today how frequent this disease is present, and how it leads to a very, very high morbidity and mortality throughout the world. Actually, in Africa and in the countries that are underdeveloped,

hepatitis C is a major problem, and in this country it has displaced B, while we have specific treatment and better ways of preventing the disease.

We have recently, therefore, attempted to focus our efforts on ways to develop a protective vaccine, and because of the nature of the organism, this will be quite difficult but possible. To have more effective viricidal drugs, we have drugs which, at this moment, will stop the disease for a short period, but then it returns and at the present moment-- Dr. Koop mentioned ribavirin, and that drug, we hope, will allow individuals to have a sustained elimination of the hepatitis C virus.

Finally, agents which will reduce cytotoxicity of the virus-- Different individuals get hepatitis C and behave differently because, of course, they have different genomes. They have different types of antibody formation. We now know that there are two different types of T-cells and it depends on which one is present. The different genotypes, there are about six of them, with fourteen different subtypes, that make the disease a very complex and varied kind of disease.

Now, we have recently organized a liver study group for the faculties of the New Jersey Medical School at Newark, the Robert Wood Johnson Medical School in New Brunswick, and the Robert Wood Johnson Medical School in Camden to initiate a multicenter, therapeutic trial for hepatitis C and, more importantly, to increase the awareness of the disease among medical students, house officers, practitioners, health workers, and the public. The Nancy Starr Foundation, the New Jersey Department of Health, pharmaceutical companies, and the two very large foundations in New Jersey interested in liver disease will be assisting with these programs.

We really have four goals. First, to interrupt the as-yet undocumented causes of hepatitis C transmission. You heard a lot of things which produce it. You have thought that maybe some people forgot what their exposure has been, but as one looks at individuals and different families, it is evident that one still needs a lot of epidemiology from the CDC, from the New Jersey Department of Health where Dr. Ellis is, in order for us to find out other mechanisms whereby one gets this disease.

The second, to recognize hepatitis C at its earliest asymptomatic stage. At the moment, we have automated screening antibody tests. They've cloned the virus. Now, the ELISA III really is the best, but, again, one only recognizes about 95 percent, correctly, people who have this disease and one has to use another dotblot test -- a rebo -- to help. But most importantly, one can use HCV-RNA studies to determine the genotype and the viral load. Now, these tests are not yet perfected. They have not been approved by the FDA; however, much work is being done on them in both research laboratories and commercial laboratories.

What one needs to do is, after having found that there is an abnormal antibody test, is to find the genotype and you find what the viral load is; then, importantly, one should obtain a liver function test. As indicated by the previous speaker, ALT is really not specific. We have been working for a number of years on a dye that is much more sensitive. The problem is it's too complex for the practitioner, and, hopefully, in the future one can then modify this so that you can, at a very early stage, using a very simple method, pick up individuals who have liver disfunction and then decide what is responsible.

Finally, one needs a liver biopsy. One of the things that has happened in hepatology -- begun, really with the organization of the American Association for the Study of the Liver, which will celebrate its 50th anniversary in the year 2000 -- we now have an International Association for the Study of the Liver-- One of the problems was that we spoke different languages. Now, we have standardized nomenclature, diagnostic criteria, and the prognosis. Just two weeks ago, we met in Italy in order to see how we could use the new inframatics age in order to determine what an individual will do who has a given disease, particularly hepatitis C, and if one has few symptoms, how you can treat them and control them, and what one then needs to do next.

And so the biopsy becomes very important-- Just a few years ago, we would do a biopsy, and we would make diagnosis of chronic, active hepatitis or chronic, persistent hepatitis thinking that they would have different outcomes. Just four years ago, we abandoned those terms so that an individual has either acute hepatitis, full-blown hepatitis, chronic hepatitis, or hepatitis associated with cirrhosis or cancer.

Our third objective is to provide prompt treatment for viremia as quick as possible. Now there has been some disagreement. I think most of the people who are doing research find that this then is, if you have the disease, get rid of the virus as quickly as possible in order to prevent its progression. And in this process it is vitally important for the person to avoid alcohol and other agents which might increase viral replication and to treat associated HIV or AIDS. At this moment, with both of those phenomena, then the aspect of hepatitis C, which would progress, is able to be controlled.

Finally, with hepatitis C infection, it's important to have medical measures to control these extirpated manifestations that the Doctor just told you about, particularly liver disease, which is associated with bleeding, fluid accumulation, and mental changes. In those patients who do not respond, they can now be considered for liver transplant in the absence of prohibition. I just reviewed 50 cases that have been done at University Hospital, and actually the survival is as good as with other causes, although viraemia is still present and one still has to have an appropriate viricidal drug in order to prevent a reoccurrence of the disease.

So I'd really conclude, members of this Committee, that hopefully Federal and the State governments will make control of hepatitis C a priority and provide the needed support so that everyone with the disease will be identified and receive appropriate treatment regardless of the person's financial status, age, gender, or ethnicity.

Thank you very much.

ASSEMBLYWOMAN VANDERVALK: Doctor, if I may, I had written in my notes here when Mr. Brownstein was speaking -- and he's not here, so I'll ask you the question-- I had written here that he was talking about the hepatitis B antibody test. Did I write that correctly?

DR. LEEVY: He meant hepatitis C.

ASSEMBLYWOMAN VANDERVALK: He did mean--

DR. LEEVY: Actually, hepatitis B, which is a virus--

ASSEMBLYWOMAN VANDERVALK: He said it was a $15 charge. But it was C and not B.

DR. LEEVY: Well, there is an A, B, C, D, E, and G. All of those viruses cause hepatitis. You're talking about C today.

ASSEMBLYWOMAN VANDERVALK: No, I know and that's why--

DR. LEEVY: So I assume he was talking about the hepatitis C antibody.

ASSEMBLYWOMAN WEINBERG: But he did say hepatitis B.

ASSEMBLYWOMAN VANDERVALK: He did say hepatitis B, but he meant C, is that most likely?

ASSEMBLYWOMAN WEINBERG: I don't know.

DR. LEEVY: Well, there's also a B antibody.

ASSEMBLYWOMAN VANDERVALK: I guess question of the time was: How much do these tests cost? And he said the hepatitis, whatever letter, antibody test cost $15. My question to you, regardless of what that prior discussion was, what type of a test should somebody have to discover that they have hepatitis C?

DR. LEEVY: Well, the test which is done by blood banks and that most people do is an ELISA test, and really the test is produced by a company in New Jersey. They started off with ELISA I, and then they made it better by making it ELISA II, and at the moment, we have ELISA III. This is a test which allows you to pick up an antibody to the cloned virus. Actually, as was said just a few years ago, we were able to call it C, but actually, in the 1970s during the Vietnam War, we had large numbers of people in Veterans Administration hospitals with non-A, non-B that they had gotten from transfusions.

ASSEMBLYWOMAN VANDERVALK: Right. So if someone has gone and received an ALT test, they can't really rely on that, then?

DR. LEEVY: No. ALT, AST, alkaline phosphate -- there are a large number of liver function tests. These tests are abnormal-- In the first place, the liver produces ALT in order to make protein out of amino acids and parts of-- They are called transamination, and those tests have been available now for about 40 years, and they have been used for all kinds of liver diseases, because when the liver cell is killed, it's released into the circulation and the blood level of those transamination go up.

When he was talking about the ALT, that's one of the transaminations that is increased with injury. He correctly said that very frequently somebody would have hepatitis C and that test is normal. The person-- They may miss the person if they just relied on the liver function test. What I've told you is, in order to make that diagnosis, you ought to use an antibody to the hepatitis C virus--

ASSEMBLYWOMAN VANDERVALK: Meaning the ELISA--

DR. LEEVY: --and that's the ELISA test.

ASSEMBLYWOMAN VANDERVALK: Okay. The reason I'm concerned about this is because I think this goes to the heart of part of the problem, that a patient is not going to be able to say, "Test me for--" But I think if the physicians are using the ALT test and that's not the test to use, then we have a broader problem.

DR. LEEVY: Well, in order of circumstances, if a person goes to a hospital or goes to a physician, and they have an illness, they will do a battery of tests -- 18 or so tests -- and among those tests you will have those

transaminations, the ALT, and the other test. So regardless of what you have, if you get that battery of tests, or SMAC, as they would call it, you would then get this.

The test for HIV or the test for any of these viral liver diseases would have to be ordered as a separate phenomena, based on the suspicion of the physician that this needs to be done. Now if you go to a physician and you do a SMAC or all of these tests and the ALT is elevated, he will then think, "Well, that person has hepatitis," and then he is probably going to then go and do the antibody test.

The question which you have discussed is whether or not one should just go out and certain individuals-- Like we used to do syphilis tests routinely. You would then incorporate this as a routine kind of test, and, of course, as the Assistant Commissioner from the Health Department says, one has to then look at this and decide in a general kind of way whether or not that is to be done.

ASSEMBLYWOMAN VANDERVALK: Okay. Thank you.

Are there any other questions? (no response)

Thank you very much.

Yes, I see a hand.

R E G I N A B R U N O: (speaking from audience) I have a general question for the doctor or anyone else who may know.

Once a person may go to--

ASSEMBLYWOMAN VANDERVALK: Could we have your name, please?

MS. BRUNO: Regina Bruno. (phonetic spelling)

Once a person may go through a test for hepatitis C and, let's say, they are found to be positive for it, is the subsequent treatment then considered -- is it considered experimental and is it covered by most medical plans? Is this known? Does the doctor know this, or does anyone else know this?

DR. LEEVY: Yes. Number one, if you were to get the ELISA test and found to have hepatitis C, you would then-- Ordinarily, the doctor would do other tests to see what the transamination and all these things are in order to follow you. They should order a quantitative test to see how much virus you have. They should then do a liver biopsy. Then, already, the FDA has approved at least three interferon.

MS. BRUNO: They have approved-- (indiscernible)

DR. LEEVY: That's right. And so that would be a part of your treatment which should then be underwritten by whatever insurance you have.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

DR. LEEVY: Okay.

ASSEMBLYWOMAN VANDERVALK: Our next speaker is Dr. Dorian Wilson, the Medical Director of the Sharing Network.

DR. WILSON: Good afternoon, Assemblywoman Vandervalk.

ASSEMBLYWOMAN VANDERVALK: Good afternoon.

DR. WILSON: Thank you for the pleasure and privilege to be here and present before you distinguished members of the Committee.

I'd just like to -- if I could just diverge. I'm going to be very succinct with my particular statement in terms of what has been discussed about hepatitis C in terms of the diagnosis. I think we heard a pretty graphic

testimony from the young lady who was here about what happens when hepatitis C is diagnosed or not diagnosed as the case may be.

The liver, you'll understand, is like a small child. It only knows how to respond in one way; it cries. And when it cries, it produces ALT, which is a blood test that is commonly done in your battery of tests, which is a routine screening battery examination -- SMAC 18 -- that you see on blood tests when you're admitted to the hospital. ALT, AST, bilirubin, cholesterol, and LDH -- these are the five tests that you will see that relate to the liver in some way.

If a physician doesn't have a heightened awareness to know why the liver is crying, they may suspect that it's crying because someone has poured too much alcohol in, as the lady referred to. They will not know that the liver is being burned or infected. The same way we would want to know specifically, exactly what is making our small child cry, we need to have a level of suspicion as to what to go after. That level of suspicion should include, even with very modest -- as you heard, the disease can be present in an asymptomatic way-- That level of suspicion should include a hepatitis panel even when there are very minor aberrations in the ALT, AST.

Again, being a liver specialist, this is what I think, but I think in the order of this being an epidemic, that physicians should start thinking along those kinds of lines.

So without further deviation I'd like to say that hepatitis C viral infection is an ominous clinical dilemma. On the one hand, it creates the need for the most sophisticated and costly medical care, including organ

transplantation. On the other hand, it significantly reduces the vital donor organ resource that answers that need.

Liver disease due to hepatitis C is an increasingly frequent indication for liver replacement. As you heard, nationally it is the most common diagnosis for which liver transplantation is done -- there being about 3000 to 4000 liver transplants done in this country a year.

Unfortunately, high recurrence rates and the need for retransplantation detract from the overall success made possible by surgical-technological advances. Not only does hepatitis C affect the ability to transplant hepatic graphs or organs, but the variable infectivity of the virus, with six major types and over fifty subtypes and quasi-species -- quasi-species referring to genotypic variations in the virus as it mutates, which is one of the reasons why it's hard for us to identify it -- as well as the staggering clinical spectrum of disease, is cause for great trepidation within the transplant community.

Glomerulonephritis or renal inflammation or kidney inflammation and renal disease associated with hepatitis C further impact a complex clinical environment. And I might add here, to further expound upon that point, just in case you didn't hear what I said earlier, what happens is, antibodies are produced to the virus during infection. Those antibody levels soar, often very, very high. They complex with components of the virus, and, basically, what happens is they get stuck in blood vessels, elicit an inflammatory response with the blood vessel that then makes the blood vessel do strange things where blood supply can't be provided to the organ. This glomerulonephritis, or inflammation of the filtering units of the kidneys, is what we see. It's not

directly related to cholesterol level, as I know, but due to this immune complex situation.

We are witnessing in New Jersey a 7 percent to 8 percent incidence in the potential donor population of seropositivity of hepatitis C by second-generation Abbott tests, such as the ELISA that Dr. Leevy is talking about. Unfortunately, across the country in OPOs, like the Sharing Network, that are responsible for the recovering and allocation of organs throughout the State and throughout the country, in fact, there is a variability in the testing and the results that are seen. So this is something that also needs to be addressed and standardized. Our close neighbors in New York are observing similar figures for the regions which they serve -- that's the incidence of hepatitis C in potential organ donors.

I can probably express and share my concern for the severity of and concern for the clinical disposition that this disease often presents by sharing my experience with one liver transplant recipient for whom I cared while serving active duty in the United States Air Force over the last three years.

Parenthetically, I might add, that based upon my experience while in the Air Force, hepatitis C is a significant problem among our members of the Armed Forces, and, as I remember, there was no screening examination for hepatitis C as I left the military, upon my exit examination. And being that, as I am aware, some of our population statistics do not account for our Armed Service men and women, their risk would appear to need to be specifically addressed.

At any rate, the patient to whom I alluded was the wife of a Full-Bird Colonel, and if any of you have ever served in the military, you don't want to have a disenchanting outcome with a Full-Bird Colonel's wife. The operation was not only successful, but went smoothly, i.e., there was little blood loss, etc. Everything went extremely well until about one week postoperatively when the presumptive diagnosis, after liver biopsy, was acute cellular rejection, the body trying to get rid of its new friend.

An additional week's worth of increased steroids and augmentation of immunosuppression -- the drugs that we use to prevent rejection -- ushered in a worsening of the clinical status of the patient that, of course, wasn't expected as we were treating the rejection. Subsequent biopsy -- another biopsy was performed -- now was consistent with recurring hepatitis. Under the microscope, these two diseases, hepatitis and rejection, look similar and, in fact, you might call them immunological bedfellows.

More therapeutic adjustments were made, and five weeks later the patient was discharged with the diagnosis of recurrent hepatitis C, posttransplant. Her liver function tests were abnormal, but luckily she was feeling well and was no longer suffering from chronic liver disease. Her organ donor was not hepatitis C positive, but that is yet another troublesome variable that sometimes enters the equation when there is an issue of acute life versus death.

I will never forget how I lamented and how unrewarding that experience was, being assaulted with not knowing whether I was dealing with recurrent hepatitis half the time, whether I was dealing with a bad rejection the

other half of the time. I settled for the idea that I had improved her quality of life, at least for the time being.

I have taken the lead in establishing some minority initiatives in this State for raising the awareness of organ and tissue donation. As you've heard, since hepatitis C is somewhat seen in increased prevalence in incidents in minority communities, you can imagine the problems that might exist in terms of forwarding those initiatives.

In summary, we in the transplant community share this burden of hepatitis C. We would like to develop a national awareness, prevention, and control program to ultimately eradicate this disease and, in the meantime, to significantly lessen its toll upon the nation.

Thank you.

ASSEMBLYWOMAN VANDERVALK: Yes, Assemblyman Felice.

ASSEMBLYMAN FELICE: Thank you very much, Doctor.

You brought out an interesting point that, as a veteran-- Let's talk about working in the field or in time of war. As you know the sanitary conditions are very primitive, and most of the time in service overseas you would be using field rations so they're sealed, but once in a great while, you'd be lucky to have the mess group come in and give you a hot meal. It's a wonder that-- Is it that there were fewer people infected with hepatitis A, B, C during World War II and the Korean War and all the others? Is that the reason that millions of men and women did not come down with the hepatitis virus?

It's very interesting because, recalling my own experience out in the field, the desert, the jungles it was very, very primitive, and I guess we can

be thankful we had sealed rations, except that we didn't know the people who were making the rations -- what they were like. But is it because there were fewer people infected at that time that more men and women did not become carriers?

DR. WILSON: That's a difficult question to answer, but I suspect, at least in part, what you're saying is true, that fewer people were infected at that time, I guess, within the military service itself. I'm actually working on -- from some of my cohorts who I practiced with while in San Antonio, Texas, at Wilfred Hall (phonetic spelling) -- getting some figures for the statistics in servicemen and women, in terms of what our transplantation rate was for hepatitis C. I remember it was very high. It was either the first or the second diagnosis that we transplant in the military as well.

Unfortunately, or fortunately, I didn't have the experience of being in the jungle during my military tenure. I did all my work in a hospital where -- much like this building. But, again, that's something that probably needs to be addressed and investigated, and an answer would provide us some insight into the course of hepatitis C.

ASSEMBLYMAN FELICE: With the information, I would imagine that education would be extremely important in the service today, because it's not always possible to get to a bathroom and use soap and disinfectants to wash yourself. So I would imagine, if not, then I think it would almost be a requirement when you're discharged to get a full testing to know that you're sending military personnel back into civilian life not knowing they possibly have contracted a very serious disease.

DR. WILSON: I agree, sir.

ASSEMBLYMAN FELICE: Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you very much.

Dr. David Gocke. You're the Associate Medical Director of the Musculoskeletal Transplant Foundation. Is that correct? (laughter)

D A V I D J. G O C K E, M.D.: Yes. Very good. Very good. (indicating pronunciation) (laughter)

Thank you very much, Madam Chairman, and I want to thank the Committee for this opportunity to address them this afternoon.

My name is David Gocke. I am, indeed, the Associate Medical Director for the Musculoskeletal Transplant Foundation and Professor Emeritus of Medicine and Former Director Chief of the Division of Infectious Disease, and Director of the AIDS Clinical Trials Unit at the Robert Wood Johnson Medical School in New Brunswick.

Prior to coming to New Jersey several years ago, my laboratory at Columbia Presbyterian in New York was the first to point out that there were many cases of transfusion-associated hepatitis which could not be explained by either hepatitis A or B and thereby opened and pointed the direction to the discovery of what we now call hepatitis C. So I have a long history of experience in the hepatitis field that I bring to you this afternoon.

The Musculoskeletal Transplant Foundation, which I'm representing, is located in Edison, New Jersey. It is a nonprofit organization founded in 1987 and dedicated to the collection, processing, and distribution of bone, tendons, and other tissues throughout the country. These bone and tissue transplants are employed in reconstructive surgery following, for example, extensive cancer surgery or serious trauma.

To date, the Musculoskeletal Transplant Foundation has distributed over 500,000 units of bone and other soft tissues to patients throughout the United States. In contrast to organ transplant, which benefits a limited number of patients -- one heart, one liver, two kidneys, and so forth -- each donor of bone and soft tissue benefits some 30 to 40 patients. So that the loss of even one potential donor has the impact on the loss of benefit to a large number of recipients.

With respect to hepatitis C and its impact on the bone and tissue banking-transplantation field, I would like to point out that we scrupulously screen potential donors both by their medical and social history and by various blood tests to be certain that hepatitis C, other hepatitis viruses, HIV, and for that matter, any conceivably infectious agent, would not be transmitted to a recipient.

In addition, in this particular kind of transplant setting, we have the added benefit that the tissue itself can be treated in ways that kill or inactivate any viruses that might be there so that it is a relatively safe type of transplantation procedure. I'm happy to say that in the over 500,000 units of bone and tissue transplanted so far, the Foundation has never had a documented instance of transmission of disease by this kind of transplantation.

However, hepatitis C does, in fact, impact the bone and tissue transplant field through the loss of valuable donors. You've just heard Dr. Wilson say that in the organ donor world something like 7 percent or 8 percent of potential donors are rejected from or are lost to transplantation. A recent review of our experience indicates that it's more like 2 percent in the population that we're dealing with. But on a nationwide level, that translates

to about 200 donors a year, and, again, using the multiplication factor I just mentioned to you, it means that something like 6000 or 8000 recipients are being denied the benefit of that lost tissue. So in this way, hepatitis C has a very significant impact in the bone and tissue bank world through this loss or waste of valuable tissue.

Therefore, we would strongly endorse the educational efforts that have been discussed here today, directed both at the general population, the patient population, as well as at the physician and health care provider groups to improve our ability to recognize, to find cases, and to prevent transmission of the disease to others.

We would also support a mandatory reporting system along the lines that have been suggested, not only for acute, but for chronic, disease. This would help to enhance or increase the attention given to the disease both by patients and physicians and would provide the public health agencies with a sound epidemiologic database on which to guide future decisions and planning.

One might think in this regard, perhaps, of piggybacking the hepatitis C testing and screening and counseling process that's needed -- piggybacking it on top of the existing AIDS testing and counseling centers, which the State Department of Health already has established throughout the State.

So, once again, thank you very much for this opportunity to address you, and we strongly support your interest and your efforts. Thank you.

ASSEMBLYWOMAN VANDERVALK: And I thank you for sharing that with us.

ASSEMBLYMAN FELICE: May I have one quick question?

ASSEMBLYWOMAN VANDERVALK: Certainly.

ASSEMBLYMAN FELICE: I know I've had a lot of questions here today.

Hypothetically, I'm a patient, and I'm in very serious-- I'm middle-aged, for instance and-- I'm not, I'm younger. (laughter) Seriously, I have a chance to have a donor give me a new liver, for instance, or a new organ, and that person tests for hepatitis A, B, and maybe even C. What are the chances of taking that organ and being treated afterwards and maybe gaining five years or ten years?

DR. GOCKE: Yes. Well, you touch on a very difficult point, and Dr. Wilson alluded to that kind of thing. There are patients who are dying because of advanced hepatitis C of the liver, who have no other choice, no other option, perhaps. Maybe the only liver that's available is a liver that is from a hepatitis C patient. Those are very difficult choices to be made, and there are groups that are attempting to look at that in a controlled manner. But you've put your finger on a very difficult point.

ASSEMBLYMAN FELICE: It could turn out to be a legal problem, too, where they say, "Well, sure I want it," and then after they have it in and they turn around and sue the hospital or the doctors for-- Not that lawyers do that, they don't do things like that. (laughter)

But that's a good question. Really, does it buy time for that person, rather than that organ going--

DR. GOCKE: Yes, I think that there are cases in which there has been at least some temporary benefit.

ASSEMBLYWOMAN VANDERVALK: I saw Dr. Wilson's hand there. If you would care to comment?

DR. WILSON: (speaking from audience) Fortunately, we do see significant survivals in that patient group. Of course, we are using livers from hepatitis C-positive patients who essentially have no clinical manifestation of their disease at the time of their demise and, two, who don't have significant biopsy abnormalities. Those livers do-- It's variable. It can be as little as one year, but it can be as long as six or seven years or possibly longer. That's fortunate in the sense, as in the patient that Dr. Gocke described, that's all we have to offer that patient who is dying acutely of liver failure.

ASSEMBLYWOMAN VANDERVALK: Yes, Mr. Brownstein.

MR. BROWNSTEIN: (speaking from audience) The key is that is informed consent so the people are aware.

DR. WILSON: Yes.

MR. BROWNSTEIN: That is--

DR. WILSON: And I was--

ASSEMBLYWOMAN VANDERVALK: I'm sorry, I didn't hear you. Could you say that again?

MR. BROWNSTEIN: That there is informed consent--

DR. WILSON: Right.

MR. BROWNSTEIN: --so the patient is aware of the options available when they need--

DR. WILSON: And that was one of the recommendations, by the way, mentioned by the NIH Consensus, for that--

ASSEMBLYWOMAN VANDERVALK: The informed consent.

DR. WILSON: Right, with hepatitis C-positive donors.

ASSEMBLYWOMAN VANDERVALK: Right.

ASSEMBLYMAN FELICE: Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you.

Assemblywoman.

ASSEMBLYWOMAN WEINBERG: I'm looking through some things we got in our packet, and actually we're not sure where this paper called *The Need for Hepatitis C Screening and Treatment* came from. It doesn't have any other-- There is nothing else here that would tell us-- But I wonder if we can find out. They say, first of all, active screening programs, such as the Red Cross Blood Donor Program, are not notifying individuals detected with the disease of their treatment options. So my first question, if we can find out whether they're notifying the individuals that they have it, let alone not notifying them about the treatment option. That is, apparently, a very large way to screen for this.

And then it says, additionally there is no effort to notify the estimated 300,000 individuals who acquired hepatitis C through infected blood products prior to 1990, which I would assume affects the hemophiliac community. In fact, there were two representatives here earlier who I saw, but they left.

ASSEMBLYWOMAN VANDERVALK: I saw Dr. Gursky wished to respond to that.

ASSEMBLYWOMAN WEINBERG: I wonder if we have--

ASSISTANT COMMISSIONER GURSKY: (speaking from audience) I can answer the first question, and that is that persons who donate in New Jersey to blood banks after screening determines the presence of hepatitis C, they are notified.

ASSEMBLYWOMAN WEINBERG: And can we find out if there is any notification for those who received blood products prior to 1990 to be screened?

ASSISTANT COMMISSIONER GURSKY: At this point, that is not being done routinely and, again, should be addressed as part of the package of activities we are currently undertaking.

It is a very appropriate issue, and I thank you for raising it, Assemblywoman.

ASSEMBLYWOMAN VANDERVALK: That's one of the things that is lurking out there that has not been dealt with.

Thank you, Doctor.

ASSEMBLYMAN FELICE: Thank you.

DR. GOCKE: Thank you.

ASSEMBLYWOMAN VANDERVALK: I think we have two more speakers.

Ms. Thelma Thiel? Am I saying that correctly?

T H E L M A K I N G T H I E L: (speaking from audience) Thiel. (indicating pronunciation)

ASSEMBLYWOMAN VANDERVALK: From the Hepatitis Foundation International, and then Dr. Howard Nathan.

MS. THIEL: Madam Chairman, and members of the Committee, thank you very much for inviting me here today. I am Thelma King Thiel, Chairman and Chief Executive Officer and a volunteer who is the Executive Director of the -- Chairman of the Hepatitis Foundation International, but I'm also the mother of a child who died of neonatal hepatitis and biliary atresia 26 years ago, so I have been working at this for a long time.

We have good news and bad news, and, of course, the good news is that a couple of years ago we were identifying 170,000 new cases of hepatitis C and with the screening of blood, now, has made it much safer. It's down to an estimated 28,000 cases -- new cases -- each year, but we still have an enormous problem because we have that pool of almost 4 million patients who are infected. So we need to look at research, education, and a support network for patients.

I just spoke to someone at the NIAID, which is the institute that does most of the research in the hepatitis area at NIH, and they're only funding about $15 million worth of research compared to billions of dollars going into AIDS research. Of course, we know that there is a tremendous problem with AIDS. We're not suggesting that any of the money be shifted over, but there is a tremendous need to increase the research dollars on the Federal level and particularly in the area of hepatitis research.

I was just listening to a television program last night that mentioned that in President Clinton's appropriations or his budget to the Congress, he was only increasing the research funding to NIH by 2.6 percent, and that's apparently the lowest that it has ever been, so we really need to have

an outcry that there needs to be much more research because that's the only way we're going to find these answers.

Going back to the education: Back in the mid-70s, very little was being taught about the liver in medical schools. Dr. Carroll Leevy and I served on a National Commission on Digestive Diseases and did some research in that area to find out that very little was going on at that time. So we have a lot of physicians out on the periphery who have had very little background in hepatitis and in liver diseases, and this is causing a major problem because, as you know, hepatitis C has recently been identified, and we need to bring them up to speed so that they understand to look for this disease and to diagnosis it properly and to know when to refer patients to specialists.

We're working very closely with the Centers for Disease Control. We have been conducting -- the Hepatitis Foundation has been conducting -- hepatitis A, B, and C education programs in cooperation with health departments all over the country. It was so successful and brought physicians up to speed on these new diagnostic measures that we decided to put them up on satellite.

We're putting on a satellite teleconference on hepatitis C on November 22. It's going to be a two and a half hour continuing education credit for physicians and nurses, etc. We have over 1000 sites identified across the country, and this is our effort to try to bring those physicians up to speed so that they are on the cutting edge so that we can cut the doctor shopping, as it were, because of poor diagnostic measures not being used and people not being identified as having a problem.

We are also--

ASSEMBLYWOMAN VANDERVALK: Before you go on-- I'm sorry, but before you go on: On that point, on the continuing education, you said it's on the Internet, and they get credits?

MS. THIEL: No. This is going to be on satellite.

ASSEMBLYWOMAN VANDERVALK: On satellite.

MS. THIEL: Not on the Internet. It's a satellite.

ASSEMBLYWOMAN VANDERVALK: How do they monitor the fact that someone has-- How will they receive the credits? How is it monitored?

MS. THIEL: We have identified over 1000 sites. That means that if an institution here-- If your hospital -- Hackensack General Hospital -- wanted to have the program, they would downlink it, and they would have a meeting on that day--

ASSEMBLYWOMAN VANDERVALK: Okay.

MS. THIEL: --that it's being downlinked, and this is also being offered to Canada and to Puerto Rico. So it's a tremendous program.

ASSEMBLYWOMAN VANDERVALK: Excellent.

MS. THIEL: It has some of the top speakers in the country and with the cutting edge information that was provided at the Consensus Conference so that they will be getting correct information to help them do a better job caring for their patients. They need to know what the history of the disease is.

Dr. Seeff, who is on our Board of Directors, is looking -- one of the questions before -- back at 10,000 blood samples that were collected 50 years ago for Army recruits, and they found that they did have hepatitis C at

that point, and they're trying to do epidemiological studies -- because they do have Social Security numbers -- to find out what the history of the disease is. That's how we're finding out that this is a very slowly progressing disease that may take 30 or 40 years for it to really get to the point -- maybe 20 years to start to develop cirrhosis in, maybe even a little bit longer for the cancer of the liver, which are the eventual problems that you're dealing with, with the patients who are needing the liver transplants. They need to know when to refer patients to a specialist, and we find that the specialists are really keeping up with the latest information, and, believe me, there is new information coming down the pike every single day.

As far as the patient goes, we're kind of an advocacy organization, and we're kind of the first line after they get that notice from the blood bank that they have hepatitis C. They're panic stricken because they don't know anything about it. Am I going to die? Are my children going to be able to go through school? This kind of thing, and they really are very, very concerned about it.

Of course, we do a bit of education personally on our hot line. We have an 800 hot line. We try to make them understand that this is a slowly progressing disease, and they say, "Why didn't I know that I had it?" Well, the liver is a noncomplaining organ. It doesn't let people know that it's in trouble until it's almost at the point of no return, and that's why these screening programs are important.

We even find that when the doctors are doing the SMAC 18 that Dr. Leevy was talking about and those little elevated liver enzymes-- Well, some physicians will say, "Don't worry about it." Well, that's an indication

that there is a problem and further testing needs to be done, and that's when they go into the screening. We're recommending that people ask for the hepatitis C test if they have any of the risk factors that we are trying to identify, and of course, that's one of the major things that you're trying to do with patients: to say, "Did you ever have body piercing done or tattooing?" We're trying to get licensure of body piercing facilities in the State of New Jersey here. We're working on the front line to try to prevent some of this from happening.

We are pleased that the incidence of new cases are coming down, but right now that is so important to get that education, and you certainly don't want patients who are identified to be transmitting this to family members or to others who they may be working with if they are coming into contact.

The firefighters and your EMT people, we're very, very concerned about them complying with the fact that they should be wearing gloves, etc. We go through a little process of educating them about how important the liver is, that it's their internal chemical power plant, and that when this virus attacks it, it's destroying liver cells and laying down scar tissue. Actually, what's happening is you're killing off the employees in your own power plant. I think once they have a little bit of an understanding of how important the liver is, then they will be much more apt to be concerned about what they're doing that could expose them to the problem.

Of course, again, that's so important for the public. How do you get to the public? Well, you can have very expensive awareness campaigns, and we're trying to get as much on radio and television and talk shows and

magazines and newspapers, but what we have done-- I believe you received a packet of our information. That entire packet was sent out to 7700 school nurses across the country so that we can begin to give them the techniques that they need, because there is absolutely nothing in the schools about the liver, why it's important, and we are expecting our children to make healthful lifestyle choices when they really haven't had any basic information from which they can make those choices. So we feel that we really need to motivate them. That's the concern that we have, and we're trying to do that in our very best way.

Then, of course, the legislators-- I've gone down and presented testimony. I think I was one of the first people who went down to Washington to present testimony on liver diseases, and that was 26 years ago. They are uneducated about hepatitis, and, of course, they're hearing about a disease of the day. You know, if we're talking about *X* disease, is it really my problem? So I feel, again, we have a very important job of educating legislators about the fact that hepatitis is something that could really impact on their families. You look at them and say, "Well, do they have a college student? Does that college student understand?"

I was recently at a meeting out in California and this lovely young lady from Berkeley was telling me that her boyfriend had hepatitis C, and she said, "I can't understand. He always cleaned off his needles with Clorox." I thought, "You know, where are we with our education? Why is he using needles in the first place?" And we don't even really know whether Clorox is going to kill this virus or not.

So we really have to get some basic information out there to help people understand how they can prevent this disease, keep it from spreading, and also to know that there are treatments available to them, and that they really need to discuss this with their physician. Again, we want educated physicians so that they can know what the options are, what the problems are going to be, what the side effects will be, and if the disease is far advanced, if they have to have a liver transplant, that there is the possibility of that virus coming back and attacking the new liver and there is additional medication. Of course, as you know, transplants are very, very costly. Again, we have a problem with the medication that they have to take for the rest of their life.

So we really want to try to get people to understand that there is a treatment that could possibly cure them. We aren't usually using the word "cure"; although, I understand that Sharing has done some research and they find that people have been off of the medication for about 10 years and it hasn't recurred. So we are hoping that there will be more people being able to say, "Yes, I am cured." But we have a long way to go.

As far as the blood banks go, I think Dr. Shalala is looking at what should be done about the look-back on the transfusions. I had a call the other day from a gentleman who said that he had donated blood about six years ago and he just found out that he has hepatitis C. When he called the blood bank, they said, "Well, we don't keep our records past five years." So, again, this puts a very important emphasis on the fact that awareness is so important. If you know that you are-- Even if you don't know-- But get back to your physician to find out whether you have ever had a transfusion or not and to be alerted to the risk factors that you're going to be facing.

I think we have a tremendous long way to go with the STD clinics. They aren't screening for hepatitis C, and I think that this is a population that if they are infected-- They already have a venereal disease so that we know they're sexually active, and they're probably into other activities, behaviors that could put them at risk. So we really need to get more of the screening done to make people realize what the treatment options are and to increase research efforts so that we can really have an impact on this problem.

Thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you very much. You've been very enlightening.

MS. THIEL: Well, good. Thank you very much. If there are any questions, I'd be happy to answer them.

ASSEMBLYMAN FELICE: That's fine, thank you.

ASSEMBLYWOMAN VANDERVALK: Thank you.

MS. THIEL: Thank you.

ASSEMBLYWOMAN VANDERVALK: Howard Nathan, the Executive Director of the Delaware Valley Transplant Program.

H O W A R D M. N A T H A N: Hi. Thanks, Madam Chairman. I'll be brief.

Usually, when transplant programs are talking to such Committees, we're talking about the organ donor shortage, but today we're talking about hepatitis C. Just so you know who I am, I'm the Executive Director of the Delaware Valley Transplant Program, and since 1974, we've served southern New Jersey for organ transplant, recovery, and patient care.

About two out of every five patients who receive transplants are transplanted through our coordinating efforts through our program. Hepatitis C, as you've heard, is now the leading cause of liver transplantation. In fact, it's three times -- almost three times -- more than any other cause of liver disease at this time that leads to liver transplant. One of the things that was talked about was the cost of liver transplantation. Because the etiology of the disease is unknown and there is a period of time of 10 to 20 years before someone has liver failure, more and more patients now are appearing on transplant waiting lists.

I just reviewed our data for 1996, where we performed 185 liver transplants; 52 of those patients had hepatitis C, which is 28 percent. For the first nine months of 1997, where we performed 148 liver transplants, 55 or 37 percent have had hepatitis C. So by the end of the year, the number of patients will probably be close to 75 patients who had hepatitis C, who had liver transplants. In New Jersey--

ASSEMBLYWOMAN VANDERVALK: Excuse me. On that point, the 75 compares to 52 of last year?

MR. NATHAN: That's correct. And that's over our whole program. In New Jersey, for the first nine months of this year, 41 patients received liver transplants through our program, of which 13, or approximately one-third, had hepatitis C. So by the end of the year, that number will probably be about 60 people transplanted and somewhere in the order of about 18 to 20 will have had hepatitis C.

Now, our sister program from Dr. Wilson, who you heard from, transplants about an equal number of livers for the northern half of the State

at University Hospital. So you can see that it certainly affects a lot of people, and the thing, ultimately, is this being the last leg of treatment, if you will, and not always, as Dr. Wilson said, a cure, because it can reoccur, and it's very expensive at that end stage to have a liver transplant. Several hundred thousand dollars could be spent to treat such a patient.

Just as a sidelight, about nine years ago my own sister was diagnosed with non-A, non-B hepatitis and subsequently did have a liver transplant, but they actually ended up diagnosing her with another liver disease called primary biliary cirrhosis. So she did not have hepatitis C, but in those days no one even knew what the liver disease was.

So I just wanted to enlighten you a little bit. I've given you a packet of information about our program, and I'd be happy to answer any questions.

ASSEMBLYWOMAN VANDERVALK: Well, thank you very much. I appreciate everybody's participation. I think we're looking at, truly, where an ounce of prevention is worth several hundred pounds of cure, when you look at the cost and the humane aspect of it. It's a significant problem and this is only the beginning. We will continue to work on this.

Thank you.

(HEARING CONCLUDED)