PRESIDENTIAL COMMISSION ON THE HUMAN IMMUNODEFICIENCY VIRUS EPIDEMIC

HEARING ON DISCRIMINATION, ETHICS, AND TESTING

The Hearing was held at the
Vanderbilt University Stadium Club
25th Avenue and Kensington Street
Nashville, Tennessee

Friday, March 18, 1988

COMMISSION MEMBERS PRESENT:

ADMIRAL JAMES D. WATKINS (Ret.), CHAIRMAN

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PENNY PULLEN, M.D.

CORY SERVAAS, M.D.

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COMMISSION MEMBERS NOT ATTENDING:

JOHN CARDINAL O'CONNOR

WILLIAM B. WALSH, M.D.

I-N-D-E-X

I-N-D-E-X (continued)

P-R-O-C-E-E-D-I-N-G-S

MS. GAULT: Ladies and Gentlemen, Members of the President's Commission, my name is Polly Gault. I am a designated federal official here and in that capacity it is my privilege to turn this over to the Chairman.

CHAIRMAN WATKINS: Good morning.

Our first panel today consists of Dr. William Schaffner, Dr. Renslow Sherer, Dr. Joseph Mercola, Dr. Arthur DiSalvo and Dr. Clark Heath.

Over the last two days we have heard from a variety of witnesses about the complex discrimination and medical ethics issues raised by the HIV infection. Well, finding solutions to the concerns raised in those areas will not be easy. The testimony presented at these hearings has prepared the Commission to address sensitive issues of discrimination and ethics related to HIV infection, with a clear understanding of those concerns.

Today, we are going to focus on another area that presents us with difficult but important questions; testing for evidence of HIV infection. We will begin by examining how the available tests are currently used, meaning what factors do physicians and others consider in ordering or recommending the test and in communicating the test results back to the tested individual.

We will then examine the issues related to the confidentiality of HIV test results and current procedures for safeguarding that information.

Finally, we will examine the many legal issues that testing for HIV gives rise to, including informed consent and the constitutional issues presented by mandatory testing.

Before we hear from our first panelist, Mrs. Gebbie has asked for an opportunity to say something briefly.

Mrs. Gebbie.

MRS. GEBBIE: Thank you.

Just very briefly, I think all the Commissioners are aware that no matter what we talk about we almost always come back to testing. As I listen to what is talked about here and in the community, I am fascinated by the jump from the technical questions about the test to questions about various specific issues and individuals, without attention to all the intermediate steps, such as the decision-making an individual

physician makes to decide to order the test for a patient or the decision-making made in a community about use of the test.

So, I am really looking forward to today and hope that we can get a much better grasp of those intermediate steps and the various things that are evaluated by practitioners and others in the process of utilizing the test, to see it as a process with many more steps than we may have been considering earlier. I think it will help us to have a background for any recommendations we might choose to make about applications for the test in any kind of a population setting.

Thank you.

CHAIRMAN WATKINS: Thank you.

Dr. Schaffner.

DR. SCHAFFNER Yes. Good morning, everyone.

The subject, as you have just heard, is serologic testing for HIV infection continues to provoke intense debate among informed and knowledgeable persons interested in providing the best medical care for individuals, as well as optimal strategies for interrupting the transmission of the virus and protecting the public health.

I believe these controversies can be resolved and I believe it is a myth that there is a conflict between civil liberties and the best personal and public health practices, but -- but -- there are certain preconditions that must be met before the tensions regarding serologic testing can be resolved. These would include, just very quickly, we need much more increased education, much more education regarding human immunodeficiency virus out in the population, so they understand the issues, particularly in regarding treatment issues.

Confidentiality must be iron clad. Non-discrimination must be assured and health departments must have increased resources in order to carry out their tasks of partner notification, contact testing and counseling.

Absent any of the above, I think tension will remain because of the all too human skepticism of those at risk, their suspicion of government and authority. However, if they are in place, we can concentrate on designing strategies, including a variety of methods, each suited to specific questions to which we need answers and to local circumstances.

Clearly, we need an assessment to the extent that the virus has spread in the entire U.S. population and you have all

heard about the CDC studies, which will start to provide us information in that regard.

I think we need to continue to emphasize voluntary testing with consent in a setting of confidentiality or even anonymity. That ought to be continued and enhanced.

We have started some experiments in our country on the use of mandatory testing. Emphasis: experiments, such as premarital testing in several states. We do not need to repeat this experiment in 50 states. What we need to do now is pause and critically examine the current experience. And, frankly, what I hear is that we will not.

To my knowledge, not a single state that has mandated premarital testing has concurrently provided the resources to evaluate the effects of the program. We won't be able to learn nearly as much from these experiments, and we ought to consider them experiments, as we ought to.

Now, on the basis of yesterday's testimony, some of it, I should like quickly to add one more example to reinforce the theme that we need data critically analyzed to advance the quality of the debate. The issue is the protection of health care personnel, particularly in hospitals. You heard among other things yesterday the argument for making such testing mandatory for at least certain classes of patients, who are going to be admitted for evasive procedures.

As the person at the Vanderbilt Hospital, who is responsible for infection control, now in my 20th year in that position, I am vitally interested in this question.

Several quick points.

First, the track record to date of conventional infection control practices is superb. The risk to health care personnel, which is never zero and never will be, is elevated above people selling shoes. We accept that. Our task is to keep that elevated risk absolutely as low as possible.

Two, recently we have introduced universal cautions designed to further enhance safety of hospital personnel.

Three, I agree completely -- I agree completely -- that the concept of universal precautions is not entirely suitable to the operating room. So, I consider the current debate valid. How then to resolve the issue? First, let's recognize that there are higher risk areas in this country than others. What may be appropriate in San Francisco may not be appropriate in Dubuque or, for that matter, in Nashville.

And it is my theme, ladies and gentlemen, we need data. What proportion of patients coming to a hospital for surgery in any given area are infected? How many false positives would result from testing and what are the consequences of that? What proportion of patients, particularly those who have been in motor vehicle accidents or other traumatic situations, had to go to operation so quickly that under the best of circumstances testing results could not be available?

What proportion of patients have had their surgery delayed because tests were not drawn, simply forgotten, results delayed or results confusing to interpret what are the causes? What proportion of patients decline testing? Will patients go elsewhere for care?

We don't have the answers for any of these questions. So, the question is amenable to study and we ought to find out the answer.

We tried to study this question in Nashville about a year ago. We could not find a single agency, foundation or other funding source, which would sponsor such an investigation. This is a matter of intense interest to health care workers throughout the country and I think ideally somewhere between five and ten hospitals around the country ought to do studies that are similar to those that I have outlined.

At that point with the data in hand we could then join with the various surgical colleges, the surgical societies with infectious disease physicians and public health authorities and produce guidelines for the surgical profession. Incidentally, it is notable that the surgical societies have been thunderously silent on this issue to date, now five or six years since the start of the outbreak. They have my sympathy.

They have no data, just as we don't, and their own membership is quite divided and intensely so on the issues. Data are what is necessary.

One last comment. The tension in serologic testing is tied irrevocably to research in drugs, effective, early in the disease. I will say it again. This whole tension in serologic testing is tied to the progress of research in finding drugs that are effective early in the therapy of the disease. If we had such a drug, the tension in testing would disappear. People would come. You couldn't beat them away with a stick, that want to be tested because they would have the advantages of therapy.

Push my recommendation, ladies and gentlemen. Push drug research. It is going faster than it was, but it could faster yet.

Ladies and gentlemen of the Commission, I applaud your efforts. I, and, indeed, the nation are grateful to you. I think our country has the capacity to curtail this epidemic and your work will provide a solid foundation, which will enable us to go forward with greater resolve and with greater success. I am at your disposal should I be able to help you any further.

Thank you very much.

CHAIRMAN WATKINS: Thank you, Dr. Schaffner.

Dr. Sherer.

DR. SHERER: Thank you, Admiral Watkins.

It is clear that the first principle of public health that we have to adhere to with AIDS, as with all public health problems, is that of engaging the public trust and the public confidence. That bears centrally on the issue of testing, HIV antibody testing and public policy.

It is clear as well that you all are very familiar with two AIDS epidemics. The first is the real problem that we face, which you are trying to address yourselves to; the second is the epidemic of fear. I think the best, most terrible example one can think of the latter in our country is the fate of the Ray family in Arcadia, Florida, in which a decent American family with three children, who carry the HIV virus, were in sequence turned away from their school, driven from their church, their home was burned and they were eventually driven from their town.

That is simply illustrative of the power of the fear of AIDS. Any public policy related to HIV antibody testing simply must consider that and try to counter it at every opportunity with the available scientific data on the transmission of this disease.

We have heard that high quality epidemiologic data is essential. We have much in hand. We have much work to do in order to improve on that data. The collection of that information is essentially a matter of research and should not be confused with the issue of public policy related to HIV antibody testing. We need aggressive research in a variety of segments and the recent CDC's MMWR on the spread of the infection in our country clearly indicates those areas where such data is necessary. That is a matter of epidemiologic research that should not be confused with public policy.

Education, through individual counseling directed towards behavior change, is the tool that we have at hand with which to control and to limit the spread of this disease.

Counseling, therefore, is the major cost that is being borne and that must be borne in order for us to be able to come to grips with the spread of HIV.

In that regard, testing is, at its best, from a public health perspective, an adjunct to that education. It must be understood in that regard. It can assist us in changing individuals' behaviors, but it can't go beyond the outcome of that counseling itself. It does not lend anything more than the counseling itself and if we are given a choice between the two, I would and I think most would choose the counseling.

Clearly, as well, we have to insist on linking counseling, the individual consent, and participation in the process with the testing process at every opportunity. I have authored an article entitled "HIV Antibody Testing and Physician Use of the Test, Consent, Counseling, Confidentiality and Caution with every Test." If we can't guarantee absolute confidentiality for individual test results, we run two terrible risks: first, the risk that we may impair the data collect, which we all agree is so critical.

Secondly, we may also indirectly lead to or promote the spread of this virus because of discouraging individuals who need this testing the most from coming forward. Many other individuals have stated these positions more eloquently than myself, including the National Institute of Medicine and the American Academy of Science. I recommend their positions to you.

We have had in my own state, I think, two examples of legislative initiatives related to testing that are the best examples of public policy errors. I can only agree with Dr. Schaffner, that we should observe the results of these two endeavors in Louisiana and Illinois and not move forward with premarital screening at this point.

The numbers, I think, are very instructive in Illinois in 1988. We estimate 200,000 people will be married in Illinois. Of those, we estimate that we will identify one to 200 people who carry the virus at enormous cost to individual taxpayers and an equal number, 1 to 200, of indeterminate outcomes of tests. I think the issue has been well-studied, thoroughly studied, in a publication by Dr. Cleary, who will present in a later panel this morning.

We will only identify 1/10th of 1 percent of all those individuals who carry the virus. We estimate in Illinois that 50,000 people may carry the virus, and yet we are going to use this test to screen 200,000 people, of whom only 100 will carry the virus. This makes no public health sense. We are using this precious resource of counseling and testing in exactly the

wrong population and with considerable morbidity, i.e., psychological morbidity, for those individuals undergoing that process.

Furthermore, in our state no one has provided this test free of charge. This policy has the effect of discouraging poor people from faithful monogamy, from getting married. The results in January in Cook County were that 40 percent reductions were observed in the number of people applying for marriages and there were increases across all the state lines in Wisconsin and in Iowa.

Most importantly, it does not make good public health sense to engage in premarital screening. We need to urgently make testing and counseling available to the 50,000 people we estimate may carry this virus, to the two to three hundred thousand people who are most at risk, i.e., homosexually active men, intravenous drug users and their sexual partners.

Another example of a policy error that passed in Illinois, but fortunately was vetoed by the Governor, was the screening of all hospital admissions. Hospital admissions primarily are children less than five and adults over the age of 50. In both groups, the prevalence of this virus is extremely low. The cost of such an endeavor would be extraordinary and the yield would be extremely low.

The practical problems inherent in testing in a low incidence population are well-described. I refer you again to the articles by Paulker and others. The number of false positive initial screening tests with ELISAs and the number of either false positive or indeterminate Western Blots is significant in this population.

This test needs to be used with caution. In every instance it should be associated with consent, with counseling by someone trained in order to give specific recommendations on how to prevent the spread of this virus, including abstinence and faithful monogamy. However, all of you will recognize that those are two practices with high failure rates.

Failing those two, we need to be specific and explicit about safe sex and safer sex and clearly include the use of the condom in those recommendations.

I agree with the comments that have been made about no mandatory use of the test and I think others have spoken very eloquently to that.

The two most important things that I think this Commission could accomplish, would be to establish a national AIDS education policy, federally supported, federally

coordinated. I think it is a tragedy to be discussing this in 1988, when we knew what needed to be done in 1983.

Secondly, I would say that you have before you an opportunity to make the beginnings of planning for what we know will occur in terms of the delivery of patient care services. At Cook County Hospital, we have 20 people in the hospital right now, over 300 in our clinics monthly. Our experience has just begun.

We urgently need planning and cooperation of an unprecedented kind between local authorities, city, county and state authorities, the Federal Government and the private sector in order to accommodate what is a growing crisis in patient care services.

I thank you very much for your attention and for the opportunity to address you this morning.

CHAIRMAN WATKINS: Thank you.

Dr. Mercola.

DR. MERCOLA: There have been three recent studies published, two in JAMA and one in the New England Journal of Medicine, which review most of the commonly cited objections to compulsory screening programs. It seems, that consistently the major objection to screening in each of these analyses revolves around the false positive rate or the specificity of the test.

Each of these authors feel that local laboratories would not be able to achieve the very high standards of performance that lab screening blood donors and military recruits have already obtained. There is great concern that large numbers will be falsely identified as carrying the AIDS virus.

This viewpoint, however, fails to consider several important items. If a false positive is found, this result is not obtained in a vacuum. This result is interpreted in light of a person's personal risk factors and if there is a question as to the accuracy of the test, experts can be consulted for additional diagnostic verification. So, rather than a confirmatory test, there is a confirmatory process.

Even more importantly, however, these tests that most analysts used in their evaluation of screening are for the most part the early first generation ELISA systems. However, refinements with these systems have greatly increased the accuracy of the test. Additionally, newer, second generation systems, using recombinant DNA technology, are currently under review for licensing by the FDA.

Both of these tests, the newer, first generation test and the second generation test offer specificities in the ranges of 99.98 percent or about 10 to 20 false positives out of every 100,000 people screened. If these tests are combined with even more accurate second generation Western Blot confirmatory tests, it seems possible to eventually reduce overall the false positive rate to well below one in a million in a widespread screening program; certainly acceptable levels.

The studies that document this new technology and some of these statistics can be found in my written testimony.

As you know, Illinois has been one of the first states to implement compulsory marriage AIDS screening. It would be helpful to share my experience as a private physician in this community as a result of this legislation being passed.

There is widespread agreement that education is the most effective weapon we have in the battle against AIDS. Perhaps some of the most beneficial effects of this AIDS legislation in Illinois has been the pressure it has put on primary care physicians to learn more about AIDS and the testing process.

In the community where I practice, this pressuring motivation has been more effective in reducing physicians' general inertia to AIDS education than any continuing medical education program. This factor should not be diminished. Informed physicians can serve as a potent force in educating the community about the dangers and appropriate precautions for AIDS.

One major item always mentioned in any screening program is the cost. The costs are generally based upon prices in effect prior to initiation of the screen. It appears that once screening is begun, there are very potent free market pressures to reduce the price of the test. Prior to initiation of the compulsory marriage screen in Illinois, a typical charge for the ELISA screen was $50.00 to the patient.

Shortly after legislation was enacted, several companies introduced lower rates, forcing the general prices for the screen down. Life Source is a company which screens the blood for northern Illinois and they have recently offered screens to physicians for the price of $8.00.

In summary, it appears that the false positive testing rates have been a major objection to more widespread screening. With the application of the current recombinant DNA technology to the ELISA screens and a refinement of the first generation ELISA systems, these arguments are becoming progressively

invalid. Many people believe that one of government's few legitimate functions is to protect and defend its citizens. This is certainly true for foreign invaders and it would be difficult not to classify the AIDS virus as anything but an invader of the most pernicious type. I would encourage the Commission to recommend more widespread compulsory testing at this time.

Aside from giving us valuable information about the epidemiology of the disease, it would serve as part of an effective strategy to protect and defend the citizens of this country.

Thank you.

CHAIRMAN WATKINS: Thank you, Dr. Mercola.

Dr. DiSalvo.

DR. DiSALVO: Admiral Watkins and Members of the Commission, I have some prepared remarks but unfortunately my luggage and I didn't get to Nashville at the same time. I will submit them if we ever get united.

I represent the Association of State and Territorial Public Health Laboratory Directors (ASTPHLD). There is a State Public Health Laboratory Director in every state.

The test is used for many purposes as you have heard: screening the blood supply; employment, such as in the State Department, the Department of Defense, Job Corps. They are used as diagnostic tests to differentiate AIDS and the AIDS-related complex or the lymphadenopathies. They are used for studying epidemiology. In the public health setting, there are two primary uses of this test: (1) to serve for alternate site testing, where counseling is provided. This diverts those in high risk groups from going to blood banks to get their testing performed and (2) to perform surveillance.

In the public health setting, there are several types of clinics which are high risk, such as venereal disease, tuberculosis clinics, jails and prisons, childbearing women and drug abuse clinics.

We feel that the testing procedure for HIV infection is excellent when it is used as a protocol, a combination of tests; that is, not just simply the screening test but followed up with confirmatory or supplemental testing if the screen is reactive. Many of the State Public Health Laboratories were performing these tests, before the test was licensed.

Beginning with the licensing of the test in March of 1985, until the end of last year, December 31st, 1987, we have examined over half a million specimens. We found over 37,000 positives, which is a positivity rate of 7.5 percent. In 1985 and 1986 the states as a whole, as well as in South Carolina, which is a low incidence state were finding 20 percent of the specimens screened were positive and now, as more and more people are being screened, the positivity rate is dropping.

In recognition of these early problems which we have seen from a laboratory point of view, the ASTPHLD has held consensus conferences. We had the first in May 1986, one in March 1987, and the third one was last week, March 1988. The problem we addressed is to set up a uniform testing protocol, so results can be compared no matter where the test is done and so the results are accurate and free of false positive and false negative testing.

We have organized a uniform reporting system. We have worked on developing an algorithm of testing procedures; that is, screening is first performed with an EIA test. Then if it is positive, the screening test is repeated and then proceed to the other components of the supplemental testing.

We have discussed quality control. We do not think there is sufficient quality control for the diagnostic laboratories and this must be organized at the national level. We have requested the Public Health System to do this. We need proficiency testing samples to be sent to the laboratories as well as a panel of blood sera of known quantity and identification to which all state laboratories would be comparing in our daily use as the standards.

One essential item we would like to address is the matter of FDA approval. All laboratory test reagents go through an approval process with the FDA. These are processed as medical devices through the Pure Food and Drug Amendment. However, HIV testing reagents do not go through this protocol. Since they were originally developed for screening drug donors, they are approved as biologics under the Public Health Service Act. This is a much more rigorous process and has more delays. You have heard other members of the panel mention new tests, recombinant DNA tests, and these have been evaluated. There is a very good evaluation by Colonel Burke, who is a speaker later on this morning, and they are excellent but they are not available to state laboratories yet.

The process must be expedited to get these approved faster and we believe if they are done as medical devices, this will enhance that process and expedite it. And we also think there should be some regulation of all laboratories performing HIV testing.

We also believe we need direct funding to the public health laboratories. There are many expenditures besides actual patient testing which we try to do which are not covered. We are active in test development and test evaluation. Each time we change test procedures, we have to compare the new procedure to the old. It is quite an expensive process in changing new procedures and new reagents. All states are bound by certain purchasing requirements. The state laboratories cannot buy the reagents that we think are the best. We have to go through expensive evaluation procedures before purchase of new reagents.

We believe we should be able to provide these tests free of charge to local physicians, which we cannot do at this time. We also believe in extra work-up of patients, who have no known risk. These patients require more than the ordinary work-up and also for health care workers. When I am involved with testing a health care worker who has been inadvertently exposed to body fluids from a patient with AIDS, we do additional laboratory studies on that patient, trying to allay their fears or come up with an earlier acknowledgment of whether or not they have infection.

Surveillance programs, which have also been mentioned, require data. We don't have all the data. We need funding to do more seroprevalence studies, so the results will be more meaningful.

And, finally, State Public Health Laboratories are reference labs. There are many blood banks which will only perform screening tests. All they are interested in is screening, and, if it is positive, discarding the blood. But we still have to be concerned with the donor (patient) at the other end. The blood banks send those samples to the state public health laboratories for more extensive testing, i.e. the confirmatory testing or the supplemental testing. We think we should have funding for that.

Thank you very much.

CHAIRMAN WATKINS: Thank you, Dr. DiSalvo.

Dr. Heath.

DR. HEATH: Thank you, Mr. Chairman.

HIV testing is obviously a most important tool for AIDS prevention. By detecting early asymptomatic infection, it lets us focus now more on early spread of virus and less on late illness and that obviously is a very basic concept for prevention.

In prevention work, the test serves two quite different purposes. One is to test individuals. By identifying individual cases of infection, we can attack the epidemic by counseling affected persons and by helping them to change risk behaviors, to receive early medical care and to trace their sex and drug use contacts.

The second purpose is quite different. It is to test populations. This lets us know where the virus is spreading at present, which population groups are the most affected and which are least. Without that kind of knowledge, we are really hard-pressed to design appropriate prevention programs or to assign our prevention resources properly.

In the case of individual testing programs, it is important, I think, that several conditions be met for the testing to be used properly. The most important, obviously, as has been mentioned, is that patient confidentiality be assured to the extent that that is possible. This calls for security of records, for continuous training of health caregivers and for adequate legal safeguards.

The other conditions that need to be addressed in individual patient testing concern counseling, both before and after testing, referral appropriately for medical care and follow-up and finally assistance in tracing contacts. These several aspects of testing I have drawn schematically in the figure, which is attached at the back of my written testimony.

Ideally, in my view, whenever the test is performed on an individual case, each of these services needs to be available and used appropriately in that case. It is not just a matter of doing the test and reporting a result.

I would agree with my colleagues here that mandatory testing at present is entirely unwarranted and counterproductive, except in the special situation of testing blood donors. Our ultimate prevention goal, I think, is to help people achieve behavior change and behavior change, as we all know, is an intensely voluntary matter. Mandatory testing seems to swim against the current.

I would also think, though, that routine testing, which is not the same as mandatory testing, in high risk settings, such as STD and tuberculosis clinics, does seem to be appropriate if you have reason to think that the level of HIV infection is high enough, 1 percent or more, and provided that you do make pretest information available, pretest counseling to the people in the clinic and that options for informed refusal of the test are available to the patient.

In the case of population testing, confidentiality is not an issue since no personal identifiers are used. There have been active debates about this, but I think that confidentiality problems are clearly not applicable. Instead, the central issues that must not be forgotten are adequacy of sample size, completeness and accuracy of data collection and capacity to analyze findings properly. Those are not to be thought of lightly.

Incomplete or inadequate testing surveys, which are easy to do, can be highly misleading and so these matters really deserve our close attention.

In my written testimony I have suggested a half a dozen specific recommendations based on these ideas, which I will not reiterate at this point.

Thanks.

CHAIRMAN WATKINS: Thank you, Dr. Heath.

We will commence our questions this morning from Dr. Lilly.

DR. LILLY: Pass.

CHAIRMAN WATKINS: Dr. Crenshaw.

DR. CRENSHAW: In regard to the testing of hospital patients, is there anyone on this panel who feels that HIV testing and the knowledge of positive status for the physician doesn't improve the quality of care that patient will get, the quality of medical treatment?

DR. SHERER: I will speak to that. I don't think anyone has directly spoken to that. My answer as a practitioner would be yes, there are many instances where I would want that information to inform my care. The issue of testing all people admitted to hospitals, I think, was addressed by -- and was really resolved, is resolved, by the application of universal precautions for infection control --

DR. CRENSHAW: Excuse me. I am heading in a really different direction. What I am trying to point out is something has been overlooked. I know that if a patient came in with diabetes and I was asked to take charge of the medical care but wasn't allowed to know whether the patient was a diabetic, all of the garden variety infections and diseases that a diabetic is exposed to should be more treated more aggressively, more enthusiastically, closer monitoring in health care; things that would be considered trivial in a healthy patient without diabetes can be exceeding serious, number one.

Number two, using this same analogy, although it is not perfect, to deal with patients who have a HIV positive status, I know that I as a physician, if I were in the wards in clinical medicine, would treat a patient whom I knew was HIV positive -- I would watch them much more closely. I would treat them more aggressively and I think most physicians would, number one.

Number two, I think that something that has been very misleading to the general public and that I think all of you can change, because it hasn't been emphasized enough. I heard the comment that because there is no cure, people aren't going to run for testing.

Why don't you start telling people that there are all sorts of cures for the diseases that kill people who are HIV positive? Not all of them, but there are treatments and cures for Pneumocystis and for a whole variety of other things that if someone gets in there early enough and knows the warning signs because the doctor has competently informed them and the doctor knows that they are infected, a great deal of improvement to the quality of care and the prompt treatment of infectious opportunistic diseases can be made.

I would like to hear any objections to that if I am not stating the case accurately.

DR. SHERER: I think you have heard support for that position. Clearly, we need to make voluntary testing as widely available as possible on the basis of identified risk. That clearly will assist and inform an individual physician's ability to provide care in the future. I don't think there is any impediment to that that exists at the present time in the context of consent from the individual and counseling for its public health value, as well as for its medical value.

I didn't hear any disagreement with that.

DR. CRENSHAW: I would like to hear the rest of your reactions.

DR. SCHAFFNER Perhaps I can get into this, Dr. Crenshaw.

I think it is important that we not overstate the case, that we be quite precise. I have never been declined permission to do a test when I thought it was clinically indicated. So, I think the concept of treating the diabetic without knowing his blood sugar is spurious. That is a circumstance, which does not come up. I think if a physician has a relationship with a patient and will sit down -- one of my

quips to the students is "Consent is never informed unless the physician is sitting." You have to sit down and talk with the patient. You will obtain consent. You ought to be able to persuade your patient.

DR. CRENSHAW: I haven't made myself clear. Obviously, no diabetic has refused. I am saying that in HIV there are those who want treatment that do not want the doctor to know. That has been discussed --

DR. SCHAFFNER That is a rare phenomenon. I think if the patient is ill, and that is what we are talking about in this circumstance -- if the patient is ill and the physician will take the time and is empathetic and interested in the patient, that informed consent will be attained. It will be forthcoming.

Second, you then address the question of whether every patient need be tested in order that health care personnel can take appropriate precautions. That also is an overstatement. The use of universal precautions with every patient, I think, will provide that assurance.

DR. CRENSHAW: All I am trying to get at -- I mean these are all important issues but I am trying to get at the specific issue of can't we inform patients, prospective patients -- a lot has been said, you know, there is no cure and there is no reason to know -- can't we generally inform and would you support informing them that there are lots of treatments that can keep them alive for a longer period of time if they -- I mean, I think the opposite message is getting across than we really could be giving to encourage people, depending on -- and want to be tested.

DR. SCHAFFNER Oh, I think we have been enthusiastic about encouraging voluntary testing and continue to be so. I think that is the cornerstone of our approach.

DR. CRENSHAW: Dr. Mercola.

DR. MERCOLA: I would just like to comment on Dr. Schaffner's reference to the likelihood that there will be a greater likelihood that more people would be inclined to test themselves if, in fact, an early cure were known.

The Commission probably is aware of some studies currently in progress, which are using low dose AZT as a treatment for people in the early stages of infection and there is a great likelihood that this, in fact, may be an effective therapy. So, I think at this point in time, we do have something to offer patients who have an infection. And as the results of these studies are made aware, we could already have

-- the leg work or the ground work could have already been accomplished so that these people are identified and they can avail themselves of treatment.

DR. CRENSHAW: The other thing I would like your comment on, perhaps, Dr. DiSalvo, is that I have gone in to anonymous testing centers to be tested several times over the years and each time I have gone in, there has been enthusiastic attempts to talk me out of getting tested. I have gone in anonymously, too, so they didn't know who I was.

I think that is reflected in what we see in the statistics, that of the people who come in, depending on where you are, a varying percentage of people actually proceed to get the blood test. Most people, once they get in the car to drive down and inconvenience themselves to get their blood drawn, generally have their minds very well made up.

So, I would like you comments on -- I know that in some areas it has done very well because I have talked to people who are discouraging those from getting tested. I think the compelling question that turns a lot of people off, that would have turned me off if I weren't so determined is if you are infected, have you thought of the consequences and do you think you can cope. And I said no, I don't think so. I am not sure how I would, but I would find a way.

I would think that would be true for any normal human being, that they wouldn't think this would be an easy thing to cope with. But would you comment on the discrepancy between the people who come in and want to be tested and the people who walk out the doors without getting their blood drawn and what is precipitating that?

If we are doing effective pretest counseling, it seems to me the opposite would be the case. Would you perhaps comment on it, tell us how we can improve that situation?

DR. DiSALVO: I am the State Laboratory Director in South Carolina, so I don't deal with that but Dr. Heath is responsible for that. I think he could answer much better than I could.

DR. CRENSHAW: Great.

DR. HEATH: You also have to realize that in South Carolina we don't do anonymous testing, so we don't have anonymous test sites. But I agree strongly, the people who come in, self-referred, for testing have screwed up their courage and thought it through a good deal, so talking them out of it is not something that our staff puts a lot of time into.

It is a different situation when you talk about starting a program that may involve routine testing in a clinic population where you think there are a lot of folks who are infected and this will be a good use of the test in terms of finding new infections and preventing further spread.

I think about this in a public health way more than a clinical care way. So, I think the use of the test medically is very valuable for people who are a symptomatic or presymptomatic. Such a use of the test is going to become more and more important as time goes on and as we find that using some of these immunosupportive drugs will help slow down virus multiplication and the progression of immune suppression before a person gets sick.

So, I think knowing a person's positivity status before they get ill is very medically important and it is basically a medical test, just to come back to this other point. In all of that, I probably lost your question.

DR. CRENSHAW: No, no, you did fine. Thank you.

In relation to your public health knowledge, you know a snapshot of what is happening in the various testing centers in the nation, how do you account for that discrepancy, which can be very wide? That concerns me. I am not sure we are doing our jobs when a significant percentage of people who screw up their courage and walk through the doors walk away without getting tested.

I think we can improve that situation. I just don't know how.

DR. SCHAFFNER I think it is a matter of reeducating people in those testing centers. Remember when the testing centers were first established? The concept was that counseling was important. It wasn't important to know whether you were positive or negative and we went through that phase very, very quickly when we discovered that patients wanted to know.

Actually, I think there is another barrier. Even in those states, such as ours, where once you get through the door, you will be tested and counseled, the waiting list to get in is still too long. I finally screwed up my courage, made the phone call, come back in two weeks for your appointment. I think we need much more resources in that regard.

DR. CRENSHAW: I agree with you. Thank you.

DR. DiSALVO: May I make one comment on that?

I don't think it is so much getting up your courage and going in the door. I think what you have to consider, particularly in our state, which is mostly rural and small towns, you have to go to the county health department and that alone is a stigma. People know why you are there. That is one of the reasons why the State Laboratories would like to be directly funded, so that we could provide this testing service to the private physicians so anybody, like yourself, who screws up the courage, can go to their own physician in private and have that test done in private, not with everybody seeing them walking into the county health department.

DR. CRENSHAW: I think that is a very valuable point.

CHAIRMAN WATKINS: We are going to shift out of sequence a bit now. Dr. Conway-Welch has to leave for about an hour, so we will shift to her next.

DR. CONWAY-WELCH: Thank you, Mr. Chairman.

I would like to get your best advice on an issue which is obvious to all of us and we certainly hear a lot of constructive information on it. We started out with the issue of mandatory testing of all patients admitted to hospitals or a special group of patients admitted to hospitals. If we dealt with that from a public health issue alone, I think that it would be very clear in terms of the issues and recommendations.

Unfortunately, imbedded in that issue are political, social, religious and economic issues as well. I wonder if you could clarify again the recommendations that you all would think, in terms of should there be mandatory testing of all hospital admissions and/or groups of hospital admissions. Could you all comment on that issue again?

DR. SCHAFFNER I think a global recommendation from the Commission for a national practice is premature. We don't have enough information. Clearly, you ought to have five -- anywhere from five to ten hospitals in this country study this question so we will have the data so that a recommendation can be made a year from now.

DR. SHERER: I would just agree that blinded seroprevalence studies, which have already been done, need to be continued. We do need to know seroprevalence in that group and have that information at hand.

As public policy, I think the consensus of the public health community on this issue is clearly against -- unequivocally, that it is poor public health policy, that the cost would be astronomical, that the disruption of the normal conduct of hospital activities would be extraordinary, that it

is unfounded for infection control because of the application of universal precautions. I don't think it should have a serious hearing here, other than gathering data for research purposes and that can be done through blinded seroprevalence studies.

DR. CONWAY-WELCH: Dr. Day, yesterday, commented on the fact that universal precautions were not useful, as far as she was concerned; one of the reasons being that she ran out of supplies that she needed in order to institute some of the most basic precautions in surgery and that is probably a valid point, but her rejection of universal precautions as being a solution was of concern because certainly that is one solution that the health profession has put forward in order to protect health care workers the seropositivity of their patients.

Could you comment on that dilemma?

DR. SCHAFFNER I understand the argument but I think the conclusion is austere. It is austere because I think that there is a whole category of health professional servants, who feel the intensity of exposure greater than an internist, for example, and who feel that the application of universal precautions is not yet entirely applicable inside the operating theater, exactly as Dr. Day and her colleagues are exposed.

On the other hand, there has yet to be a surgeon who has acquired infection. The true risk, I suspect, is going to be very, very low. I don't think that the quality of this debate will be enhanced, will be advanced one iota until the situation is carefully studied.

We ought to regard the question as a valid one. We ought to empathize with the deeply-held concerns of at least a large proportion of surgeons, and since this is an eminently studiable issue, we ought to provide the information.

DR. SHERER: I would also add, I think that in my opinion the internist or the surgeon, who bases his or her behavior in patient interactions on the basis of a test is making a serious infection control error. That certainly is one of the reasons for the principle of universal precautions, the obvious point being that false negatives are found early after the infection for six weeks to six months or more and also later in the stages in infection for persons with AIDS. In most of those cases, it is recognized that infection is present.

But that clearly is a solution that universal precautions provides. I would hate to think that we would embark on public policy in this regard simply for lack of supplies, the first point, which you began with. We clearly need to make these supplies and take these precautions and implement them nationwide in hospitals and accept that cost.

DR. MERCOLA: I would like to comment on Dr. Schaffner's point that at this point there are no surgeons who are infected with the virus that we know of. Another factor to consider is that many surgeons are not testing themselves, so they may have acquired infection and just be unaware at this point.

Another consideration would be many hospitals, at least in my area in Illinois, if an employee of the hospital is accidentally punctured with a needle, they are screened routinely for hepatitis, but they are not being screened for AIDS.

DR. SCHAFFNER Well, they ought to be.

CHAIRMAN WATKINS: Dr. SerVaas.

DR. SerVAAS: This question is to Dr. Mercola.

We are all proud of our leader, Admiral Watkins, because he zeroed in on pushing the FDA and funding the FDA to get the drugs to help the patients immediately and get rid of the bottleneck, because we know there is a bottleneck and the drugs are just there.

In your opinion, isn't it equally important now that we are into the testing phase here to push the FDA to review the AIDS antibody tests that are there and the antigen tests to hurry it along so that we can get our false negatives out of the way and that we can get on with voluntary testing? If we could put to rest the problem of false positives, then we could say to all Americans, you know, it is not expensive to get tested. If we could -- what would you think -- since you are in private industry more or less. Humana Hospital isn't a government thing and you can act more quickly in many instances probably than government bodies.

If we got the word out that for $3.00 you can be tested -- and that is what the Red Cross takes for the test, and that includes the screening test, which we know gives some false positives, but which all doctors that I know would never tell a patient that they are positive after the screening, that -- and the Red Cross also includes the confirmatory Western Blot.

Now, we already have pretty much laid to rest, as I understand it -- and I would like your feeling about it -- the false positives on the -- false positive problem with the confirmatory Western Blot done at good labs and, of course, if it is done in a poor lab, we worry about it still and that is the other thing that I would like you to talk about and that is

don't you think that we should set up an organization in the FDA or do you think -- probably the FDA -- to get medical device -- call this a medical device and have the labs certified, who are going to be doing the confirmatory Western Blots because we know if they are done properly, then only the mixing up of the tubes can give you a real false positive, where a patient would be told that.

Doctors should all be trained never to tell a patient until they do have the confirmatory test. Would you agree that it is dangerous at this point, Dr. Mercola, for us to confuse the public with information about false positive tests not being -- as being a problem and there is some literature that is out that would refute Dr. Burke, for instance, who says it is one out of -- way back it was one out of 135,000 and Dr. Brooks Jackson, who got none out of 580,000, no false positives.

There is literature that shows that a man who predicted that we would have a large number of false positives if we tested that many people in the State of Minnesota -- I am talking a long time to get to the point and I would like you to comment about the urgency of getting the FDA to certify the labs that are going to be doing the confirmatory tests so that we can lie to rest in the view that the public has -- if we lie that to rest and if we said it is free -- anyone who wants the test can have it free, knowing that it costs $3.00 and because there wouldn't be so many confirmatory tests, it wouldn't really cost that much and we could lie to rest all this rhetoric about it is so expensive.

Now, we know why it is expensive. It is expensive because we need all of this pretest counseling that in many instances is telling people, you know, should you or should you not be testing but we are talking about the American citizens who want to be tested.

And then I have a question for Dr. Sherer.

DR. MERCOLA: It is a very complex question or set of questions.

Let me just first respond by saying I would firmly agree with Dr. DiSalvo's position, that in fact strong recommendations of encouragement should be made to have the FDA consider repositioning the AIDS into -- I forget the specific terminology, but I am sure it is in his written testimony.

The issue of false negative is really almost laid to rest. Most of the tests currently available and licensed by the FDA are nearly a hundred percent sensitive. They will pick up nearly every single person infected so that clearly the major

issue is the area of the false positives or the specificities of the test.

The first generations currently licensed by FDA have been improving the technology to the point where, as I mentioned earlier, there are nearly 20 false positives on the initial first generation ELISA screens out of a hundred thousand.

DR. SerVAAS: But we all know about the false positives on the ELISA, but no doctor is going to give that out.

DR. MERCOLA: No, I realize that but those 20 false positives need to be subsequently reconfirmed with the Western Blot.

DR. SerVAAS: Exactly.

DR. MERCOLA: Currently, the Western Blot is very labor intensive and very costly.

DR. SerVAAS: That would average out, though, because the Red Cross averages out at $3.00 each --

DR. MERCOLA: No, I realize that if you are going to just do the test. Just let me continue and that is the recombinant DNA technology is also being applied to the Western Blot system, which will also dramatically improve the ease of the test and the cost of the test. So, the whole cost factor can be seriously reevaluated in the future, as these tests are licensed by the FDA, but there certainly needs to be a caution.

The first generation tests are good as they are presently evaluated. There may be some factors that we are unaware of, such as E coli contaminants, changing of the virus, which may impact on our ability to effectively screen for this disease in the future. So, they should seriously evaluate it, but it is my understanding that in Europe the first generation screening systems are not even being used. It is exclusively second generation systems.

So, I would encourage the Commission to make that recommendation.

DR. SerVAAS: And these tests, to your knowledge, are now being held up for approval by the FDA?

DR. MERCOLA: Yes. They are currently under review. There are two companies at this point -- one, I understand, is Abbott and there is one other company -- it is in my written testimony -- that currently have submitted data to the FDA for approval of their test.

DR. SerVAAS: So, it is crucial for our Commission to fund the FDA to get those reviews through, so we can be as current as Europe in our first generation test.

DR. MERCOLA: But certainly to seriously evaluate it because we wouldn't want to have a test on the market that was inferior in any way long term that would be counterproductive.

Another issue, too, is that there are seven companies that currently license the ELISA screens. Within that range, some are more accurate than others. When you start screening large populations that can be a serious factor. As opposed to us having 20 false positives per hundred thousand, you might have a hundred or two hundred and then other factors come into consideration.

DR. SerVAAS: At the FDA, it is our understanding that there is also a test that will do both HTLV-1 for cancer-causing sexually transmitted virus and the HIV simultaneously. This test also could be reviewed if we could put some emphasis on funding because of the FDA lack of funds to get the reviewers to do these tests, to review these tests. Is that, in your opinion, one of the urgent problems for the conditions you address?

DR. MERCOLA: I would agree with that. As I said earlier, the major objection that most serious investigators have to more widespread application of screening seems to be this issue of the false positive rate and with these new systems that the technology is available, if we can implement them, that component of the argument to more widespread screening would be eliminated or should be eliminated.

DR. SerVAAS: Thank you.

CHAIRMAN WATKINS: We have to move along.

Dr. Primm, before we start here, I have to remind all the Commissioners, we must terminate this panel at 10:30. We have a very tight schedule today. We have to be out of this building at 4 o'clock this afternoon. So, I would like to restrict our questions to one. I would like you to think about focusing it to one of the panelists and unless one of the other panelists feels that they have got a serious problem with perhaps another panelist's answer and he wants more information, I would like to move along.

If we can do that, I think we can get more out of the pressed time we have.

So, with that, Dr. Primm.

DR. PRIMM: At the Harlem Hospital Center where a number of people, who are seropositive, come into these drug units. And at San Francisco General Hospital -- Dr. Schaffner, I think you were here when Dr. Day spoke yesterday and she talked about the number of people who come into the hospital emergency room, where she is the chief orthopedic, I guess, trauma person there and a number of them are positive.

She also talked about the lack of equipment available. Dr. Sherer, you are at Cook County Hospital, another hospital that I am very familiar with, that I know that equipment is not always available; yet, we talked very much about the infection precaution procedures being implemented.

Suppose they don't have the kind of things to carry out the infection precaution procedures that you have indicated. What do you recommend for surgeons who -- orthopedic surgeons, surgeons who deal with gunshot wounds and so forth and so on in these major city hospitals, where it is unrealistic to think that all the time they have things available because you know they don't and I know that they don't, and I don't know about you, Dr. Schaffner, you are here at Vanderbilt, but in the major cities where public hospitals are, we don't have them available.

Wouldn't it be of some help then to surgeons and others to know the seropositivity status of individuals, who might be coming into that institution for surgery. A lot of the people -- they can't get consent because the people are unconscious. What would you recommend then?

I think these are important factors to be considered before we blatantly talk about Utopia being present in all of our institutions, which is not the case.

DR. SHERER: It is certainly true that Cook County Hospital is often short of critically-needed supplies. I can't recall the time, however, when rubber gloves, masks or goggles were among those. They are widely available for the procedures that might put individuals at risk in the trauma unit and in vascular surgery and labor and delivery.

I think it is really important to underscore this discussion with just the data that is at hand on health care workers, who appear to have acquired the infection as a result of their occupations. There are 12 at my last count reported worldwide and the studies that have looked at the rate of infection among health care workers find it to be zero or extremely low. That should just be the context in which we have this consideration because really every effort has to be made to implement the universal precautions that I support. We are doing this at County Hospital. I believe the other hospitals that have

the highest burden of patients are taking the same steps and we simply need to maximize those efforts.

I repeat, and I would like to comment on a couple of points that were made earlier -- Dr. SerVaas, I think you have stated an ideal that we all aspire to. I hope that physicians now know how to use this test and don't inform patients. I have personal experience with many such instances and not just people being informed that they have a positive test, but that they have AIDS on the basis of a positive test, which, of course, is an incorrect representation of the test results.

I also don't think that it is true to say that we have licked the problem of false negatives. We do have an antigen assay that appears to be useful, but we have not instituted wide application of that assay in any sense. False negatives still are a serious concern.

DR. SerVAAS: I didn't say that. I thought -- I said we have licked the problem of false positives when we use qualified labs. We all admit there is a great need to do more to prevent false negatives.

DR. SHERER: That is true. It was Dr. Mercola, who said that, and I disagree with the statement. That is something that we will be with and I want to also support the comments on the critical need for FDA standardization of Western Blot techniques and of the laboratories that perform them.

Indeterminate Western Blot studies are still a considerable problem in many laboratories in Illinois, as well as nationwide and that does represent a continuing problem. I don't believe that we will have a technologic fix in the sense that I am hearing here that will settle all the issues of testing and their problems, particularly in mass screening use.

CHAIRMAN WATKINS: Dr. Walsh.

DR. WALSH: I seem to have come in today where I left yesterday and that is confused.

I hear from this panel several things, generally in opposition to increasing the amount of testing, even whether you do conditional testing or routine testing on hospital admissions and so on. And then I hear repeatedly that you don't have enough data to make certain conclusions on the extent of the disease, the incidence of the disease, the prevalence of the disease and this all affects medical practice and what we are going to do and it just -- I am beginning to be concerned because we had difficulty in this interim report answering the questions on incidence of prevalence.

For those of you who have read it, we had difficulty and based on what you all have said this morning, I just wonder whether it is going to be premature for us to make any recommendation by June the 24th.

The CDC is just starting some routine testing in a body of hospitals. If they follow the usual pattern, something that they start now, they may report on by November or December and they clutch it to their chest like it is top secret and you can't get a hold of it until it is properly evaluated.

Other things that bother me are the blank conclusion that people lose jobs, homes and insurance. Some of you that said that their insurance -- that they lose their insurance if there is a false positive and so on and, yet, 75 percent of the people are all covered by group insurance and they don't lose their insurance.

We have the insurance problem of some 37 million people, who are totally uninsured and if they fall into that category, of course, they are in trouble, but so are 37 million other people in trouble if they have heart failure in that group.

My question, therefore, is really -- the word "mandatory" raises a flag with everyone. I have brought up before a fact that was suggested by the AIDS group in Hawaii of getting away from that term and using the term "conditional testing" as a way of gaining access to more data. In other words, what is wrong, if just for data collection, we do routine testing on hospital admissions? What is wrong if in premarital testing with the people who are to be married, are willing to pay for it themselves -- it is no cost to the taxpayer -- if they pay for it themselves, it gives us another batch of data that is spread across not necessarily high risk groups, but the data that would give us information as to just where we should be going with this disease and I don't see how we are going to get data collection without broader collection, preserving confidentiality, preserving anti-discrimination and all that business, but it seems to me that I keep hearing from witnesses that we don't want to do routine testing, but we don't have enough data to tell us what to do. Now, how do you get the data if you don't want more testing to get a better idea of what we are dealing with?

Do we have a million and a half seropositives or do we have three million or do we have 800,000? Statements were made by some of you that such and such a publication has given us assurance of that. That is baloney because I know of five other publications that will disagree and as long as they are sound scientific disagreement, I don't think we should accept any

publication with the data that we have at hand as being authoritative enough to make a conclusion.

So, that is why I am confused. I don't understand the resistance to more routine testing or conditional testing, if you will, and then the complaint that we don't have enough data. We have complaints even from members of our Commission that the CDC is too slow, that they don't do this and they don't do that and I have that complaint also, but how are we going to get the data?

DR. SCHAFFNER I think the goal is worthy, Dr. Walsh, and I think that if we realize that we will not have a perfect answer but we will have pieces of answers and we do, indeed, have parts of those answers now, I think we can proceed.

Recall that the nationwide information from first time blood donors is available; recall also that we have information on military recruits. We are now in process nationally under CDC sponsorship of doing a whole series of anonymous testing studies, which are going to provide us a whole lot more insight into the kind of answer that you were looking for. How widely prevalent is infections of this virus, knowing it is an imperfect result.

I think in part what you are hearing is that we are also provincial, as well as interested nationally. We would like to know what is happening down our street and it is difficult for each of us to do the kind of mini anonymous testing survey that we would like because I think resources are limited.

The further application of routine but voluntary testing in such settings as sexually transmitted disease centers, tuberculosis clinics, et cetera, et cetera, I think is going to provide us a lot more information.

DR. WALSH: Because we hear that on the amount of routine testing that has been done hasn't justified the results -- I think if you get only five out of 200,000 or whatever it is or 50,000, it does justify because it tells us that perhaps we should be more optimistic about the degree of seroprevalence than we are. Maybe we don't have a million and a half and that gives us some information.

You know, if we are going to do a test -- you and I practice the same kind of medicine, supposing we did away with all those screening lab tests that come in. How many of those really tell us anything worth -- and, yet, we do them on every patient and if we were to make the positive findings we get from, say, a seropositive patient on everybody who comes into the collective hospitals, we would abandon that test, too. We

wouldn't want to do that because we pick up one knowledgeable test it helps out.

This is a disease that causes death for the next decade at least and that is the thing that is giving me confusion. I don't understand.

CHAIRMAN WATKINS: We have time just for one answer and then we are going to have move on.

DR. DiSALVO: I firmly support routine testing in certain groups in which it is epidemiologically indicated. I don't -- I agree that it is not epidemiologically indicated in premarital testing or as a routine hospital admission for all admissions. It should be done selectively and certainly, as mentioned before, our TB clinics and -- tuberculosis clinics, I think it definitely should be done.

CHAIRMAN WATKINS: Ms. Pullen.

MS. PULLEN: I wanted to ask Dr. Sherer about his position on AIDS counseling for newlyweds and how to protect them and potential babies that could be conceived, but since time is limited, I would like to ask Dr. Mercola some things about written informed consent and the practicalities of that in the child care setting because I think this is a more important issue to get at than how persons view premarital counseling.

In Illinois, we have a law that says that no person may perform or order to be performed an HIV test without written informed consent of the person upon whom it is to be performed. Could you comment on, one, the consent form that is the standard form that is being used and its usefulness as a counseling and then its effect; two, the blanket policy of written informed consent in all cases and what the effect of that is and specifically the problems, perhaps, that are caused for health care workers and others in the line of duty, who will become exposed to potentially virus carrying body fluids and must weight for six weeks to six months until their own antibodies either do or do not appear to determine whether that exposure was to virus or just to blood?

DR. MERCOLA: I have a copy here of the consent form that Humana Hospital currently uses and, as you can see, it is quite long. This is the minimum that could be put together and still meet the full compliance of the law as currently passed in Illinois.

There was a great concern for maintaining the confidentiality and making certain that the person was fully aware of some of the potential complications of false positive tests. As a result of that, the form is, from my experience and

many other physicians, tends to be quite confusing and impairs a really effective counseling effort. At this point in time, I have not had any patients of mine who -- where this form has impaired them from actually proceeding with a test, but it has actually been relatively counterproductive in basically providing the intent of the law, which was to inform the person.

So, there is certainly room at this point for improving the form and making it simpler to expedite consent. Now, there certainly is the other practical issue of obtaining informed consent in a hospital setting for the situations which you described. Obviously, that is an issue and, in fact -- I am not quite certain of the details of the law as it is constructed, but I believe there is a provision, which allows for testing of individuals if, in fact, a health care worker is accidentally punctured.

MS. PULLEN: Not that I am aware of in Illinois, not yet.

DR. MERCOLA: Okay. Then I was confusing that. So, that certainly is an obvious problem with the Illinois law as it is currently constructed because there is no way that that particular, potentially-infected health care worker would know what their -- more accurately, what their risk of infection would be from a needle puncture.

So, it is a serious problem and I think some strong effort needs to be made to revise the law that has been passed in Illinois and is certainly being considered for approval in other states at this time.

CHAIRMAN WATKINS: We have two Illinois panelists today so you have two questions, if you would like to ask another one.

MS. PULLEN: Thank you, Admiral Watkins.

Dr. Sherer, a year ago you stated at a public health issues forum at Sangamon State University, which was that instead of doing premarital, what should happen is that applicants should be advised and counseled universally to always use condoms in their marital relationship. Do you still hold to that view?

DR. SHERER: I don't recall exactly that. We did provide an alternative to this law, which I think is proving itself to be a poor public health policy. That alternative would be to make a basic AIDS pamphlet, educational material available in the clerk's office, have a couple sit down and review that and have there be additional numbers there for further counseling, if necessary, and for testing, to testing

and counseling centers and to have that be a requisite for individuals seeking marriage licenses.

Your earlier point about what about infants, which I know is one of the, I think, the intents and we all share, I think, great concerns for the problems of AIDS and infants. Eighty percent of those infants, as you know, are born out of wedlock. The clear vector of the infection in infants, in minority populations in our country, in AIDS in women, is substance abuse. And if we are serious about addressing that problem, we will take steps to make more treatment slots available for the 80,000 estimated drug users in Illinois, of whom only 8,000 are able to get to any kind of therapy at any time.

I would commend the Commission for the preliminary points it has already made on the problem of substance abuse. That clearly is where we should focus our attention if we are serious about addressing that. That would be a cost effective, a viable alternative to what has been widely acknowledged as, I think, poor public health policy.

MS. PULLEN: On the point of substance abuse, I agree with you, but would you please answer my question, whether you still believe counseling marriage license applicants to consistently use condoms in their marital relationship is the answer?

DR. SHERER: I certainly subscribe to the Public Health Service recommendation of faithful monogamy as a viable alternative to the HIV epidemic and to the threat in a couple, but it is clear that marriage doesn't necessarily provide any protection. In an era where recommendations to heterosexuals are, if they have had multiple partners, particularly if they have potentially had partners with other risk factors, yes, then I think that safe sex using condoms is a reasonable alternative for those individuals.

Certainly another alternative would be for them to seek that counseling, seek the testing and, if negative, then, of course, then protection is not necessary, but, yes, I think that that is a reasonable alternative for any heterosexually active individual in 1988.

DR. SerVAAS: No babies? I have 11 grandchildren.

DR. SHERER: Dr. SerVaas, I think if people are considering pregnancy and childbirth, any woman is considering that, then clearly counseling and testing is appropriate and establishment that there is lack of infection before proceeding with pregnancy is the appropriate steps that should be taken.

I don't think there is any likelihood that our recommendations from the Public Health Service for the prevention of AIDS is going to threaten the ongoing American family.

CHAIRMAN WATKINS: We have only five minutes. I would like to restrict the remaining questions to questions only directed to the panelists, one or more, and then if the panelists would be willing, we would like to receive the answers to those questions and then perhaps there will be some additional we will come up with that the Chairman of the Commission will send to you individually and ask you further questions.

Dr. Lee, do you have --

DR. LEE: I will yield my time on this illustrious panel.

CHAIRMAN WATKINS: Mrs. Gebbie.

MRS. GEBBIE: I won't.

I must admit, I don't share Dr. Walsh's confusion. I think we have heard consistently from almost every witness we have had that they see a need for more testing in conjunction with counseling and properly planned programs and I have heard that over and over again. So, he and I may need to talk.

My question is directed to Dr. Schaffner. You have suggested that we should collectively construe the State of Illinois or the State of Louisiana as a national experiment on the question of how well and how effectively premarital testing programs work, but nobody else should rush into it until we evaluate those.

If we construed it that way, if that is what we decided to see it as, what ought we have funded or constructed around that law that would allow us to evaluate it and at what time interval ought we set that up so that we could decide, you know, hey, it was really brilliant and we should follow it or, no, it has some flaws and we should do something else in the rest of the country?

DR. SCHAFFNER Well, I think we should have done a number of things. One is that just an assessment of number of marriages and analysis of where any changes in rates of marriage are taking place, to find those couples more precisely demographically. I think we can do concurrent evaluations in the surrounding states where it was clearly anticipated people would go in order to avoid getting the test or just perhaps

avoid paying for it, and look at Illinois or Louisiana residents, who are marrying out of state.

I think there is room for a series of interviews from a sample of people who have married out of state and married in state to see what kind of attitudes about it. Those kinds of things, I think, would help us a great deal.

MRS. GEBBIE: At what intervals should we --

DR. SCHAFFNER I haven't designed the study, but I would think you would have a lot of information after the first six months.

MRS. GEBBIE: My written follow-up to all witnesses would be for some further elaboration on that evaluation model. What we should do to critique this kind of decision and help us apply it elsewhere.

CHAIRMAN WATKINS: Mr. DeVos.

MR. DeVOS: The fact of the matter is I guess we are really not interested in testing. What we are interested in is treating patients properly and preventing the spread of this disease and our whole shift is on the technical aspects of testing, which is how we help do those things.

Therefore, I am always interested in costs and this panel knows that. We also know in this disease, the progression of it is a multiplier effect. So, I guess we are going to need more data as to whether it is economically valid to prevent other people from getting it, which will lead to 400 or a thousand or whatever, and the cost of doing that as opposed to testing a whole lot of people.

That takes some real work ahead when we start studying the real cost of taking care of those people who get it, to say nothing about the human suffering that is involved. So, testing, maybe you can confirm for me, is it 99 percent reliable and is it and can it be done for under $10.00?

DR. DiSALVO: I would like to respond to that.

Yes, it can be done for under $10.00, including confirmatory testing, and it is one of the best tests we have in medical laboratory practice. Sensitivity and specificity are greater than 99 percent. If we get 90 percent in many of our tests, we are elated, particularly in syphilis serology and fungal serology. Over 99 percent -- it is a tremendously good, accurate test.

MR. DeVOS: That is all I want to know because I hear this smoke screen all the time against testing, that it is not reliable and it costs too much and I thank you.

DR. MERCOLA: It is 99.999 --

MR. DeVOS: I understand that but I hear all the other confusion on costing all the time with numbers being thrown around and non-reliability and I think that is important to get on the record very quickly.

CHAIRMAN WATKINS: I would like to, in closing the panel out, Dr. Schaffner, Dr. Sherer and Dr. Mercola, if you would, please, to send me a letter and review the bidding in your area on hospital accreditation in the area of administration of confidentiality of health information and tell me if it is put to rigorous examination in that accreditation process, if there should be changes made in the accreditation of hospitals, to look into it, not only in the confidentiality, but the casual revelation of any information needs to be sampled and looked at very hard to build the credibility so that those individuals coming in and receiving the counseling and the advice would have a very good feeling that there is a tough system, a tough regimen in the country, and raise the awareness within the hospital administration area, that this is an important area and could we put additional emphasis on that.

So, one, I would like to know what you think you have today and could it be strengthened by us making a recommendation on the accreditation process in the area of confidentiality and in the area of broach of that confidentiality, of how you would -- maybe Dr. DiSalvo would do the same thing for me -- how the breach of that confidentiality would be treated in the accreditation process review? How would they look at that? How is it handled? How aggressive is it? How willing to cooperate is the hospital?

Let me know if you think that is a valid point that we can make comments on.

We thank this panel very much for coming here. We are going to have to move on to the next one. I am very sorry.

The next panel is on the effects of Testing and Dr. Jerry Sandler, Associate Vice President for Blood Services, National Headquarters, American Red Cross; Dr. Paul Cleary, Division on Aging, Harvard University Medical School; Dr. Steve Morin, American Psychology Association, Chair, Psychology and AIDS Task Force; Dr. William Lawson, American Psychiatric Association, Department of Psychiatry, Vanderbilt Medical Center and Colonel Donald Burke, Chief, Department of Virus Diseases, Walter Reed Army Institute of Research.

Thank you very much for coming today.

Dr. Sandler.

DR. SANDLER: Admiral Watkins and Commissioners, thank you for your invitation to testify today.

I would like to just highlight some of the points that are in my written testimony, which is available to all of you. I am a professor of medicine and I am responsible for the Red Cross's 56 regional laboratories, which conduct 37 million laboratory tests for infectious disease each year.

During the past three years these laboratories conducted 18 million ELISA tests and an additional 36,000 Western Blot tests for HIV antibodies. That is, we do one-half million tests each and every month.

In addition Red Cross regional blood centers have notified more than 2,000 persons who denied risk behavior for HIV infection when they donated blood, but their blood test subsequently tested positive for HIV antibodies by ELISA and Western Blot.

Based on that experience, I would like to make some comments.

First, with reference to large scale laboratory testing in low risk populations, as you have just heard, it is very doable and it can be done reliably. When we test 10,000 people in a low risk population, namely a blood donor population, we come up with 1 indeterminate test result and that indetermination I would like to explain to you by analogy to a pregnancy test. If you test the woman very early in pregnancy, you may get an equivocal answer. You just wait a little bit longer and repeat the test, nature takes its course.

The same is true of an HIV infection. If you will give the laboratory two tubes of blood from a person with an indeterminate, one taken early on and a second some weeks later, they can tell you that the first one was an equivocal result and the second one is either positive or negative.

I hear the argument about testing low risk populations is not feasible because of large numbers of false positive tests that would result. On the contrary, a well-run laboratory, using FDA-licensed ELISAs and Western Blots, supplemented occasionally by recombinant ELISAs, can distinguish positive tests from negative tests. Such testing can be done if that is to be the goal of public policy.

For the record, may I interject a couple of comments about Dr. SerVaas' quote of the Red Cross $3.00 figure for HIV testing. I think it is extremely important that we understand that that is the cost for bottles, that is, a reagents only cost figure. That is not the cost per test for a full scale testing program.

Secondly, I would like to relate some general information on the subject of donor notification.

Recently, I reviewed 900 reports by Red Cross physicians, who conducted donor notifications. Only 50 percent of current blood donors with positive tests for HIV antibodies admitted risk behavior, compared to more than 90 percent one year and two years ago. But second, in-depth interviews, conducted by trained interviewers revealed that more than 90 percent of these same donors were identified to have risk behavior.

People simply aren't talking openly about risk behavior as they did, probably because of increased concerns about confidentiality. Our observation that 50 percent of blood donors with positive HIV antibody tests presently do not openly admit to risk behavior is, therefore, the result of an unwillingness to talk to blood center personnel about it, rather than a discovery of new, unrecognized routes for HIV infection.

We estimate that 5 to 10 percent of donors being notified today are genuinely surprised by their positive test results. Most of these, but not all of these, persons are single women, who admit to sexual relationships with men, who they know are or suspect to, be IV drug users or bisexuals.

All persons being notified of positive tests need immediate and ongoing counseling. The subjects for counseling are straightforward. They are public health, (how not to infect others the way you got infected), medical, (what is the meaning of the test), and psychological.

Thank you. I would be pleased to answer any questions.

CHAIRMAN WATKINS: Thank you, Dr. Sandler.

In interest of Dr. Burke having to leave, we will go next with Dr. Burke.

DR. BURKE: Thank you.

I am the Chief of the Department of Virus Diseases at Walter Reed. I am personally responsible for the design and conduct of screening in the U.S. Army. I also assist the other

military services in their screening programs and have done so for two years.

I wish to address a number of the common misconceptions and concerns about HIV screening programs. My comments derive from experience and not from theory.

The first concern is that false positive test results are common. That may be true in some public laboratories or in some private sector laboratories, where quality control is feeble. In our own program, the false positive rate is 1 out of every 135,000 individuals tested. We have measured that number and we know it to be true.

Second, the cost effectiveness of HIV screening is questioned. We do our testing under a contractual relationship and pay $4.00 per person tested. This includes transport of specimens, testing of specimens and reporting of results. It costs us about $300.00 in the New York, San Francisco and Washington areas for every case detected; that is, for every HIV-infected individual detected laboratory testing costs are approximately $300.00.

Third, some hold that the logistics of establishing HIV screening programs are insurmountable. Mr. Taft, the Deputy Secretary of Defense, directed on 30 August 1985, that we would begin testing of all applicants for military service. Within six weeks we had a fully functioning program in place that was testing 60,000 people per month.

The fourth concern is that suicides are commonplace when wide scale testing is implemented. Thus far, among applicants for military service, there have been 1.8 million individuals tested; 3,000 have been found to be HIV infected. To date, we are unaware of anyone who has committed suicide in direct response to being told of the diagnosis of HIV infection.

Fifthly, some contend that the requirement for pretest counseling renders testing programs too expensive. In our civilian applicant testing program, pretest counseling consists of distribution of a one-page fact sheet. We reserve individualized, one-on-one counseling for post-test counseling to persons who have tested seropositive. The cost of pretest counseling is nil.

Sixth, it is often said that because there is no cure for HIV, testing is useless. HIV-infected persons can be directly benefited by knowledge of their infected status. First, they can be assured of a prompt diagnosis and effective therapy of opportunistic infections. Second, HIV-infected persons, who know their infected status, may be able to slow progression to AIDS by careful attention to diet, physical

fitness and avoidance of other infectious diseases. Third, HIV-infected persons can avoid the guilt and pain of having unwittingly transmitted a potentially fatal infection to their lover or spouse.

Concern number seven is that wide scale screening for HIV will "drive the epidemic underground." This is commonly said. To date, a grand total of only 75,000 HIV-infected persons have been diagnosed as HIV-infected through alternative test site programs. This represents about 5 percent of all of the HIV-infected persons in America today. Restated, 95 percent of HIV-infected Americans remain totally unaware of the fact that they can transmit a fatal communicable disease to their sexual partners. As a direct consequence of a national failure to encourage wide scale routine testing, the epidemic is already underground.

In closing, I reject the passive and fatalistic attitude, championed by some, that effective routine HIV testing is beyond the capability of the U.S. public health machinery. The means are in hand today to establish an accurate diagnosis in each and every case of HIV. We as a society must abandon the strategy of ignorance. We can no longer systematically deny the rights and benefits of painful but critically important knowledge to the 1 1/2 million Americans who carry a fatal infectious disease.

We must set as a clear goal, wide and free availability of high quality HIV testing.

Thank you.

CHAIRMAN WATKINS: Dr. Cleary.

DR. CLEARY: Yes. My name is Paul Cleary and for the past several years, I have been conducting research on the notification of seropositive blood donors at the New York Blood Center. I am concerned about maximizing the positive impact of those blood test results.

When biomedical tests are evaluated, technical performance is usually the prime consideration. Indeed, much of the debate concerning the appropriate use of tests for HIV antibodies focus on the error rate of those tests. Many people do not realize how many HIV tests results will be incorrect, especially in low prevalence populations.

However, I would like to disagree with Dr. Mercola, when he said the several papers that have analyzed testing programs hinge on the number of false positives. I think Mr. DeVos slightly overstates it when he says it is a smoke screen

but I would agree with him that in many cases this emphasis is a detraction from some of the more important issues.

I would like to argue today for the importance of considering a broader array of consequences of HIV testing before implementing testing programs. Furthermore, I will propose that testing should not be conducted without careful analysis of the potential impact on the persons being tested and that any testing should be conducted by persons who have received substantial training in the interpretation of test results, in providing support to seropositive individuals, and in promoting behavior change.

We recently analyzed the effectiveness of a hypothetical national compulsory premarital screening program. This example highlights, I think, some of the issues in compulsory screening. In our analysis approximately 1,200 infected individuals, who had not already transmitted the virus to their partner, would be detected each year. Many of those persons might alter their behavior to prevent or reduce the spread of the virus to others, but this is the best result achievable in a program that would screen more than three and a half million people.

As many as 380 people with false positive results would be told incorrectly that they were almost certainly infected and many of these people probably would experience severe psychosocial morbidity. More than a hundred infected individuals would be told that they were probably not infected and this false reassurance could increase high risk behaviors.

There would be other less important but logistical difficulties in implementing a mass testing and notification program in a premarital setting. It currently takes up to about four weeks for some testing sites to complete a series of EIA and Western Blot tests on a sample. It would be necessary to develop protocols about what information, if any, should be given to patients, who are EIA positive, pending Western Blot results. Also, if test results were needed prior to marriage, the test sequence would have to be initiated about a month ahead.

The financial and opportunity costs of a national screening program would be enormous, probably exceeding a hundred million dollars annually. Such an expenditure might be justified if the program could sufficiently reduce the spread of HIV and if other, more cost effective efforts were already being taken. Considering that there are probably between one and one and a half million infected individuals in the United States and that a hundred million dollars represent more than the Federal Government spent on AIDS education in 1987, a compulsory premarital screening program does not appear to be a sensible allocation of resources.

Let me emphasize again here that I don't think false positives are the issue. The issues, as Dr. Sherer emphasized, is that education is a critical component of screening programs.

Another potential negative impact of mandatory screening programs is that they may discourage people from seeking information or contacting health authorities. Again, as Dr. Sherer indicated, and the press has reported in Illinois, where mandatory premarital screening has been instituted, many persons are leaving the state to be married or are avoiding marriage altogether. Thus, testing programs that are compulsory may alienate the very persons they are intended to help.

The difficulty of promoting behavior change among seropositive individuals cannot be overemphasized. HIV infection is feared and stigmatized and it is extremely difficult for infected individuals to tell others, such as sexual partners and physicians, about their infection.

Furthermore, the behaviors that put others at risk, intravenous drug use and sexual behavior, are notoriously difficult to change.

Let me emphasize that HIV screening is something I am strongly in favor of and it can be an extremely effective public health tool. HIV antibody tests are almost indispensable for making the blood supply in the United States as safe as possible.

The screening of donated blood, however, is so effective primarily because it is easy to discard infected blood and thus definitely prevent the transmission of HIV. In order for a screening program to be effective, I think there are several conditions that must be met.

One, the program must reach a large number of persons who are at high risk of HIV infection.

The testing program should not alienate individuals who are at high risk.

A series of tests must be used under carefully controlled conditions.

And, finally, and most importantly, there must be a way of maximizing the positive impact of the test and minimizing the negative impact. It is important to remember that simply identifying an individual as infected does not necessarily have any positive impact. It is necessary to promote difficult behavior changes for a testing program to have any positive effect whatsoever.

In order to maximize the likelihood of these conditions being met, I make the following recommendations.

As Dr. DiSalvo recommended, a task force should be developed to coordinate and monitor standards for HIV screening test protocols and these standards should be enforced nationally. One problem that has caused a great deal of confusion is the lack of uniform standards for certain tests, such as the Western Blot. Epidemiologic, clinical and public health activities would be facilitated if only standardized, licensed tests were used.

I agree strongly with Dr. Burke that we can do much better than we have been doing.

More rigorous procedures should be established for monitoring the performance of laboratories performing tests. Monitoring programs such as those conducted by the American College of Pathologists have been extremely useful in this regard.

Three, programs should be developed to train health professionals concerning the advisability of testing for different types of persons, the interpretation of test results and the meaning of HIV infection. These programs should train physicians, nurses and other health professionals in such topics as the epidemiology of HIV infection and the natural history of HIV infection.

Four, programs should be developed to train health professionals concerning how to provide support to and encourage behavior change among seropositive individuals.

In order to maximize the impact of testing programs, they should in almost all cases be voluntary and anonymous. If it is not possible to ensure anonymity, rigorous procedures should be established to ensure confidentiality.

The importance of developing training programs for medical and paramedical professionals cannot be overemphasized.

Believe it or not, I think everyone in this room is in agreement. We all share a common goal of reducing the spread of HIV infection. Since the virus can only be spread, for all practical purposes, by a limited number of behaviors, it is critical that we focus extra effort on developing strategies for modifying those behaviors among all individuals and especially among HIV-infected individuals.

Thank you for your attention.

CHAIRMAN WATKINS: Dr. Morin.

DR. MORIN: Thank you.

Mr. Chairman and Members, thank you for the opportunity to present the views of the American Psychological Association. My name is Steve Morin. I am the President of the California State Psychological Association. I am also an Assistant Clinical Professor of Medicine and Senior Investigator at the Center for AIDS Prevention Studies at the University of California, San Francisco.

I am the chair of the American Psychological Association's Task Force on Psychology and AIDS.

A little over a year ago, I was invited to Atlanta to address the CDC on testing issues. I was one of the few behavioral scientists that were involved in initial planning on the testing issues. It became clear in the course in the deliberations in Atlanta that there was considerable confusion about and not much definition to the term "counseling" as it was being used in discussions of a prevention campaign.

Following that conference, APA attempted to pull together some definitions of what would constitute "counseling" and "education." From this effort evolved a position paper, which I have submitted for your consideration. It is sponsored by the Coalition for AIDS Prevention and Education, which is a group of 24 national professional associations, who have signed on to this position statement.

What the position paper attempts to do is define what is meant by "counseling" and how counseling can be effective as part of a prevention campaign.

Dr. Cleary has spoken about the need for behavior change as part of a prevention campaign. Our efforts have been to focus on what will facilitate the kind of behavior change that would, in fact, result in stopping the spread of HIV infection.

You have my written testimony which you can read. I do want to go over some of the recommendations.

We believe that testing as part of an AIDS prevention campaign should be voluntary rather than mandatory. This is because AIDS, by and large, is a behaviorally transmitted disease. We are talking about voluntary behaviors. In order to change and facilitate the change of voluntary behaviors, one needs to have the cooperation of the person with whom you are working.

We also believe that testing programs should be anonymous, whenever possible, and in the absence of this, that

they should be confidential with prohibitions against inappropriate disclosure. This comes as part of a desire to remove the barriers that are currently present, that prevent some people from seeking counseling and testing.

We also believe that testing should be part of a counseling program rather than vice-versa. In other words, we would like to see routine counseling available. We have targeted certain places where it makes the most sense to start with federally-funded programs. These would be family planning clinics, prenatal care clinics, sexually transmitted diseases clinics and substance abuse treatment centers. Here you will find, in all probability, the greatest number of people who are potentially infected.

What we are suggesting is that routine counseling be available. If in the pretest counseling, testing seems to be advisable, based on the history that is obtained, then the testing would go forward and post-test counseling would then be made available.

We believe that as part of the pretest counseling, it is important for individuals to be informed about the legal ramifications of HIV testing, including local and state laws about disclosure, confidentiality and non-discrimination.

Pretest counseling should involve prevention education. We make a differentiation between "education" and "counseling." Education is giving people information, i.e. factual information about how the virus is transmitted. Counseling involves making an individualized assessment of that individual's risk and attempting to give specific recommendations, tailored to that individual, about avoiding future transmission of the virus.

It would also involve informed consent, so that it would be clear that all people understood the implications, including the psychological implications, of a possible positive test results.

Post-test counseling should include further education about preventing infection and assistance for the seropositives in managing the potential psychological and social consequences of infection.

Follow-up mental health treatment should also be made available where an assessment indicates that the individual's commitment to behavior change is unclear or where severe psychological distress is evident. Our surveys indicate that of those tested through alternative test sites, approximately 7 percent would make use of follow-up counseling if it were made

available. Currently such services are not funded through alternative test sites.

We believe that an effective program that targets specific federally-funded programs would cost about $400 million for an initial start-up. It would be somewhat less expensive if it were continued.

We further believe that one of the ignored issues in the whole epidemic has been the mental health implications of the AIDS epidemic. A number of people, not only people with AIDS and ARCs, but particularly seropositives are known to be considerably more anxious and depressed than people who test negative.

We believe that there needs to be emphasis on mental health treatment for these people and for significant others of these people, as well as health care providers. We are recommending a $25 million appropriation directed through the National Institute of Mental Health to states in order to facilitate AIDS mental health treatment across the country.

We also believe that in order for these programs to be effective, you need, in essence, an army of counselors; people who are well-trained, not only about AIDS, but are also well-trained in how to work with people to facilitate behavior change. This is going to require a major allocation of funds and resources to train these people to be effective.

We also think that these programs need to be routinely evaluated so that they can be improved as they go forward.

Again, thank you for the opportunity to present these views.

CHAIRMAN WATKINS: Thank you, Dr. Morin.

Dr. Lawson.

DR. LAWSON: Mr. Chairman,, Members of the Commission, I am pleased that you invited me to speak to you. I am William Lawson. I am Assistant Professor of Psychiatry at the Vanderbilt University School of Medicine. I am also the Chief Medical Officer for the Department of Mental Health and Mental Retardation for the State of Tennessee and I am pleased to represent the American Psychiatric Association, a medical specialty society representing over 34,000 physicians nationwide, to discuss with you the multi-faceted issue of HIV antibody testing.

I am going to just pretty much agree with what some of the other members, particularly Dr. Morin, has already

recommended and the American Psychiatric Association supports, affirms the idea that all psychiatric patients who are to be treated based on their clinical conditions and that neither serological status nor HIV infection should impede the delivery of appropriate medical-psychiatric treatment.

Further, we support the idea consistent with our own guidelines that HIV serological testing should not be performed solely for the purpose of routine screening or staff awareness. As physicians, our association supports the position of the American Medical Association that testing for an antibody to the AIDS virus, when used in conjunction with appropriate counseling -- and Dr. Morin has already, I think, addressed that important issue -- can serve the important public health purpose of providing impetus for behavior change that minimizes the risk of AIDS virus.

We would emphasize that testing conducted along, in the absence of appropriate supportive counseling and without strictly adhering to confidentiality of test results is insufficient and there is some evidence that this could also be counterproductive.

We further feel that the types of behavioral changes needed to reduce the transmission of HIV infection is further supported by knowledge about AIDS and targeted education programs and we feel that those are the most effective tools in the arsenal of public health strategies aimed at motivating behavioral change.

Some of the questions that have come up include: Will knowledge of test results affect behavior change or stimulate undesirable reactions in the infected? Will a negative status lead to responsible behavior or engender a false sense of security? These kinds of studies are currently underway, but unfortunately this knowledge is limited because there hasn't been any other HIV-like infections existing in the past.

However, we can offer some guidance in terms of how to counsel and treat the individual under many of the pre and post-test scenarios. We cannot predict the outcome of knowledge of test results for individuals.

When we look at the literature, it is pretty mixed. The only thing that can be said for certain at this point is that knowledge of test results is clearly associated with this host of symptoms, ranging from depression, suicide and stress and to some, denial, and this is an important symptom because denial of the person who tested HIV positive, of course, can jeopardize others.

Current research is suggesting that learning one's serological test results can have either beneficial or adverse effects. We urge the Commission to recommend in subsequent reports the need for additional research to clearly identify the psychiatric ramifications of serological HIV testing and to define appropriate criteria for its use.

Education of different populations continues to be an important endeavor at ADAMHA. An innovative targeted approach to reach high risk groups, such as HIV drug users and to reach out to minority communities must continue to be evaluated.

More important than testing, we feel, is to expand outreach programs, especially since infection by IV drug users offer the most significant method of infection of low risk populations. Outreach programs directed to this population must be expanded.

Some have made the argument that testing shouldn't be at all and part of that argument stems from the observation that the psychological impact, as well as some of the documented social consequences of testing can be significant, including such matters as job loss, as well as the failure to be able to get appropriate referrals of people who are going from essential institutional settings into more deinstitutionalized settings.

On the other hand, we recognize that testing for medical diagnosis and management is critical. Clearly, this issue needs to be addressed concomitantly with the issue of the effectiveness of this information on social change. It is also essential that testing is done, whether the results are positive or negative, that pre and post-test counseling be done tailored to the needs of the patients.

As Dr. Morin has suggested, we found instances unfortunately in which the pre and post-test counseling was not useful but was meaningless to the patient. So, it must be directed to the specific patient populations that we are working with.

Statutes which mandate reporting of positive test results with clear patient advisers, we feel, may be keeping large numbers of infected and uninfected persons away from testing altogether. Mandatory reporting, especially in the absence of nondiscrimination guarantees, undermine the success of a voluntary testing program.

The goal of the testing program is to reach individuals at high risk of contracting AIDS. Most are already in minority groups fearful of government and are much less likely to come forward to be tested if there is a chance that their names will be reported. Our primary objective is to get

people tested, educated and into treatment when necessary. Mandatory reporting of those in need, we feel, will drive them underground and away from the held that they need.

The APA makes it clear that patients must be confident that issues discussed with their physicians are private and will not be divulged. We feel that a breach of confidentiality is only a last resort and is to be utilized only after scrupulous attention has been given to all other alternatives.

In situations where the patient HIV status is documented positive, our guidelines encourage the physician to work with and advise the patient to either terminate the behavior that places other persons at risk of infection or to notify individuals, who may be at continuing risk of exposure. This policy permits the physician to notify a third party believed to be at risk for infection only if the patient has clearly refused to change behavior or notify those at risk.

As I am sure that you know, the issue of testing is in reality several important sub-issues, which cannot be examined in a vacuum. The members of the American Psychiatric Association stand ready to assist the members of this Commission, as well as others, in the development of public policy responsive to individual safeguards and societal concerns.

CHAIRMAN WATKINS: Thank you, Dr. Lawson.

Our first questioner will be Mr. DeVos.

MR. DeVOS: Like some of you, I get fascinated with this need for more testing and more data. In the corporate world we have a new product. That is the same thing all my research people always tell me. Well, we can't go yet, we need more data. And if I listened to them forever, I would never get anything done.

It is sort of like going to the President now with a recommendation that we can't give you a recommendation because we don't have enough data. So, I have a very simple question today and I think, Dr. Burke, you have helped us greatly by getting rid of some of the confusion and misconceptions, but maybe just -- we have two men in the psychological field here. What is the one thing we can do -- we have all these various problems with testing and fear and all the rest of it -- what is the one thing we could recommend to the President of the United States that he could do to get people who are at risk to come in for a test?

DR. BURKE: We may get some divergent views on this but I think we may actually come to a common ground. I believe

that antidiscrimination is the key to having an effective program of testing, test-linked counseling. That is public health through testing.

MR. DeVOS: You see assurance in that one --

DR. BURKE: Yes, and I think there are a couple of ways to achieve that. One of them is through passage of forceful new legislation, but another one is to enforce existing legislation with high visibility. I believe that we could recommend to the President and to the Surgeon General of the Public Health Service that when there are blatant instances of unfair discrimination, like the case of the Florida boys, that they should speak out very clearly. They should teach the nation that the infection with HIV is really an unfortunate situation.

We need that leadership. We need it in legislation and we need it in the public relations so that the public in the United States understands fully the implications of the disease for those unfortunate people who are infected.

MR. DeVOS: If I come out with a new product and I want to get it sold, I have to have a slogan, a message that reaches people who are potential for this deal. And I am looking for that one message to deliver to these people so that instead of all this arguing about voluntary and all this, we forget that argument -- so that they will want to get tested so badly, just like they want to buy my product so badly, they will stand in line to do that.

DR. MORIN: Let me try to reshape your question here.

Having been involved for the last three years in marketing the test in San Francisco, we have done extensive advertising. We have even done a market research survey of why people will be tested and why they won't be tested.

The arguments that bring people to testing include first -- now, there may be something of medical benefit from knowing one's antibody status. Second, people are very concerned about the possibility of infecting others. And third, people who have not had much risk behavior and do have a certain level of anxiety hope to have some relief of that anxiety. Those are the major reasons that are found in marketing research on the test.

However, I beg to differ because I don't think we are trying to sell the test. What we are trying to sell is behavior change and what we are trying to do is prevent the spread of the virus. You can get behavior change without the test.

In San Francisco, we have set up a number of projects where people come in and talk about their need to change behavior and they do it. Group support is important for behavior change. We have a seroconversion rate that is close to zero among gay men in San Francisco. That is remarkable. This kind of behavior change has been facilitated through voluntary programs. It is now the group expectation and the community expectation that people do not do those things that spread the virus. That has to be our national way of thinking, that we do not spread this virus and we are going to do whatever we need to do to make sure that doesn't happen.

MR. DeVOS: I am a positive guy, who believes most people are well-intentioned and honorable and that is why I think if you appeal to some of that, we are going to get some place.

DR. SANDLER: I wonder if I might make a comment on that and that would be, I think you have to get on with it and that is the way to move with it. It was June 1985, only a few months after the antibody test had been licensed, the Red Cross decided at that point -- now, that is an awfully long time ago -- that we were going to start notifying people with positive tests and we did it and we have been doing it since.

Now, a lot of people today are still wringing their hands but we have been notifying people who came into blood centers -- and remember, we have just the opposite situation. We have a person who has signed on a dotted line saying I have no risk behavior. Now, since June of 1985, we have been going to those people and saying the lab test is sufficiently reliable for us to come to you and tell you you may not do any blood again. You are potentially infectious. You must get counseling. The sky has not caved in.

DR. LAWSON: Let me just also address that point. I want to agree with the other panelists that the issue really -- and I think if there is one message, it is really not to base the program on information about test results because I think the literature is pretty clear that it may or may not cause the desirable behavior that we want.

I think the positive message, as the San Francisco experience has described quite well, is that using education programs targeted, we can produce change. Unfortunately, as most of the studies that look at the impact of drug abuse programs have demonstrated, minority groups are differentially not involved. I think that if the President is going to get one message, we have to target to those groups, who have not been reached before and we will have to push the idea that it is possible to change people's behavior with the appropriate educational programs, but it is very unclear as to whether

knowledge of test results is going to bring about the kind of desirable behavioral change that we would like to see.

MR. DeVOS: Dr. Morin, would you be kind enough to send that report to the Commission to the attention of the Admiral, so that we could have that data in our file and then for this report?

DR. MORIN: Yes.

MR. DeVOS: Thank you.

CHAIRMAN WATKINS: Mrs. Gebbie.

MRS. GEBBIE: I think Dr. Cleary has a comment.

DR. CLEARY: I would just like to second the opinion that I think that we do have the data. We can proceed; we should proceed. Obviously, at the New York Blood Center we test every unit of blood. We obviously advise people. We think we have been very successful. I think you can make a tremendous impact.

What we want to do is minimize shooting ourselves in the foot, if you will. We want to contact people and we want to have screening as inclusive as possible. I think to do so we need to recognize that one, the things that prevent people from coming in are fear of disclosure and, two, once they do have a positive test result, we want to maximize behavior change.

In the Blood Center, we have been told by persons -- and this makes us shudder -- that they have actually donated blood to have their blood tested because our program has such a good reputation. I don't think that is the way to proceed. I think the way to proceed is to establish a high priority for quality counseling, quality support throughout the country. I think we have enough models to do that today.

CHAIRMAN WATKINS: Mrs. Gebbie.

MRS. GEBBIE: The longer we go on, I guess the harder it is to just ask a question without some comment.

I remain impressed and feel the need to reemphasize that when we are certain that all witnesses are answering the same question, there is a remarkable degree of cohesion in the answers. Our problem, particularly around this particular piece of the debate, is that we often don't ask sufficiently clear questions, so we get three different answers because people interpreted the question somewhat differently.

The focus on behavior change, to me, is critically important because I want some people that are currently negative to change their behavior, too, so that we don't feed into the epidemic and I get concerned if we narrow it.

Given that there is that remarkable degree of cohesion when we really stick to looking at each question very precisely, but also given that because of the confusion in this debate, we have got some policies already made or some people already dug in onto viewpoints, based on early experiences -- I guess I am harking back to some testimony we have heard on developing community policies and such -- how do we construct the debate from here on out so that we can take that degree of cohesion and really clear views on moving ahead and make it happen?

I think having a slogan or clear, positive thing will be helpful but it is still going to have to be translated into actual programs or something. Is that doable at a single national level or ought we move toward a recommendation that allows that cohesion to be acted out at a local level or at a state level or at a regional level or at a subgroup level that somehow cuts across geographic boundaries but is targeted around drug users or some other subgroup?

I think we really need some discussion from as many of you as can comment on how we make that next move.

DR. CLEARY: I think we should do both. I think we should move immediately at a national level to disseminate information. I think it is appalling that we have materials available that have not been distributed. I think it is striking that European nations with much, much lower levels of prevalence, have been much more aggressive in disseminating information about this disease.

The country is very knowledgeable about AIDS, about routes of transmission. It is less knowledgeable about things such as casual transmission and so on. I think that is counterproductive and feeds into the epidemic. So, I think that is one recommendation you could make.

I also think that we know that such type of programs are destined to failure unless there is more localized, more subgroup specific and more tailored types of interventions, both among populations in general and among persons who are seropositive. So, I think it has to be nationally coordinated, it is not a local problem. There has to be a national response immediately; however, that will not suffice. I think there also has to be detailed levels of programs, both at state and local levels, to address the specific issues in different communities.

DR. MORIN: I agree. I think where we are finding a lot of common ground is the agreement of facilitating behavior change, both among positives and negatives, is the only way we are going to stop the spread of the virus. There is general agreement on that. How you do it and who does it, have become major policy problems.

Theoretically, the Centers for Disease Control should be facilitating the national program on preventing the spread of the virus. You will find that they have very few staff with expertise in the behavioral sciences. They offer virtually no technical assistance to the states and local programs on how best facilitate behavior change.

All of these programs are going to have to be organized and run at a local small unit level because that is the only way you are ever going to reach people on a one to one basis and facilitate the kind of change we are talking about. This is how best to facilitate these prevention programs.

There has been a general lack of leadership from the CDC in facilitating targeted, local prevention programs.

DR. LAWSON: I just want to add to that two other points and that is I agree with your points, but I would add another dimension and that is the communication change. Obviously, if we provide information at a local level, we run into a very interesting phenomena and that is that the usual mechanisms that we would have that would work very well for the majority of the community may not reach the black and Hispanic populations and it is not because of some overt effort of discrimination. It is because the usual mechanisms have not been designed in the past that have been meaningful to reach those populations. What we need to do is to look at and recognize that there may be different methods of communications, perhaps through the churches, perhaps through an informal network, in which we need to address those concerns.

Another way it is looked at is also in terms of modality. It is interesting that there has been very little discussion in terms of the chronically mentally ill and, yet, we well recognize that these folks make up a disproportionate number of the homeless. Why is that? I suspect it is because we have compartmentalized the homeless, the mentally ill in one dimension and AIDS in another dimension and yet we see them as a potential and major vector because of the fact that they are frequently victimized and also because this is a population of folks who are very, very likely to end up homeless, perhaps because of the presence of HIV infection and not having access to the usual kind of support facilities in the community.

DR. BURKE: I think another perspective on it is that we are finally coming to the realization that we need to address the problem of AIDS and HIV primarily as a medical problem. It is in the best interest of our society and it is in the best interest of the individual to know fully about his own medical condition. If there are obstacles to achieving this goal, they must be overcome. One of the obstacles is the discrimination. Another is the problem of false positive testing, but we are moving beyond that now.

The issues are how can we get everybody in the United States, who is infected with this virus, to know that they are infected and how can we do that with the least unfavorable impact to the individual. If we can take those steps, then we have a very realistic chance of beating the epidemic. And I think that is largely what our panelists are saying here today is that the medical goal, the medical diagnosis, the medical approach to the epidemic is achievable, and it is achievable now.

CHAIRMAN WATKINS: Dr. Burke, let me have a quick follow-up on that because it is an extremely important point you are raising.

The Centers for Disease Control have recommended and the Medicine Policy Council of the White House has approved the so-called family surveys. These include the 30 SMSA. They also include going out for bid for three pilot cities, in which actually seroprevalence data are going to be obtained. If you were responsible for preparing the three pilot cities properly to -- with the idea, with the objective of a hundred percent volunteerism because we can prove our ability to the extent reasonably practical on anonymity, confidentiality, prevention from discrimination in those cities, would you not then build a strategy along the line you recommended as a precursor to conducting that, to ensure that the value of the seroprevalence data in the three pilot cities were optimized or would you just let it happen?

In other words, you are all telling us that certain precursors have to take place to get the seroprevalence data to be valuable. So, would you give me your strategy then -- let's say you are in charge and let's say Nashville was a selected site and it was one of the 30 SMSAs, which it probably is not, but let's say that you were responsible to build that strategy so when the testing was actually done by the health officials in this area to obtain the data, you would feel comfortable that people would be willing to come forward and participate because it is not only in their best interest but also in the interest of public health, what strategy would you build then, starting at the national down to other levels?

What are the things that go through your check-off list?

DR. BURKE: That is quite a tall order, sir.

CHAIRMAN WATKINS: But that is the order that is at hand and we are getting all around it, but we have to deal with it and we have had the rhetoric and the generalities. Now, let's get specific. What is the strategy that you want us to recommend, to pass to CDC to say you must -- because I have asked this to the director of the Centers for Disease Control and he agrees that something like that ought to be done ahead of time, so that we don't just let it happen with technical people doing it, without all the other psychosocial interest at hand, in place properly.

DR. BURKE: There are two separate approaches to screening. One of them is to develop data. If that is your primary interest, then it is essential to get a very representative and unbiased sample of the population. And, frankly, I think that in the current psychological milieu of the United States, that is close to impossible on a voluntary basis because of the two or three years of background that we have had. Maybe five or ten years from now, once the psychology has changed in the United States, that it may be possible to get 100 percent voluntary participation in an HIV screening program.

The second use of testing is as a medical device for the individual. There it is up to the individual physician to provide the test to the individual, to make sure that they understand the effects of that virus on themselves and their loved ones. So, what I am saying is that I don't think it is possible to have the perfect model in place within the next year and expect a hundred percent of Americans to come forward for testing. I think that is just too fast a time scale to expect realistically.

The purpose of the family of surveys is to develop data. It is not designed to have a direct impact on disease transmission. It is primarily a surveillance tool, rather than an intervention tool.

CHAIRMAN WATKINS: I understand, but if you are going after even good data, would you not want to have some kind of an objective to achieve a percentage of participation on the statistically valid information so that it is useful or would you hold off -- would you recommend holding off until you did that because otherwise it could be counterproductive.

DR. BURKE: Once you have made that recognition that there are two possible uses of testing; one, surveillance and second, interventive, then you can proceed to conduct your

surveillance and say, okay, how can we get an unbiased, good representative sample of the population. There are a couple of places to do that and I think, by and large, the CDC's approach is reasonable; that is, to go to hospital admissions and do identifier-unlinked studies; to go to women who are delivering babies and to determine what the prevalences are there.

I think to try to go out into the population right now and expect a hundred percent cooperation is just unrealistic. We are going to have to use the best data available, which is people who come routinely into contact with the medical profession.

CHAIRMAN WATKINS: All right. Have you recommended then that there are not be a three pilot city seroprevalence, blood-letting effort because you don't think it is a proper to go to get the right data, that we are not going to get the right data unless we lay the proper groundwork?

DR. BURKE: Well, it is a question, again, of how you go about obtaining those samples.

CHAIRMAN WATKINS: I am not talking about the 30 SMSAs. I am talking about the three major pilot cities, in which seroprevalence data is going to be obtained in a random basis to get the right demographic information that is necessary to determine seroprevalence in those three cities and perhaps related to the 30 SMSA data in those three cities.

DR. BURKE: I think at this point the data may come out of that may be very difficult to interpret, sir.

CHAIRMAN WATKINS: Well, are you recommending that it be deferred until such time as we are ready to run it properly in order to get the right data or is it still valuable data no matter who participates?

DR. BURKE: Tough question, sir. I think that it probably will be valuable data in that it will reveal infection in some individuals who no one expected to be positive. That it may not give a cut of the actual distribution of infections in that community, but I think that the value that may come out of that is that we may be surprised in a survey of that nature.

So, I would go ahead with it, sir.

CHAIRMAN WATKINS: Thank you.

Dr. Lee.

DR. LEE: I will yield to the distinguished Commissioner on my left.

MS. PULLEN: This is the first time I have been on Dr. Lee's left.

[Laughter.]

I would like to point out that in terms of the audience, I am to Dr. Lee's right.

Dr. Burke, would you please comment on whether you believe that universal HIV screening of patients at Walter Reed Army Hospital either is having or will have an effect on the delivery of health care in that facility and what effect?

DR. BURKE: We conducted a blinded survey at our hospital, about a year and a half ago to determine how frequently patients were being admitted to our hospital, that were totally unsuspected of being HIV positive. As you are aware, we have a very aggressive HIV testing program in the military and for someone to slip through our nets, that is remain undetected through clinical suspicion through our screening programs, we thought would be unusual.

Nonetheless, we did find that about one out of every 200 admissions to the hospital was a patient with an unsuspected HIV infection. That information was in turn provided through the channels in the Department of Defense to help make decisions about whether or not military hospital admissions should be routinely tested. The Army policy, which has just gone into effect just within the last month or so, is that hospital admissions, all hospital admissions, should be routinely screened. This policy hasn't been implemented yet, so I can't tell you whether or not the routine screening has had a favorable or unfavorable impact.

Let me add parenthetically that the blinded type of survey that we did in our hospital, that is to take the blood samples that were being sent for other routine tests, remove the patient identifiers from the blood tube, and test, is something every hospital in the United States could do today very simply and at very low cost.

When I am told that the resources aren't available to determine the prevalence of HIV in a given hospital, I frankly don't believe it. It means that people don't want to do it. There are ways that each jurisdiction can develop this type of prevalence information and make the decision hospital by hospital. Is it worth it? If a hospital in Des Moines finds that there are no persons who are infected, then they might decide not to implement routine admission testing. If a hospital in New Jersey found in a blinded study that 1 to 5 percent of their admissions were patients with unsuspected HIV

infections, then they might want to seriously consider routine admission testing.

CHAIRMAN WATKINS: Dr. Walsh.

DR. WALSH: Well, for the first time in a couple of days, I am finally encouraged and unconfused because particularly of the testimony of this panel and particularly with what Dr. Sandler and yourself have said about your experience. When you stop to think that between you, you have 25 million tests or tests that have been done, you haven't chased anybody underground. You haven't had anybody commit suicide and I think that the stress that maybe where we have gone off is we get in the use of the generic term of "public health" and then you get into basically a political organization, which is an organization of public health officials, and that is where a lot of the civil liberty arguments arise and we lose sight -- and I think your use of the term "medical knowledge" is perhaps better, the medical approach to this is better and it might give us a key of how to go because the data that you two have presented, to my mind, is an invaluable sample.

It also is an invaluable demonstration that the people whom you have diagnosed are for the most part grateful and for the most part do go to counseling and get counseling, which is an essential cornerstone of what many of the civil liberty arguments have been about.

I just feel that the waters have been so muddied by some of the other testimony that we have heard, that I feel like I have just had a wonderful cold shower hearing this panel and I think you have given us a much better sense of direction because you have recognized concerns; you have recognized, you know, the confidentiality and discrimination, but you have demonstrated that you are thinking ahead for this country. And as you pointed out, Dr. Morin, the behavioral change, once you have the knowledge, is very important, but the knowledge of the disease is an important aspect of the receptivity because I still maintain that most people want to live as long as they can and they are not going to run away from a test. And I heartily endorse a modification, perhaps, of the education programs as they are now constituted.

Dr. Cleary pointed out, you know, that CDC is sitting on some stuff and so on, but I am not one who believes sending out 20 million pieces of literature to a lot of houses is going to accomplish a thing, but I think if the kind of education that you are talking about -- and I think that is what Dr. Cleary is getting at -- is so important that if you educated people, as Dr. Crenshaw tried to get out earlier, as to the value of why this test is being done, what is the positive side of testing, how are

-- you know, this is good for your country; it is good for your health; it is good for everything that we are doing and it is the only way to contain the epidemic. I think we could put away so much of the fear and I really don't have any questions because I am just sitting here thoroughly delighted.

CHAIRMAN WATKINS: Dr. SerVaas.

DR. SerVAAS: Jerry Sandler, you fired the first blast when you said that I called this a $3.00 test at the Red Cross and I want to tell you that if you are paying $3.00 for your little bottle and then just the test, then you should buy them from us because we are paying $1.21 and we buy a lot fewer than you do and I can tell you that you had better get next to your purchasing agent because I really --

CHAIRMAN WATKINS: That may be a conflict of interest, Dr. SerVaas.

DR. SerVAAS: But, Dr. Sandler, there must be some misunderstanding because in the interest of testing and knowing what it costs, I researched this before I came for this testing period and I was told that the Army now pays a little less than $4.00. So, I didn't believe the Army necessarily, so I called Damon Laboratories from whom they buy their tests, with whom they contract. Isn't that right? And I talked extensively with Damon Laboratories over a period of several months.

They assured me that they charge the Army $4.00 and that includes the Western Blot on the positives. Now, they said the Red Cross gets by for less than $4.00. In fact, they said the Red Cross, it costs them only $3.00 because the Red Cross has so few Western Blots to do. They have only ELISAs and ELISAs are very cheap. They said we do 8,000 every night, 8,000 ELISA tests. That is the screening test, as you all know. And they don't really have to send out too many for the confirmatory test, which costs us at Mayo Clinic $23.00. We don't send out a lot either but a lot more than you do per capita.

Now, at the blood banks you aren't going to send many Western Blot tests out, of course, because you don't get that many coming in with their positive blood. So, if you are really paying $3.00 for your little kit, then you really are paying too much because Damon Laboratories feel -- and before you get to answer, I have a question for you and it isn't this -- Damon also said and there are other laboratories besides this commercial lab, that they send 40 knowns out to the -- they receive 40 knowns from the Army every -- with every batch every month and if they get them wrong, if they get any of those known tests wrong, then they don't get paid or they have to do them over.

Now, this is their way of certifying the Damon Laboratories or whatever other commercial laboratory they use. Damon said they could do our tests in the Middle West for $5.00, including everything. That includes your little bottle. That includes the Western Blot, if necessary, and they would like a little more experience to see how many Western Blots they would need to do.

Now, the reason that I wanted to make that clear is we -- I feel so very strongly about testing because we have always -- my entire professional career has been in prevention. So that we do mammography and all the other things, spirometry and early detection of disease. So, I have nothing in my career except testing in my effort to prevent the spread of -- it would be the easiest, most logical thing for us to be concerned about and that is why I have researched it.

Now, I have the feeling that we are sitting here dragging our feet, Jerry Sandler, in exactly the same way we drug our feet when we knew how many kids were dying or going to die from hemophilia and we just said, oh, we must test a little longer; we must study this a little longer before we defer the blood. And I just have one question that I want to ask you when I get through, but I want to tell you that the history shows that we first knew that the hemophiliac -- the first hemophiliac patient had Pneumocystis pneumonia very early months, late December or early 1982. Now, when we knew that there were those at the Hemophilia Foundation who were very concerned and many people knew that because they pooled the blood, so many people would be getting AIDS from the blood for their Factor 8.

Now, we knew that in '82 and the stress from the people who were so -- getting more than their share of heartburn because they couldn't convince the CDC. They couldn't convince the Red Cross. They couldn't convince the AABB, the blood bankers. They couldn't. They tried. And do you know that all through '82 and through -- when in '83 did we start deferring high risk blood, do you -- well, I will ask you that later.

I can tell you that it was not until Don Francis said as far as I am concerned the assembled leaders of the blood banking industry are about to take a course of action that could be best termed negligent homicide. This was a year before we started deferring the blood that is the reason we are looking with great compassion at the sad fact that 9,000 more -- upwards of 9,000 kids, boys and girls, but mostly boys, are now AIDS positive and are going to be suffering from AIDS. This is two years, almost two years, but the blood bank -- and I think, Dr. Cleary, you mentioned the New York Blood Bank. In the words of the New York Blood Bank in 1983 were there are at most three cases of AIDS from blood donations and the evidence in two of these is very soft. And there are only a handful of cases among

hemophiliacs. This is the then president of the New York Blood Center. These are non-profits.

And do you know that it was the for-profits, who first deferred high risk blood and when we first started deferring blood from the special interest groups, we said we won't defer blood from those who are not promiscuous, just those who are completely promiscuous about their sex life, but the story is a sad commentary and it is blood on the hands of the foot draggers and the people who said let's sit back and wait until all the facts are in; we really don't have many cases, but all of these poor kids were getting their Factor 8 infused into their arms by their mothers during this time.

Now, my question to you, Jerry Sandler, since you picked on me and said I wasn't right about my facts, my question to you is, the Red Cross, is it true that the for-profit Alpha Therapeutic Corporation or whatever, were the first and that the Red Cross and the other non-profit blood banks came in quite a lot later as far as deferring any high risk -- as deferring the high risk blood and what defense do you have for the slowness with which our public health people and our people at the CDC and our people at the blood banks, the non-profit blood banks, at their reluctance to begin deferring blood when it was very apparent that that blood was going to kill a lot of people? When did you start deferring blood compared to the for-profits?

DR. SANDLER: Hi. Dr. SerVaas --

DR. LEE: Could you clarify the question, please?

DR. SerVAAS: Because we are doing this all over again. We are sitting here dragging our feet.

DR. SANDLER: I have taken some notes, Dr. Lee.

CHAIRMAN WATKINS: There is a strong letter that follows, Dr. Sandler.

DR. SANDLER: Dr. SerVaas, I can assure you that there was no intent on my part to do, other than trying for the record, correct a factual reference to the cost. It certainly wasn't a blast. My wife can tell you what a blast is from me when I really mean it.

With regard to the facts about the cost, we purchase 18 million test kits from one particular manufacturer, Abbott Laboratories. I can assure you that no one in the world buys the individual Abbott ELISA test cheaper than the American Red Cross. The cost of the bottle is well less than $1.00, the actual bottle. But we have to buy a lot of bottles for proficiency, for the protocol. We do not use the free Western

Blot service available to all users of Abbott Laboratory's test. We go to DuPont Laboratories and pay over $30.00 per test in order to get an FDA-licensed Western Blot.

So, the cost of the bottle -- that was just a way of saying "reagents only." The cost for the Red Cross to do the test varies by community. In some communities we have only two positive tests per 100,000 people. In some other communities we have more than 50 positives in the United States and outside the United States, outside the continental United States, where we test also, we have extraordinarily high numbers. So --

DR. SerVAAS: Jerry, I explained that all in my question. I have only one question for you.

DR. SANDLER: Oh, okay. Sorry.

DR. SerVAAS: And that is we know that it varies according to how many Western Blots you do. Of course, it does, but my question is about the blood because I am so concerned that we are sitting here, we are looking for more ways to slow down the thing that Don Burke could do for us. I think that voluntary testing -- I wouldn't be so strong about this except I can tell you that people line up to be tested voluntarily and we have never had a breach of confidence and we have never had a case of discrimination on the people we have notified and we have never notified anyone without a doctor doing it when they are positive without counseling and I can't tolerate our sitting here as a responsible group with this health care crisis raging and we are still looking for more statistics, but, Jerry, I want to know -- I want to show that history is repeating itself.

So, I want you to tell us how long did you wait to defer blood after we knew that these hemophiliac kids had died or had AIDS? How long did we wait? From 1982, when Francis pounded on the table and the CDC and everyone tried to get them to start deferring high risk, how long did we dawdle?

DR. SANDLER: On the subject of dawdling, the definitive, scientifically-responsible act that could have been taken was to begin implementing testing. The chairman of Abbott Laboratories was given the first FDA license at 10:00 in the morning on March 2nd, 1985, which permitted us to take definitive action. Ten minutes after the chairman of the board of Abbott Laboratories got the license, I met with him in the Federal Building at 300 Constitution Avenue and made an oral agreement and that night we started to test. Now, that --

DR. SerVAAS: Jerry, that is not my question at all because Shadle(?) at the CDC says the test is fine but if we just spent more time doing a better job of deferring bad donors, we would have a lot fewer slips at the blood bank.

Now, my question is -- we are talking about deferring blood so that the hemophiliac kids, who were already getting infected, we didn't defer the blood. That is the biggest thing we could do, the biggest thing at that point. We didn't have an FDA-approved test. But we could defer the blood, which we did do before we started testing, a good while before, but not for about a year and a half.

DR. SANDLER: Dr. SerVaas, let me explain --

DR. SerVAAS: Two years, what was it?

DR. SANDLER: You are quite right. You are absolutely right. Individual people -- and you have named at least two of them, who are employed by the CDC, did make those statements and the American Red Cross turned to the CDC and asked what is the position of the CDC. Now, in the same way that you as a member of this Commission have said several things, what you have said is not, necessarily, the position of this Commission, nor was what Don Francis said the position of the CDC. We respond to CDC recommendations. We do not, necessarily, respond to opinions of individual employees when these opinions are not reflected by their organizational policies or recommendations.

DR. SerVAAS: All right. There were bomb threats -- the National Hemophiliac Association had bomb threats on their office when it was even talked about deferring the blood because it was against the civil rights of the people who were supposed to be able to give blood and not stigmatize them at a time when their rights were just then being brought forward.

Now, these are high risk people and the population sided in but, Jerry, it is blood on our hands and you know it is and if we do the same thing again that we did for the hemophiliacs, then we can spend a lot of time with individual cases and tragic cases, but there are so many of them, and they went on so long unnecessarily, that I feel right now -- in Indiana we lost two mothers because they didn't know that their spouses, their husbands were -- one was a bisexual and the other one was a former drug addict -- we lost two mothers and one baby and another sister who now has it.

Now, that is just people that I know about and I think it is blood on our hands that we don't let people know that they are AIDS positive and I think that Dr. Cleary or any other doctor who confuses the cost with a lot of expensive pretest counseling for people who have had blood transfusions or were former drug addicts and now are not, pretest counseling can draw the costs far up and his article in JAMA was described in a most unflattering manner by the AMA yesterday to me, as being not very responsible, but the word was "insipid."

Now, that was someone who came here from the AMA and I have to agree that the battle lines are forming, Dr. Sandler, and, Jerry, I don't think that we want to do the same thing in foot dragging that we did and let the for-profits in this case start deferring blood before the non-profits and that includes AABB and the Red Cross.

My question to you is how can you explain just that one thing. Why you waited so long and why when responsible people could show you that those people were getting infected, why did we not take action?

DR. SANDLER: I guess when you are paying people to give blood, you can't trust them as much. So, you probably have to take action a little bit differently when you are paying people to tell the truth, as opposed to people volunteering.

If we want to spend our time, Admiral Watkins, on this subject, we can. I think some of us are going to try to catch an airplane.

CHAIRMAN WATKINS: I think we really need to move along. If there are any other comments --

DR. SerVAAS: Well, there is just one. There was a commercial reason. They were selling to the hemophiliacs and they were threatening their own customers by giving them the blood and then their doing it really forced the for-profits to start doing it, to defer that blood. It is a tragic tale.

CHAIRMAN WATKINS: Dr. Crenshaw.

DR. CRENSHAW: Thank you.

Dr. Burke, from conversation that I recall in the past, you said one thing to me that I thought was pretty compelling in response to the question the Admiral asked, what could we do to get the American public to really respond in a way to make these kind of studies meaningful.

What you said to me is that if the President got on the air waves and really made a plea saying we need your held, this is really important to our national health, et cetera, and not just saying this is something that, you know, would be nice if you did, but really made a plea and asked for all Americans to be responsible and to come forward and to really help on this issue of these three cities or however it were done, that that in and of itself, if it were done well and if it were done and marketed widely, which it would be if he preempted channels, could turn the whole thing around.

Do you still believe that and am I quoting you accurately?

DR. BURKE: Thank you, Dr. Crenshaw.

I appear here today as a representative of the Department of Defense and it is not my position to advise directly the President of the United States.

DR. CRENSHAW: I am sorry. A little procedure and protocol there.

DR. BURKE: However, we did have this conversation; I believe that a high level of leadership in the Federal Government would be very helpful in the national effort. If the President were to do this, I would personally be delighted.

Let me add that that is my personal opinion, that the national effort requires this type of additional emphasis to ensure full public participation. With that caveat aside, yes, I still hold to that position.

DR. CRENSHAW: Thank you. The other thing I would appreciate your comment on is if hypothetically -- and I want to just deal with this hypothetically -- when the antibody tests became available, if the recommendations made by Walter Reed Army Hospital on reclassifying the disease to stages of HIV positive and if the same way that AIDS is being dealt with, the whole infection were -- beginning in '85 -- how far ahead would we be? What advantages would that have provided? And somewhat in line with Cory's comments, Dr. SerVaas' comments, are we foot dragging and how much longer can we endure this with the void of knowledge it leaves us with?

DR. BURKE: I have fairly strong views on this point. I think the time has come to recognize that the term AIDS itself and the whole concept of AIDS is an anachronism. We know that the etiology of this disease is the human immunodeficiency virus. This Commission is named the Commission on the Human Immunodeficiency Virus and, yet, the Centers for Disease Control continues to report on a weekly basis only the AIDS cases.

Because we don't have in place on a national level any mechanisms for surveillance for HIV in the community, we have no idea about what is happening to the real epidemic. The real epidemic is the virus infection as it occurs today. AIDS cases in 1988 are HIV infections that occurred in 1978; that is, the data we are amassing today on AIDS is a decade old. As an epidemiologist, I cannot make rational decisions and I cannot make allocation of resources based on data which is a decade old.

So, I think it is important to change the focus away from AIDS. The only way to do that is to be more aggressive

about diagnosing HIV infections wherever and whenever they occur. Once you have diagnosed an individual, it is a straightforward matter, using certain staging systems like the Walter Reed staging system or others, to determine which patients are early stage HIV infections and which others are late stage infections.

But I think we would we would be much further ahead today in our understanding and in our approach to this disease if from the beginning, when the blood tests were available, that we aggressively applied those as widely as available. They are good tests. This is a medical condition requiring diagnosis. Those diagnoses should be reported on a regular basis. We should deal with this disease as if we would any other.

DR. CRENSHAW: Thank you.

And then, Dr. Morin, I wanted to publicly compliment you on the leadership you have shown in San Francisco, where you have encouraged widespread testing in the gay community, where by contrast to your sister city on the East, that is not yet the program that is being taught from within the gay community. Would you elaborate on that a little bit.

DR. MORIN: Well, first of all, it is not widespread testing. We are recommending people come in for counseling --

DR. CRENSHAW: Well, test-linked counseling, but I mean I have heard you speak much more strongly about encouraging gay men in San Francisco to be tested, as long as it is done with counseling and I think that it reflects very important leadership there that I would like to see get a little more contagious.

DR. MORIN: We believe there are certain advantages for gay men being tested and particularly those who are positive, to monitor their health status, and to attempt to find ways of medically intervening early in HIV infections, so that one can ward off the deterioration of the immune system by early intervention. That has proven to be a very successful argument with gay men, particularly those who fear they might be infected.

Let me comment just briefly, however, because I think some of the comments here need to be clarified. The voluntary programs coupled with counseling work remarkably well in terms of facilitating behavior change. The only data we have to date on whether you get behavior change or not in the mandatory testing program really comes from the military. The follow-up data on people who were traced in Colorado, reported by the Colorado Health Department, indicates virtually no behavior change.

Behavior change has to do with the quality of the exit counseling. It seems to me foolish to go forward in identifying all of these people who are infected and then proceed to do nothing in terms of facilitating behavior change with such people.

DR. CRENSHAW: I think we would all agree with you on that point.

DR. MORIN: And talk about foot dragging -- let me talk a bit about foot dragging in the prevention effort. Since July of last year, legislation that would supply the funds to do the counseling at sexually transmitted disease clinics and substance abuse clinics, as well as prenatal care and family planning clinics, has been stalled in Congress.

Right now, if you go into a sexually transmitted disease clinic in the United States, no one talks to you about HIV infection. I think that is foot dragging. I think it is irresponsible. Why is that legislation stalled? It is stalled because certain members of Congress have become fixated on testing everyone in the country and have become completely irrational about it. Others completely oppose nondiscrimination provisions, which are also included as an incentive to testing in that bill.

So, you have two big barriers to actually doing effective prevention education and counseling in this country --these two issues.

DR. CRENSHAW: Well, I would emphasize that, speaking for myself and I hope eventually for the panel, I think testing is as important for negatives, to ensure that status, as positives and I will certainly do everything I can to bring that along.

My last quickie, because I don't want to absorb too much time, is for Dr. Sandler. I was pleased to hear that and to have been aware that the blood banks are notifying. What is the lag time? It used to be 45 or 65 days before you were allowed by certain state laws in some areas to tell someone who donated blood that they were positive.

I don't want you to go into all the reasons that that is there because I think those are fairly well-discussed, but what is the lag time now? Do you notify them within the week, immediately or are you waiting for two or three months?

DR. SANDLER: I wish there were a quick answer to that. Each one of our 56 regions operates within a state that has its own laws and there are an enormous variety of programs in each one and there is just really no general statement.

I can make this general statement. We are not notifying promptly. I think that is one thing I could certainly say, but there are delays that are necessary for a variety of reasons. There is no two notification programs that are alike in the Red Cross with regard to notification. The process is highly individualized.

DR. CRENSHAW: So, you can't make a general statement, but within a week or two --

DR. SANDLER: It is not as soon as a week or two under any -- it requires considerably longer than that.

DR. CRENSHAW: What could we do to help because you are saying not soon enough and I agree with. I think we ought to get that knowledge back to people as quickly as reasonably possible. How can we help to facilitate that?

DR. SANDLER: The limiting factor on that is the absence of alternatives for some people to get a quick test back. Let me explain. If we became known as the place that in town were you can get a test result back in writing in a week, we will become the place for high risk individuals to get tested in every community. We would like to have our answers come back sooner, but if we were the best test and the quickest test in town, the safety of the blood supply would be threatened.

What can you do? If there were multiple, confidential, anonymous, places for anyone with risk behavior to be tested, then there would be no concern on our part to get an answer really back fast, but we are holding back in certain communities so we are not the best show in town.

DR. CRENSHAW: Thank you.

CHAIRMAN WATKINS: Dr. Lilly.

DR. LILLY: I am going to pretend that I am Rich DeVos for a minute and ask a cost question. We have actually had a good bit of discussing of cost but basically we haven't been talking about cost effectiveness. I took some figures from page 2 of Dr. Cleary's presentation about having to do with testing of candidates for marriage license applicants, where he suggested that there might be approximately 3 1/2 million people, I think, tested per year and then taking various figures as to how much that test might cost, I first took Colonel Burke's estimate of $4.00 and then more recently I took Dr. SerVaas' estimate of $5.00 and then calculating that procedure might identify 1,200 positives in any given year, to see just how much it had cost to identify that positive and depending on the

figures you took, it came between 40 and 90 thousand dollars per identified individual.

Now, given the fact that we all seem to be in agreement that just doing the test is not the point, but -- not just identifying people who are positive is not the point, but that of changing behavior is the point, I am wondering if anyone thinks that we might do better with that 40 to 90 thousand dollars by another approach, such as education?

It is addressed to whoever has an opinion on the subject.

DR. CLEARY: I was quoted and have an opinion, so I will respond. I think in many senses cost is a red herring. I think if we had a test that had an efficacious impact, almost all of us would spend very large amounts of money to implement the test. It can be done relatively cheaply.

Let me come back to the quote from Damon Laboratories. I phoned Damon Laboratories to see how much they would cost and they gave me a quote, which was substantially higher. I don't remember the exact cost right now. My second question to Damon Laboratories was does that include counseling? And they said yes it does. We will send you a pamphlet if you have a positive result.

I am not sure that those of you who have not worked with seropositive individuals understand how enormously difficult it is to change behavior, how carefully you have to work with them to tell partners, to change their behavior. It is an enormous task.

And the direct answer to your question is yes, I think we could spend those monies more effectively by encouraging counseling, encouraging testing, but above all things, focusing on the behavior. We have to change behavior if we are to stop this epidemic. And I agree there has been foot dragging and I will tell you where there has been foot dragging.

We do testing at the New York Blood Center. We have tested and screened and notified 1 1/2 million blood samples, okay, but there is still reluctance among many people and there is a lack of funds to do the appropriate counseling. We have a federal grant and it is a demonstration grant. We are doing a study on counseling. There are no direct services monies to do that kind -- the cost and the false positives and the technical issues are a red herring. We need to get out there and stop foot dragging, but to change the behavior and I think Dr. Burke could address this himself, but I have heard -- you know, the fact that you are identifying those new persons in the hospital

indicate that something in the screening program is not efficacious.

We have to change the behavior, stop the spread. Identification is fine but stopping the spread, keep in mind, is the ultimate issue here.

DR. LILLY: I would concur as I stated yesterday, as a matter of fact, to someone else who made that point. I have always felt that the best reason for deciding to impose a policy with respect to testing or anything else is to ask one's self will this measure be effective in halting transmission of the virus.

DR. BURKE: I would like to respond to that also.

I think that some of the numbers used in the original article by Dr. Cleary and his colleagues were probably substantial underestimates of the actual prevalences. Those were largely based on blood donors, who are extremely prescreened ahead of time. So, those costs of $40,000.00 per case are probably well off of the actual figure. I think the cost figures that I presented earlier are probably much truer. So, I think the cost/benefit that is given in the Cleary paper is somewhat off.

I do agree, however, that the purpose of HIV testing programs in the civilian community is not simply to identify individuals who are positive but to allow targeted use of counseling resources on those individuals. I actually prefer the term of "targeted counseling" or "test-linked counseling" as the reason for doing the testing. It is not just to test per se.

Then, once you have found somebody who is positive, it makes sense to spend a substantial amount of money on those individuals, who are positive, to ensure that they do deal with their disease, that they don't deny, that they don't transmit the infection to other individuals. It would be wise for this Commission to recommend that there be made available a substantial amount of funding for counseling services for individuals who are detected as positive in screening programs.

I think this is a point on which the panelists here would all agree: if effective mechanisms for counseling of positive persons were in place, then widespread testing could have a very favorable impact on the epidemic. Fair enough?

DR. LILLY: What kind of counseling -- post-test counseling do positives receive, who are applying for entrance into the Armed Services?

DR. BURKE: There are two levels of testing that we do in the military. One is applicants for military service. The other one is people who are on active duty. For persons on active duty, we have full responsibility for their medical care. Persons that are found to be HIV positive become involved in extensive long term relationships with chaplains, psychologists, psychiatrists, other social support services. The situation is different for individuals who are picked up through the screening of applicants to military service, for whom we do not historically have the responsibility for their medical care. For example, if a person has a heart murmur, we do not provide medical care for his heart murmur.

But what we do for HIV positive persons which we do not do for any other disease, is we bring that person in. He is told in person by a physician of the diagnosis and then he is given a list of all of the resources available in his community for people that are HIV infected. So, we do go that extra mile to make sure that counseling is available, and that individual knows where to get it.

CHAIRMAN WATKINS: We have to make it short, Dr. SerVaas.

DR. SerVAAS: Okay. Just one thing about that, Dr. Cleary, about the marriage, the couples, the getting married -- you don't want to tell them to use a condom. You don't need to counsel them to -- they are getting married possibly to start a family so that you want them to be free to practice sex the way -- you don't have to change their behavior. What do you have to change their behavior for unless they are positive? And that goes with what Dr. Burke says. We really want to protect the women and men who might be unknowingly, unwittingly marrying someone who is positive and that, I think, no one should deny us from being able to do in a very inexpensive, confidential, voluntary way.

DR. LILLY: I didn't understand the point, Dr. SerVaas. What are you disagreeing with?

DR. SerVAAS: Why do we need counseling to muddy the waters? We need a lot of counseling when they are positive but our hands are tied constantly in some states because we need personal post-test and pretest counseling for blood recipients, seven year olds. A kid doesn't have to change his sexual behavior at seven year old to be told he is negative, but you need negative counseling, too, in some states and this is absurd and it costs millions in legal fees for a lot of people who are trying to help. It is really absurd to have some rules about pretest and post-test guidelines where you are trying to help the blood donors, the blood recipients, the blood transfusion

recipients in states where they make it very difficult to do voluntary testing.

CHAIRMAN WATKINS: Let's let the panelist answer now, Dr. SerVaas, and we have to close it out.

Dr. Cleary.

DR. CLEARY: We are talking about a national prevention program. The best national prevention program is not to look under the lamp because the light is there. Premarital populations are low prevalence and it is a snapshot. It is a one point in time snapshot. We do want to counsel negative persons so that they will not subsequently transmit or receive the virus. We do want to counsel persons who are positive so they will not spread the virus. The point is we want to go where we are going to have the most impact, using the programs that have the most impact. We want to be inclusive and we know that anonymity and confidentiality promotes inclusiveness and we want to be effective and we know that a major emphasis on behavioral change increases effectiveness.

CHAIRMAN WATKINS: Any disagreement on the panel on that?

I would like to thank you very much. This is an extremely informative panel. We would like to keep our dialogue with each of you open between now and the time the Commission terminates on the 24th of June and I can assure you there will be additional questions we would like to have as prompt response to as possible.

Thank you very much and we will recess for about ten minutes and then we will be back here to start the next panel promptly at 12:15. Bring your lunch, Commissioners.

(Whereupon, at 12:05 p.m., the meeting was recessed, to reconvene at 12:15 p.m., the same afternoon, Friday, March 18, 1988.).

A F T E R N O O N S E S S I O N

CHAIRMAN WATKINS: Panel 3 concerns confidentiality of medical records and reporting, and we have with us today, Ms. Rita Finnegan, Executive Director, American Medical Record Association, Chicago, Illinois; Dr. Charles Wallas, Member Board of Directors, American Association of Blood Banks, Arlington, Virginia; Mr. Harry A Woodman, Vice President of New York Life Insurance Company, New York; Dr. Fredia Wadley isn't present in the room, but we hope that she will join us shortly and Dr. Willard Cates, Jr., Director, Division of Sexually Transmitted Diseases, Center for Prevention Services, Centers for Disease Control, Atlanta, Georgia. Welcome, Dr. Wadley, and we will proceed now with testimony from Ms. Finnegan.

MS. FINNEGAN:: Good afternoon, Mr. Chairman. My name is Rita Finnegan, Executive Director for the American Medical Record Association. AMRA is a professional association with 29,000 members who are responsible for assuring the accuracy and confidentiality of patient information in a variety of health care settings. AMRA welcomes this opportunity to share its views with the Presidential Commission as it strives to address a range of very complex and controversial issues. The HIV epidemic is a human tragedy of unknown proportions. Extensive and intensive research needs to be done to find appropriate answers to many questions about the HIV. In order for that research to be effective, there must be a solid and valid baseline of data. Herein lies a major problem. Accuracy of information needed for this baseline is dependent to a large extent upon accuracy of information provided by those being tested and treated for AIDS. The assessment of where we are as a nation in response to the HIV epidemic is fraught with error because persons who may be willing to come forward and be tested and thus, be counted, as well as those who are already suffering from diseases caused by HIV infections do not have the assurance that their personal right to privacy will be protected. AMRA members are strongly committed to putting into action the principles spelled out in our guidelines for handling health data on individuals tested or treated for the HIV virus.

Copies of this document were earlier provided to the Commission, and there are additional copies at the desk in this room. All efforts to protect patient confidentiality in any type of health care setting are only as effective as the persons who are responsible for maintaining that protection. A concrete example of the effect of a breach of confidentiality is offered for consideration. The January 8, 1988, Journal of the American Medical Association reports the case of a young man whose life was ruined by the inappropriate disclosure of a positive HIV antibody test. The man had been diagnosed 6 months earlier as having AIDS, was following safe sex guidelines and refrained from

donating blood or semen. Without his consent, a physician ordered an HIV antibody test and sent the results to the local health department. The man's employer was notified, and he was fired. The townspeople found out about it, and he was socially ostracized. His landlord asked him to move. He lost both his health and life insurance. Ten days after that test was taken, this man's life was ruined. Caregivers especially need to be aware of the critical need for strict confidentiality safeguards for this kind of information. The adverse psychological and economic effects of disclosing test results have been documented in many such reports, often resulting in suicide attempts or major depressive illnesses. Given the appreciation that any system will only be as strong as those responsible for maintaining that information, I urge the Commission to consider several options as it develops recommendations to give to the Congress. First, AMRA believes the public needs a better appreciation of how health information is protected in all cases, not just information related to AIDS. Not only must our profession be vigilant about this matter, but the entire health care community, as well, including the health insurance industry. Secondly, we believe that many in Congress and some representatives of the Administration make an assumption about confidentiality laws that is not particularly valid. Not all 50 states have adequate laws to protect the confidentiality of medical records.

There are some states which have very limited guarantees of patient confidentiality protection. Until recently, Montana was one of those states. However, last year Montana became the first state to adopt the uniform health care information act. The uniform act was drafted in 1985, by the Uniform Conference of Commissioners on State Laws, endorsed by AMRA that same year and approved by the American Bar Association in 1986.

In spite of dedicated effort on the part of the national law commission and AMRA, the Uniform Act has thus far been introduced to the legislatures of only nine states. To date, Montana is the only state that has passed this law. Our reason for focusing on the uniform act is because we believe it provides the best legislative language to guarantee confidentiality protection for individuals while at the same time defining disclosure policies for those who have a legitimate need for the information contained in the medical record.

The need for uniformity and confidentiality protection has been stressed repeatedly by such key figures in health care as Secretary Bowen, Senator Kennedy, Senator Quayle and Congressman Waxman. AMRA believes that if such uniform laws were adopted throughout the country, we would have a firm legal

basis for guaranteeing protection of an individual's right to privacy.

We, also, believe that prodding from the Federal Government would speed adoption of this state law. A precedent for such action was established with the withholding of highway funds until certain state statutes were adopted. By adopting this uniform law throughout the country, AMRA's specific confidentiality principles could be more easily applied to achieve that fine balance between the protection of patient rights and the public need to know. AMRA's policy on handling HIV information concurs with the policy statements recently issued by the American Hospital Association. AMRA and AHA agree that when patients are HIV positive and have been diagnosed as having AIDS this information should be a part of the record so that providers of care can render proper treatment and take necessary precautions. Such records should be maintained with the health records of other patients in physically secure areas under the control of the medical record manager. Health care facilities need to have strict policies that indicate action to be taken if a staff member inappropriately discloses sensitive medical information which represents another reason why states need to have uniform confidentiality statutes with penalties for violation of the law. These sanctions could then be used as the basis for adopting uniform health care facility policies.

Additionally every health care facility must educate all employees to the importance of confidentiality and outline the consequences of violations. In this educational programming the special sensitivity that must be accorded information about individuals who are infected with the HIV virus must be discussed, as well as the adverse consequences that could occur if information is erroneously released.

AMRA believes special protective measures must be taken in health care facilities offering screening programs to detect the presence of antibodies to the HIV virus. Such programs may identify individuals who display no active signs of infection. AMRA firmly believes that anonymous testing is possible and should be voluntary. AMRA recommends that voluntary testing records be retained only for the length of time required by law on a manual basis, then shredded. We recommend manual files because present computer systems do not have adequate controls to restrict access to the sensitive information only to those who need to know.

It should be noted that when apparent breaches of confidentiality occur, the cause is often the patient. Patients and their families often communicate the fact of their test or illness to another person, never expecting the information to be redisclosed. Often the name of the health care facility is included in the conversation. So, when the information becomes

known, it appears that the facility breached confidentiality, when in fact, it was the patient's own doing. A major Chicago health care facility averaging over 400 HIV tests per month for the past few years has never been accused of a breach of confidentiality.

Until the general public has an educated and informed sense that their rights to privacy and non-discrimination are being protected in the health care environment, the true picture of HIV prevalence is not likely to become a reality.

I commend the Commission for its intensive work and the credibility it has established in such a brief period. I thank you for the opportunity of testifying here today on behalf of the American Medical Record Association.

CHAIRMAN WATKINS: Dr. Wallas?

DR. WALLAS: Mr. Chairman and members of the Commission, my name is Charles H. Wallas. I represent the American Association of Blood Banks on whose Board of Directors I serve.

I am Director of the Blood Bank and Transfusion Service and an associate professor of pathology at Vanderbilt University Medical Center. I am certified by the American Board of Internal Medicine and the American Board of Pathology in blood banking and clinical pathology. I am honored to be here today to address the important issue of confidentiality as it pertains to HIV-related information in blood banking and transfusion medicine.

The American Association of Blood Banks brings particular expertise to these hearings. The organization is the professional medical association for those individuals and institutions engaged in blood banking and transfusion medicine. It sets standards for and inspects and accredits blood banks and transfusion services. AABB member facilities numbering 2400 collect nearly half of the nation's blood supply and transfuse over 80 percent of all the blood collected in the United States. The 8000 physicians, scientists, technologists, administrators and nurses who are individual members of the American Association of Blood Banks work to advance transfusion medicine as a science.

Throughout its 41-year history the American Association of Blood Banks has been dedicated to maintaining an adequate blood supply and making it as safe as possible for the American people. Experience has demonstrated that this goal is best achieved through a volunteer blood donor system.

In the prepared statement which was submitted for the record of this hearing, I outlined some of the procedures

utilized in blood banks and transfusion services to protect the privacy of medical records and to guard against unauthorized disclosure of privileged information about the volunteer blood donor. Exposing donor identities to discovery would discourage most donors from donating. The American Association of Blood Banks therefore believes that confidentiality is essential for maintaining an adequate blood supply that is as safe as possible.

The American Association of Blood Banks also believes that the confidentiality of medical records outside the blood center is crucial to controlling the spread of AIDS. AIDS, AIDS-related complex and HIV seropositivity are stigmatizing conditions. The potential for unwarranted disclosure of personal information or HIV antibody status is a disincentive to voluntary testing. More importantly, lack of confidentiality undercuts the efforts of the public health community. To achieve the public health goals of detecting, controlling and preventing the spread of AIDS, it is important to identify and obtain the cooperation of infected individuals. This can be accomplished by providing alternate test sites, other than a blood center, where individuals can go for confidential evaluation and testing and by ensuring that their medical records and diagnostic information will be kept confidential.

The American Association of Blood Banks recommends that the Commission consider federal statutory protections for personal identities and records related to HIV counseling and testing. The protections we recommend are no more than those provided under the standard doctor-patient privilege. However, the American Association of Blood Banks believes that protective legislation is necessary because state courts are beginning to make exceptions and draw distinctions to the general rule against non-disclosure in the blood donor context. For example, during the last week of February, the US Supreme Court declined to review the appeal of a Texas Appellate Court decision requiring a hospital to turn over to plaintiff's attorneys the names and addresses of blood donors whose blood had been used in the care of a deceased infant. This decision is contrary to a 1987 decision rendered by the Supreme Court of Florida. Cases with similar confidentiality issues are currently pending in California and Colorado. Decisions, such as in the Texas case will have serious effects on the outcome of these cases and ultimately on both volunteer blood donors and high-risk individuals seeking testing and counseling.

To strike a balance between the need for confidentiality and the duty to protect the public health, the American Association of Blood Banks, also, recommends that the Commission allow for certain exceptions to any confidentiality protections. Permissible exceptions could allow a treating physician or other appropriate party to notify certain

individuals and institutions of a person's test results. Such parties might include blood, organ, semen and breast milk banks, spouses or other known sexual contacts, state health officers, if required by state law or court order and health care workers who might be exposed to infection as defined by the Centers for Disease Control.

Given these differing legal interpretations and the explosion of AIDS-related legislation at the state and local levels, the American Association of Blood Banks would, also, urge the Commission to recommend that the US Food and Drug Administration preempt state and local regulation of blood donor suitability criteria, product labeling requirements and the conduct and interpretation of testing including HIV testing. This is necessary to ensure nationwide uniformity and the ability to share blood supplies across state lines to meet emergencies or shortages.

In summary, the American Association of blood banks is making four specific recommendations for your consideration. One, in order not to deter blood donation, protect the confidentiality of blood donor records.

No. 2, in order to encourage those potentially at risk for AIDS to be tested and counseled, protect the confidentiality of records generally, thereby controlling or preventing the spread of AIDS.

No. 3, to protect the public health, allow for certain exceptions to confidentiality protections in order to notify parties, such as blood centers, spouses and health care workers of a person's positive test results.

No. 4, to ensure that blood can be shipped across state lines, allow the US Food and Drug Administration to preempt state regulations regarding blood donor criteria and blood testing and labeling.

On behalf of the American Association of Blood Banks, I thank the Commission for the opportunity to testify. I commend you for your efforts and wish you every success. Thank you.

CHAIRMAN WATKINS: Thank you. Mr. Woodman?

MR. WOODMAN: Good afternoon. I appreciate this opportunity to present information on protection of confidentiality by life and health insurers. I am chief underwriter for New York Life Insurance Company and am past president of a national organization of professional underwriters. I am also the immediate past board chairman of MIB, an information exchange to prevent insurance losses due to

fraud or omission and am chairperson of the Society of Actuaries' Committee to monitor the spread of AIDS.

Before discussing confidentiality of HIV-related information, I would like to emphasize the critical importance to life and health insurance companies of testing for HIV antibodies.

The risk among persons who are seropositive is much greater than that for virtually all other uninsurables. For example, the mortality risk is five to 10 times greater than the risk among most persons who are uninsurable because of recent malignancies or coronaries. Moreover, many of these seropositive persons who were not previously interested in insurance are now likely to apply because of their seropositivity, often for maximum benefits.

Blood testing, which includes the established three test protocol for AIDS antibodies, is solely based on the amount of coverage applied for or because of medical indications. Before blood is drawn, we obtain the written consent from the proposed insured to perform tests, including those for HIV antibodies. It has always been our concern that sensitive information should not be conveyed to an employer or agent or be improperly accessed through MIB. Section 13 of the NAIC's (National Association of Insurance Commissioners) Model Act on Insurance Information and Privacy,, which has been adopted in 13 states and is applied uniformly by most companies in all states, prohibits the disclosure of personal or privileged information to any person who does not have a need to know.

I will describe the steps taken by New York Life to keep information about test results from agents, as well as company personnel. To the best of our knowledge, preservation of confidentiality is approached with the same degree of dedication by the overwhelming majority of life and health insurance companies. If a blood test is HIV seropositive or indeterminate, the lab sends the test results directly to our chief medical director. These results are not transmitted by the lab through the normal route and hence are not handled by our regular underwriting staff. After receiving these test results, our chief medical director sends a letter by registered mail to the proposed insured suggesting consultation with a physician. No disclosure is given to any other person. The application is declined, and the reason given is "current medical findings." A non-specific abnormal blood test code is reported to MIB. The phrase "current medical findings" is used to describe all examined test findings that require declination. Using this non-specific nomenclature to cover a variety of reasons for declination prevents the agent and field office personnel from deducing the specific reason. Information pertaining to seropositive or indeterminate test results and to

other declinations for blood or urine findings is maintained in a special confidential file. It is never attached to the application file.

I also wish to comment on actions which MIB has taken. MIB has a distinguished history of maintaining confidentiality through strict security measures. On several occasions, MIB has voluntarily supplemented its procedures in response to privacy concerns. Last year the specific code for an HIV seropositive test result was voluntarily withdrawn, and results are now included in a non-specific code under which a number of other test results are reported. Through the efforts of our national organizations, the American Council of Life Insurance and the Health Insurance Association of America, as well as state organizations, individual companies are well aware of the special need for the absolute confidentiality of information relating to AIDS. If breaches occur, we feel that they can be handled by present state regulatory mechanisms. We expect that if needed changes regarding confidentiality are recommended by the NAIC, they will be quickly adopted by most companies in all states as has been done previously with NAIC proposed legislation.

Finally, there is every reason to believe that insurance companies will continue to act on their own to maintain their excellent record of confidentiality. After all this is only sound business practice, since the price of carelessness has always been the loss of consumer confidence. With the advent of AIDS, companies have even more reason to care. Thank you very much.

CHAIRMAN WATKINS: Thank you, Mr. Woodman. Dr. Wadley?

DR. WADLEY: Mr. Chairman, members of the Commission, Commissioner James E. Word of the Tennessee Department of Health and Environment could not be here today, but he asked that I bring you these comments. Human immunodeficiency virus antibody testing at our counseling and testing sites within the Tennessee Department of Health and Environment for the most part are done on an anonymous basis except at the Metropolitan Davidson County Health Department here in Nashville where we do confidential testing. However, at Metro, verification of identity is not required, and obviously fictitious names are sometimes given, and I might add accepted. We estimate from one-third to one-half of those names are false. Blood samples are sent to the state lab without a name but a number. Only one person in our department has access to those names and numbers, and this information is kept in a locked file.

Test results are not released to anyone other than the individual tested. So far, there have been no known breaches of confidentiality. Across the state, however, at other health

departments we are beginning to offer a choice of anonymous or confidential testing. It has been necessary to have confidential testing because often individuals come to our health department for other services (tuberculosis, prenatal, sexually-transmitted disease, family planning), and give their name. Later it is determined that an HIV test is appropriate and that individual accepts testing after counseling.

At the Metropolitan Health Department here in Nashville, we, also, have an HIV Plus Program which offers an initial health evaluation to those individuals found to be seropositive. The medical records of these individuals contain the HIV antibody test results, but this practice is explained to them before they enter this program. Records are kept in the program area in a locked file, and there have been no known breaches of confidentiality. At this time before the Tennessee General Assembly is a bill to strengthen our confidentiality statute relating to sexually-transmitted diseases. This was felt to be indicated, not only by the Department of Health and Environment but, also, by the Tennessee AIDS Advisory Committee. This bill defines AIDS as a sexually-transmitted disease and specifically outlines the conditions under which information concerning a sexually-transmitted disease can be released.

There is, also, a bill before our General Assembly to require mandatory reporting of HIV antibody positive individuals. Although many members of the Tennessee AIDS Advisory Committee could recognize some advantage to reporting the group voted not to endorse this bill because at this time in Tennessee, it is felt that confidentiality statutes are not strong enough, and antidiscrimination measures should be taken first to protect for employment, housing, school attendance, etc.

Even with improvements in these areas, there was a concern among some members of the Committee that future legislation might allow the reported names to be given to blood banks, correctional facilities, schools, insurance companies and so on.

Other considerations relative to mandatory reporting which should be considered are: developing a reporting system that is very sensitive to confidentiality; convincing private physicians to report; deciding if laboratories are to report and what constitutes a positive test; and determining what is to be done with the reported names. There are some advantages that could result. For example, we could collect better epidemiologic data to monitor the disease. Secondly, we could provide education and counseling to those diagnosed in the private health sector. Then last, but not least, we could provide partner notification. One important consideration is how to convince those with high-risk behavior that

confidentiality will be kept so that they will continue to seek testing.

I recognize that even with improved confidentiality laws there is always a possibility of a breach, and, therefore, some type of discrimination. In public health in Tennessee our record with confidentiality has been excellent. Commissioner Word and I would have to support mandatory reporting of HIV seropositives after reasonable efforts have been implemented to decrease the risk of confidentiality breaches and discrimination because of the advantages in disease control that reporting could provide.

Until this has occurred, Commissioner Word is supporting anonymous reporting of HIV seropositives as a means of having better data to study the extent of the infection in Tennessee. Thank you.

CHAIRMAN WATKINS: Thank you. Dr. Cates?

DR. CATES: Thank you, Admiral Watkins, members of the Commission. I appreciate the opportunity to share my views and the views of CDC concerning the confidentiality of information collected during counseling and testing for antibody to HIV.

Let me begin by thanking my colleague Russ Havlak who was primarily responsible for accumulating the aggregate data that you have in the written testimony before you.

I wish to state in the strongest possible terms that confidentiality along with a companion concern of antidiscrimination is a pivotal factor in determining whether we will succeed in preventing the spread of HIV in this country. At present, CDC has 59 cooperative agreements to carry out AIDS prevention programs. As shown in Attachment A of my written testimony, about one-third of these areas perform all HIV testing within their prevention programs in ways that maintain the anonymity of each patient, namely, no names are provided. In the remaining two-thirds, antibody testing is confidential, namely, personal identifiers are collected with the assurance that this information will be secure from any release that is not authorized by the patient.

Of the 40 areas which offer confidential testing, over half, also, offer anonymous testing for patients who preferred this way of determining their HIV antibody status. Where testing is anonymous, confidentiality issues do not arise. When testing is confidential, the issue is whether health departments can back up their assurances that personally identified AIDS-related information can be secured from releases to which the patient does not consent.

Every state has a statute protecting the confidentiality of STD records. Most were enacted in the years between 1930 and 1960, and generally are firm but non-specific. Unfortunately, most of these STD statutes do not shield records from release through litigation. Nevertheless, overall during the 40-year record of performance by the nation's health departments concerning STD confidentiality is outstanding. Even without legislative protection to support them in many cases, health officials have often heroically avoided releases of information that could have harmed individuals, as well influenced community trust in their disease control programs.

Turning to Attachment B of the written handout, you will find a summary of the current status of AIDS and STD confidentiality statutes plus reporting provisions throughout the country. Regarding confidentiality, only 13 areas specifically shield AIDS-related records from subpoena. However, this is more areas than currently have extended this protection to other STD documents. Regarding reporting, 49 areas have made AIDS reportable by classifying it either as a communicable or a reportable disease.

The problem is that few states have ever enacted statutes to protect the records of non-STD communicable diseases from release because they were usually not sensitive and rarely in demand or the subject of litigation. AIDS obviously has changed the situation. Appendix B, also shows that 12 states currently require HIV infection to be reported. Only four of these, Colorado, Minnesota, Texas and Wisconsin have confidentiality laws covering AIDS which protect against release through litigation. Making HIV reportable without stringent confidentiality protections is potentially dangerous. While the reporting of HIV infection is a valuable public health tool (which can support both surveillance and prevention efforts), the absence of stringent confidentiality protections could present risks that would undermine the benefits of being able to directly contact the HIV positive person.

In the future, testing will be more widely available in settings where maintaining strict confidentiality will be more difficult. For example, confidentiality in hospitals is much more difficult to maintain than in health departments where records are used for limited purposes and access to them can be restricted and rigidly controlled. Therefore, antidiscrimination provisions are an absolute necessity. While the release without consent of personally identifiable AIDS-related information may not be totally avoidable, we certainly can enact and enforce measures that would discourage unwarranted discrimination against people with HIV infection and provide redress when they are victimized by such acts.

DHHS feels that confidentiality around AIDS and HIV infection is best strengthened through state legislation. Therefore, we believe that the Commission should endorse a federal leadership role by recommending the development of model legislation on confidentiality for presentation to states. Since the confidentiality on sensitive health records is an area of particular concern to CDC, and especially to us in the STD arena, we have watched the developments in this legislation arena with interest for a number of years. Our Attachment C provides a prototype state AIDS and STD confidentiality statute.

To prevent the spread of HIV, swift and decisive enforcement of antidiscrimination laws is as important as having such provisions in the first place. In reviewing the alternatives, we believe this responsibility would be most efficiently discharged at the local level through state legislation and city or county ordinance, rather than through new or broadened federal statutes in this area. Therefore, DHHS feels the Commission should endorse some model legislation for presentation to the states on antidiscrimination covering all fields relevant to AIDS patients, housing, education, employment, insurance and medical care. To ensure prompt adoption of this model legislation, we believe it should be supported again, with the strongest technical assistance and backing possible from the federal level.

Thank you again, Mr. Chairman, members of the Commission for the opportunity to share our views on this important matter. I hope these remarks are of help to you.

CHAIRMAN WATKINS: Thank you, Dr. Cates. We will commence our questioning with Dr. Primm.

DR. PRIMM: Ms. Finnegan, you have had considerable experience over the years managing hospital records and patient records.

Yesterday we had a number of individuals report to us that there was a need to have information available on the seropositive or seronegative status of people in hospitals. These witnesses testified that over seventy people may come in contact with a patient's chart, and that information is sometimes divulged. I asked one of the witnesses yesterday what would be one way of protecting that information? Perhaps you may have some suggestions yourself for the Commission regarding protecting sensitive medical data in hospitals and health care settings.

MS. FINNEGAN:: You have identified a very real problem in health care institutions, and our association has studied it a great deal. We believe that the first priority is patient care, taking care of the individual who is infected.

Therefore, we recommend that the information on the patient's condition, lab tests, etc., should be included in the patient's medical record. It has been our experience that when you designate by special seals or you identify with special warnings, etc., that there is information somewhere else about a patient instead of in the medical record, that you draw more attention to the problem than if you include the information in the patient's medical record. We do, however, believe that every health care institution must have an extremely good education program on confidentiality in order to ensure that all employees from housekeeping up through the medical staff are well educated in the provisions regarding the privacy rights of that patient.

DR. PRIMM: Have you had any experience with use of computers to transfer this information? One of the speakers yesterday suggested that use of special codes to enter the computer in order to get out certain information might be a way of safeguarding against confidentiality breaches. I know this is an almost impossible question to answer, but since you have such a plethora of experience in this area, I thought maybe you could give us some insight. What about computers?

MS. FINNEGAN:: Actually our association believes that it is more dangerous to include the information in computerized systems at the present time than it is to maintain it manually, because the security provisions that most health care institutions have adopted with regard to computers are not satisfactory. People have passwords and things like that, but it is not at all uncommon for one physician to allow another one to use the password for someone to look over your shoulder while you are putting the password in. We just do not feel that computer security is what it should be. I think the number of hackers that have gotten into important computer systems in this country indicates their vulnerability. Therefore with the present state of the art, and we know that could change tomorrow, we feel that for many institutions their records should be maintained manually. There may be a small number of institutions that feel they have an adequate computer security system, but as we have looked at institutions, their computer security for medical records is not what we believe it should be.

DR. PRIMM: Thank you.

CHAIRMAN WATKINS: Dr. Lilly?

DR. LILLY: I just have a couple of questions. A point of information, Mr. Woodman. At one point you said that your codes do not allow disclosure of information to people who do not have a need to know. I was wondering, how do you define a need to know?

MR. WOODMAN: Only somebody who is involved in the underwriting process has a need to know. Beyond that, we keep sensitive information out of the hands of the regular underwriters to the maximum extent we can, and we keep information out of the regular underwriting files and put them in special confidential files.

DR. LILLY: Okay, so that would be a strictly in-house need to know?

MR. WOODMAN: Yes, any individual's records would be protected. I mentioned that the MIB does not contain any specific code for HIV seropositivity, only a generalized code which includes a number of other abnormal blood test results, and that MIB confidentially is quite highly protected.

DR. LILLY: We have had a great deal of discussion in these and other hearings about confidentiality. I think this may be the first time that I recall that the subject of breach of confidentiality by court order has come up.

I am wondering to what extent the information that the insurance industry might collect in this manner is subject to that type of breach of confidentiality that you might have to supply it by court order.

MR. WOODMAN: The action of our company, and I suspect most companies, and I know the action of MIB would be to notify the party involved that we have received a court order to allow them to take any appropriate action on their part and possibly restrain the court from getting that information.

DR. LILLY: How long do you store that information?

MR. WOODMAN: We store confidential information for a period of 7 years. Confidential underwriting information is not stored that length of time.

DR. LILLY: Dr. Cates, you referred to the fact that you, you being the government, has expressed a distaste for federal legislation banning discrimination and mandating confidentiality. I find myself very unclear as to the reasons for that. What you do recommend is, or at least, you personally recommend is that the government devise model legislation. With respect to such model legislation, do you have any idea as to the extent to which a federal recommendation of state adoption of model legislation has ever proved successful in the past?

DR. CATES: STD model legislation, developed at the federal level, eventually helped the enactment of state legislation to protect records. Again, the position of the Department is that this is a state-based responsibility and that

we will work very closely with each of the states to provide them with model legislation and will use our federal "persuasive" powers to get that enacted.

DR. LILLY: At one point racial discrimination was, also, considered to be a state responsibility, but the Federal Government at some point changed its mind. Do you think that that might happen with respect to AIDS-related discrimination?

DR. CATES: It is certainly possible that the Federal Government will change its mind.

CHAIRMAN WATKINS: Mr. DeVos?

MR. DeVOS: I pass.

CHAIRMAN WATKINS: Dr. Conway-Welch?

DR. CONWAY-WELCH: A point of clarification, Dr. Wallas, I believe that you said that you recommended that the Commission consider federal statutory protections for the confidentiality of personal identities and records related to HIV counseling and testing with certain exceptions. One of those exceptions was to permit notification of test results by the treating physician or other appropriate party to certain individuals and institutions, and one of those was blood, organs, semen and breast milk. That is the official position of the association. Is that correct?

DR. WALLAS: Yes, it is the official position of the association that you maintain clearly a delicate balance between protecting the right of the patient who is being tested and those in the health care system who have a need to know, and I think a donor center clearly is such an area. It would be terribly important for a blood center to know if an individual infected with AIDS had donated unknowingly so that we could notify recipients of that donation.

DR. CONWAY-WELCH: I am trying to see mechanically how that works. That is done after the person donates blood that there would be history taken that would indicate that he had --

DR. WALLAS: Currently what is being done is different from that. I can expand on that, if that would be useful. What is being done currently falls under the generic term of look back in which any time a donor comes in who previously tested HIV negative and now tests confirmed positive for HIV, they track back through the donor records and notify hospitals about previous donations so that we can see about notifying and testing the recipients of those units to potentially prevent these individuals from transmitting to others. There has, also, been a general recommendation that all patients be tested who

received large quantities of blood from 1977 to 1985, when testing was instituted, particularly in areas where they could have received blood from potentially high-risk donors.

Those are in place generally in terms of lookback and locally in terms of the other program that I mentioned, but we are not currently reporting in the other direction. We do not yet have blood donation information from those who have HIV infection.

DR. CONWAY-WELCH: Is that contrary to Dr. Wadley's comments? I think perhaps I may have misheard. Did you say something to the contrary, that current recommendations from your perspective would be that it would not be appropriate to notify or to include exceptions? I am not sure if I am making myself clear. I don't think I am. I thought I heard a difference in opinion between you and Dr. Wallas, and I was trying to clarify that, but I think perhaps I did not. Thank you.

CHAIRMAN WATKINS: Mrs. Gebbie?

MRS. GEBBIE: In exploring this whole issue of records and confidentiality laws, Dr. Cates, one of the things that just occurred in recent revision of our laws in Oregon was abandoning the old distinction between sexually-transmitted diseases and other reportable conditions. Since that is not always clear immediately upon a condition becoming important to public health, we extended that same broad protection that you outlined here to any condition of public health importance that becomes reportable. Has CDC looked at that or are you really convinced that narrowing this only to STD records is the way to go? I would appreciate some comment.

DR. CATES: I don't know CDC's position on this. My personal view is exactly as you described. The whole arena of public health has become much more complex and more subject to litigation. Thus, the extension of statutory protection for confidentiality to the range of communicable, or even reportable, diseases would provide a better umbrella than just STD. It has been vital to STD because of the partner notification process that we heard discussed back on March 1.

MRS. GEBBIE: Thank you. May I sneak in two questions here if I am real fast? Mr. Woodman, a number of us have only peripheral knowledge of the MIB, and in fact, most of what I know about it is what I hear from people terrified of any of their information ending up in it because it is viewed as something almost worse than a black hole of Calcutta, something like a sieve out of which all sorts of data can fall.

You have described the fact that things are stored under fairly broad codes so that it is not HIV specific, but it is simply some odd blood test which certainly provides some comfort, I think, were there to be a leak. The other thing that I am not clear on is what controls there are on the quality of the data going in. That is, I would have less concern about some information on me going into something like that, if I were certain that it wasn't just somebody looked at one test result sideways and said, "Oh, my gosh," and ticked it off on a form and sent it off. Rather, that there are some quality controls to make certain that it is really, accurate, and it has gone through rigorous criteria on the way. In addition to whatever comment you would like to make, I think it would be helpful for us to see the written policies governing that filing and release of data from that bureau.

MR. WOODMAN: Regarding the quality of the information, it is up to the reporting company as to what is reported. The MIB has no direct control over the quality of information. However, the MIB does require that the reporting company do self-audits and report those self-audits to MIB, verifying that the code was correct and the information underlying the code was correct. The MIB also does its own audits, with visits to each company at least once every 3 years. Randomly-selected records are reviewed to obtain the same assurances that the information is correct and the code is correct. Even if an incorrect code were reported to MIB, it still would not do a great deal of harm to the individual because a company cannot act solely based on MIB information. It can use MIB information only as an alert to make its own independent investigation, and it must take action solely on the basis of that investigation. So, if an incorrect code were in MIB, it would not harm the person other than to perhaps delay the processing of an application. There is a procedure for correcting that information, if it is determined that it is incorrect.

MRS. GEBBIE: And you are reasonably certain that your member companies follow that process of not acting solely on the basis of that information?

MR. WOODMAN: Yes, the results of MIB's own audits have been excellent in that respect. That is not to say that it could not happen. Nothing is perfect, but I feel that it is just about as good as it could possibly be.

MRS. GEBBIE: Thank you. I would appreciate receiving the written backup on that. My last question is for Dr. Wallas. You spoke of the preemption of state laws regarding blood banks, the requirements for donors and requirements for documentation and so on. It was unclear to me whether you wanted that preemption because some states aren't meeting a minimum standard

and are therefore putting people at risk or because some states are demanding an excessive standard and therefore causing everybody else problems or just because it is plain confusing to have 50 state standards, and you would rather tidy it up and have one.

DR. WALLAS: I don't think we are talking about the safety issue as much as we are about the ability to meet individual variations and state requirements which could potentially prevent blood being shipped across state lines from Tennessee to Kentucky. For example, if Kentucky required certain labeling requirements that Tennessee did not require, it would be impossible to ship the blood across the line because it would not meet Kentucky's laws.

So, primarily the issue is one of compatibility from state to state so that we do not tie up the ability to share resources around the country because shortages are frequent, and there are often areas that have blood that could ship to other areas if we did not have restrictions that would prevent that.

MRS. GEBBIE: There are a lot of areas where we don't happen to have a federal law, but among the states there is a cooperation that sorts out that kind of thing. Is this a hypothetical problem or are there real examples of incompatible state laws that are preventing the use of blood across state lines?

DR. WALLAS: This is at the moment, I believe, somewhat hypothetical, but there are increasing numbers of legislative initiatives in terms of labeling requirements that could potentially impair the ability to ship. I cannot cite you specific examples, however. We could provide that information to you, if you would find that useful.

MRS. GEBBIE: I would find that very much useful. Thank you.

CHAIRMAN WATKINS: Dr. Lee?

DR. LEE: First of all, Dr. Cates, it is a pleasure to see you here again. You are clearly in a good humor whenever we see you, and this cheers us up, and I am happy to see you. My first question is to you. We had a prior witness who made a very obvious statement, and I don't know why this isn't the case. Why doesn't CDC report on HIV infection; why do they keep reporting on AIDS?

DR. CATES: Yes, I was in the audience when that statement was made. CDC is in the process of collecting what we feel is the most accurately available information (through the family of surveys) on the current level of HIV infection.

Moreover, the December 18, 1987, MMWR supplement (the report to the Domestic Policy Council) provides the best available summary data regarding HIV infection. CDC strongly supports Dr. Burke's call for the focus on HIV infection, not AIDS.

DR. LEE: Thank you. Let us get into this confidentiality and the law business a little bit, Dr. Wallas. In my experience which is very extensive, being as old as I am, the law always gets what it wants.

Let us look at how the law gets what it wants. We are subject to the sunshine laws. So, is everybody else. We have just heard the gentleman from the insurance company make the statement which Frank Lilly picked up on that his information is available, quotes, to anyone who does have a need to know, end quotes.

Now, since an insurance company is in the business of underwriting insurance, I assume that anyone and everyone in an insurance company can find out that information. Furthermore, insurance companies are notably not eleemosynary institutions. To the best of my knowledge, if you were turned down for any reason for any policy, this is public knowledge and is spread to every other insurance company in the world, as far as I know. Now, if this gentleman from the insurance company wants to tell me this is not the case, he can do so. I would not believe him.

Now, what are we going to do about the fact that confidentiality is a complete myth? I mean let us look at what happens if you are in Rich DeVos' company, say. You put somebody in your personnel department and somebody has to process the insurance forms. Insurance is a huge hole. Somebody has to process the insurance forms. You would not have to see AIDS. All you have to see is Kaposi's sarcoma, Monilia, pneumocystis, funny lymphocyte counts, and away we go. Now, that is transmitted to this MIB. It is transferred to anyone and everyone in the insurance company. It is transferred to the personnel director at the company where the person works. The personnel director reports to the president of the company, and forget about it. Who are you fooling? I mean we are not 25 years old. So, why do we talk about this? How can you in the insurance industry come to us and talk about confidentiality? But I know what you are going to say. What I want to know is what Dr. Wallas says. What can we do about the lawyers? You know, Shakespeare had some great comments about them. It wasn't damn the lawyers or drown the lawyers, but it was something close to that. What are we going to do about this? Because you know they are going to come. They are going to overturn this and that and the other thing, and they are going to get into it.

DR. WALLAS: Relative to donor information specifically? What would you like me to address? I mean dealing with the lawyers is --

DR. LEE: When you talk about confidentiality, I mean do you see any hope, sir, in keeping them out of this information?

DR. WALLAS: I think that it is discouraging, indeed, that the Texas case occurred. I think that Florida stood fast in terms of donor confidentiality records. I think it is critical that we have some sort of national standard that prevents that, and I am not sure exactly what that involves because I am not a lawyer.

However, I think that it is critical if we are going to continue having voluntary blood donors appearing at donor centers to give altruistically. We are going to need to protect the information they provide or we won't have voluntary blood donors. I don't have a solution for you. However, I think it is a critical issue, and I think it is one that needs to be addressed by this Commission.

MR. WOODMAN: Mr. Chairman, may I at least rebut Dr. Lee, even though he is not going to believe me?

DR. LEE: I want to believe you, but I have learned not to.

CHAIRMAN WATKINS: The rest of us are objective and have an open mind, Mr. Woodman, press along.

MR. WOODMAN: Thank you. First of all, we have to make a distinction between underwriting and claims. In the underwriting process the information can be maintained within a small unit, and that is exactly what we do, particularly with highly confidential information, such as HIV seropositivity, as I previously described.

Claims information that is administered through a personnel office, obviously would be protected with respect to confidentiality only as carefully as the personnel office handles it. In an insurance company the claims information is handled much the same way as the underwriting information is handled. But if an individual working for a manufacturing concern or whatever does not have the confidentiality maintained by that company's office, it is not the fault of the insurance company. Dr. Lee indicated that it becomes general knowledge when a person is declined for insurance; that is not true. An underwriter might discuss that with another underwriter, but that is forbidden procedure. Because we are not perfect, it can happen but I think with someone declined

because of seropositivity, that type of information which we recognize as sensitive would not be exchanged.

Underwriting actions by an insurance company are not reported to MIB. We only report coded information on a medical impairment. So, I hope I have at least made some progress in dispelling some of the concerns you have.

DR. LEE: No, you really haven't, but that is all right. I am saying that if you send in these helper suppressor T cell ratios into the MIB, I mean the ballgame is, you know, everyone knows about it.

MR. WOODMAN: It is a non-specific code.

DR. LEE: Who can get into the MIB? Any private detective, I assume by making a phone call and stating that he is XYZ and --

MR. WOODMAN: No. It is a user unfriendly system. There has been no record of hackers ever getting in, and the only persons who have access are authorized persons in an insurance company who are MIB members and who have a need to know.

CHAIRMAN WATKINS: Mr. Woodman, a follow-up on that. What could you tell Dr. Lee about your own internal audit program within the MIB or other networks that are sampled to see that your policy is actually carried out? This is one of the big problems. We have great policies around. Very few people carry them out right. So, the question is how do you police your own system for need-to-know access? Have you done some sampling of that? If so, how good is it? Are there any reports on it that can demonstrate? You say that you have not had any breach of confidentiality. Is that a matter of record of the proper auditing agencies that are tasked to do that kind of thing within the MIB or other insurance networks?

MR. WOODMAN: The MIB has never been accused of any specific breach of confidentiality or had any legal actions brought against them. Certain MIB information conceivably could have been leaked by an underwriter but not by the MIB itself.

CHAIRMAN WATKINS: What would happen in that case with the underwriter? Would he then follow the litigation under state law? Is it highly disciplined within the system so that everybody is irate within your organization network?

MR. WOODMAN: Yes. Underwriters have a professional obligation, and they are also employees of a company. It certainly would be highly unacceptable to the employer to have an employee accused of breaching confidentiality.

CHAIRMAN WATKINS: You say that the number of those cases are small or zero?

MR. WOODMAN: Or zero. I am not aware of any record of any such cases. Each company conducts a self-audit, as I mentioned. They are required to examine a number of cases each year and assure the MIB, through an audit by someone other than the underwriter who handled the case, that the information was correctly reported. Also, as I said, a MIB representative visits the company every 3 years and asks the company prior to his visit to pull certain selected files with the highest possibility of error because of the particular code involved. These are then carefully reviewed by the MIB auditor.

CHAIRMAN WATKINS: Dr. Lee, did you have any further questions?

DR. LEE: No, I will pass.

CHAIRMAN WATKINS: Dr. Walsh?

DR. WALSH: Would that we lived in a perfect world. If we were as great automatons as some of us would like, I would suppose that we wouldn't even have HIV to worry about, but nevertheless I am concerned a bit about one or two things. Philosophically I have a natural reluctance to any new federal legislation that will interpose itself between physician, patient and the like. Most of the witnesses, while stressing the necessity for confidentiality, and we all agree with it, have indicated that the system by and large has worked very well, as Dr. Cates has pointed out. It has really worked quite well in the normal relationship and even our quizzical Dr. Lee was going back 8000 years at one comment to talk about how confidentiality has always been a part of our system in medicine.

I would like to get your comments on whether you are really interested or want new federal legislation or perhaps federal leadership exhibited by guidelines or parameters that the states could follow. Secondly, be it law or guidelines, if my philosophical reluctance is overcome, while I have heard much about confidentiality, I have heard much about public health, I have heard much about medical management; I have not heard any comments on what should be the status if a patient who is seropositive following counseling rejects behavior change. Nobody seems to want to address this part of the epidemic. Does the confidentiality law or guideline that you are talking about protect society against this potential assassin if behavior change is absolutely rejected by that individual following counseling or counseling is rejected following the discovery of seropositivity? Those are two of the questions. I don't see

that we gain anything by beating the system to death or by asking the insurance industry to take undue risks, by not having conditional testing if people who are seropositive want to suddenly by one-half million dollars worth of insurance and so on, and impose, therefore, a penalty on all other policy holders who in the long run have to pay for that loss. This is why I am fearful. I don't know of any federal law that will cover everything. I hate the thought of a federal law because it will create a new career for lawyers because there is no federal law passed that a lawyer won't contest. So, I am concerned as to the difference between law and guidelines, common decency in recognition of confidentiality and the like. So, I welcome the comments
of any of you on those three questions.

MS. FINNEGAN:: Our association believes, along with the American Bar Association and the National Health Commissioners that state legislation would be the best approach on this particular matter, and Secretary Bowen recently wrote to the governors of all of the states to urge consideration of that legislation at the state level. So, we share your concern about federal legislation. We would prefer to see legislation at the state level with reference to the confidentiality of medical records.

DR. WALLAS: I come back to the problem with the blood donor and restate my concern that we have Florida which has upheld confidentiality of donor records and Texas which has bolted from that position, and so, we face now the potential for variability in the protection of the donor. It is my feeling that if we go on with states allowing lawyers to get into donor records that we will destroy the volunteer blood donor system. So it is my feeling that we need to move above the state in this particular issue and guarantee the confidentiality. Unfortunately, the Supreme Court of the United States refused to hear the Texas case. It would have been very helpful if they had not done that. So, I don't have an answer for how to deal with it, but I think if we allow the states to set their own rules in this particular issue, we will create havoc with the donor supply, and so, I think we need to rise above that level somehow and perhaps have some uniform approach that applies to all states.

DR. WALSH: Is no one going to comment on my question about what to do with the behavioral change that is rejected?

DR. WADLEY: I will take it. First of all, I would like to say that I agree that when you talk about confidentiality and what we have done with the system in the past, I think we have done darn well.

DR. WALSH: Darn well, that is right.

DR. WADLEY: In fact, sometimes I am almost insulted when they talk about how bad it is because I think we have got an excellent record, and when STD records have been subpoenaed by a judge I have gone in with a plain manilla envelope, talked them into it that they didn't need it, and that was long before AIDS ever came on the scene. Secondly, as far as what I am relating to in public health, there are already model guidelines for CDC, model guidelines by TMA, and if states want to do it, they can, and states that are wanting to do it are doing it, like Tennessee right now.

The issue of knowingly exposing has become very bothersome for public health officials, and sometimes I think they would like to put their heads in the sand and hope that it goes away. The problem many times is first of all, there is no system of documenting when you come in for anonymous testing. There has been an occasion in Tennessee of where a patient states that he is not going to change his behavior. This is very rare, and this happened to be an individual that had many other mental health problems. We were able to intervene and get that individual off the street. But that bothers us tremendously because for the most part we have very little way of knowing unless it is the rare situation where they tell us, "I am going back out on the street, and I don't care what you say," but that is bothersome to us.

DR. WALSH: As I say, again, we find that is relatively rare. I agree with you. It is relatively rare, but again, nobody seems to want to address it. I just feel that if we are looking for federal guidelines or state laws, this has to be addressed, even if it is only 2 percent, if we are going to contain this disease. We have got to address it.

How about you, Dr. Cates? You must have some thoughts on it? Again, as an individual, and I realize you cannot speak for CDC.

DR. CATES: Fortunately, these situations are rare events, probably much less than the 2 percent you cite. In those circumstances where it occurs, we favor a graduated approach in terms of offering individuals increasing incentives to change behaviors before you start imposing penalties to restrict behaviors. We call this the "least restrictive alternative" approach.

CHAIRMAN WATKINS: Mrs. Gebbie, follow-up?

MRS. GEBBIE: Just to comment on that, I think the reason people haven't talked about it is that we have not asked these panels to address that question. In fact, there have been

a number of conferences and meetings among public health officials on that issue. There are guidelines developed, and I know that it would be possible to assemble quickly a panel of people who have varying views on that and some ideas about guidelines. So, I guess I get a little nervous when we say that nobody has talked about it when it is partly because we haven't put that question to panels of witnesses.

DR. WALSH: I disagree with you, Kris, with all due respect, because, we have had witness after witness ask for federal legislation, this kind of legislation and that kind of legislation. We have seen witnesses attacked by the panel in one way or another for alleged violations of confidentiality, and yet, I feel that indeed, if you are going to talk about federal legislation guidelines or state legislation, that is an important part of it. I don't think it should be relegated to a special session where we can sit up here and look down and say, "We have got a bunch of right wing kooks out there now who are going to talk about driving people with a whip to the state because they won't take behavior change."

MRS. GEBBIE: I think you are misrepresenting that view. I think the issue of control of persons who are not following up appropriately with counseling is neither contradictory to confidentiality nor an essential part of it. It is a separate debate piece of this epidemic, and I just get real nervous when we start jumbling subjects together.

DR. WALSH: I disagree with you.

CHAIRMAN WATKINS: Dr. SerVaas?

DR. SerVAAS: I just had a quick question for Dr. Wallas. Are the blood banks finding it more difficult to get donors now? Have you had a big dropoff in the number of people who are giving blood?

DR. WALLAS: I can speak for the Red Cross situation in this community. The number of donors has been dropping gradually over the last 3 years. They are finding themselves increasingly having to try to import blood from other centers to try to meet community needs. The only reason that we haven't had a major crisis as a result of the falling number of donations is that fortunately physicians have begun to be more circumspect about the use of blood and that has probably been a spinoff of the increasing public concern and physician concern about potential transmissible diseases from transfusion, but it is clear that we are seeing increasing difficulty recruiting donors. We still have a problem with donors incorrectly thinking that they can acquire HIV infection by being a blood donor, and we have a major public relations issue around all of that.

DR. SerVAAS: Has the fact that hospitals do autologous blood or clean the blood and reuse the blood during surgery, or directed donation, that is sometimes used I understand in New York with the C sections, affected the number of people donating blood? Obviously you wouldn't be giving blood if you were going to go donate blood for surgery coming up. Does that have anything to do with the dropoff?

DR. WALLAS: That is difficult to assess. It is very hard to know whether directed donor programs have fragmented the blood supply which is clearly a concern. I don't think there are any good data one way or the other about that issue.

In terms of whether people are not donating because they are waiting to donate for themselves, also, I don't believe there are any good data, but I firmly believe that we have a need to encourage our patients and counsel with our patients to donate blood for themselves in anticipation of surgery and a recent article from San Francisco General Hospital suggests that perhaps 10 percent of blood needs could be supported by autologous transfusions. So, I think that is clearly a goal to shoot for.

DR. SerVAAS: Have suits against the blood banks been a major problem? I believe that Irwin Bank had some problems.

DR. WALLAS: Most states currently view blood as a service and not as a sale, and therefore, by and large blood centers have not had successful suits against them relative to transmission of disease.

DR. SerVAAS: But are there a large number of suits being defended?

DR. WALLAS: I think there are, but I cannot give you a number, and if you would like that information, I think that the American Association of Blood Banks could provide that. I think that is an ongoing problem. Would you be interested in that information?

DR. SerVAAS: Yes.

CHAIRMAN WATKINS: Dr. Crenshaw?

DR. CRENSHAW: I will defer to Dr. Lilly.

CHAIRMAN WATKINS: Dr. Lilly?

DR. LILLY: I thought I had already had a turn.

CHAIRMAN WATKINS: All right. Dr. Lee has another question.

DR. LEE: Ms. Finnegan, you know, as Mr. Woodman well knows, it takes an unskilled amateur approximately 30 seconds of looking at a chart to tell whether that person is HIV positive. The clues are ridden through there. Now, if I were running an insurance company, I wouldn't care whether anybody put HIV positive in there. I would look for about 15 other little things and tell my people to find out what the story is and put a big black star on that guy's application.

What is your organization doing about that, because any lawyer can get any chart, as I know, as we all know? Is there anything you can do about that?

MS. FINNEGAN:: The major thing that we can do is to make sure that the patient has provided an informed consent, and by that I mean --

DR. LEE: Informed consent for what?

MS. FINNEGAN:: For the release of the medical information to the insurance company.

DR. LEE: I think a lawyer can get that chart no matter what. They can subpoena the chart. Lawyers aren't worried about informed consents or anything like that. There is no consent form that anyone can sign that a lawyer cannot crack.

MS. FINNEGAN:: A lawyer will have to have a case filed in order to issue a subpoena. It is true that if someone is determined to get information, they can get it, but there are many things that we can do to prevent information transfer in the majority of cases, and that includes having informed consent of the patient and counseling the patient so that the patient understands what he is signing. We find today that large numbers of patients are paying their own bills rather than have information sent to their insurance companies.

DR. LEE: I love it. I believe it.

MRS. GEBBIE: A follow-up on your firm position that this confidentiality issue should be handled at the state level. We have got about 10 years of experience with one very specific federal confidentiality law, that governing records dealing with drug and alcohol. Is your message today that such law was a mistake? Why isn't that confidentiality legislation providing a handy model for this particular set of records we are talking about now?

MS. FINNEGAN:: All right, the federal legislation on drug and alcohol records is one of the ones that has made lawyers rich, as we have discussed earlier. It has recently

been revised, and no one can interpret it in many instances. There were problems with it the first time, even its applicability. Some attorneys said it applied to any hospital that took Medicare money. Others said that you had to run a special program for the treatment of alcohol and drug abuse patients, and now, supposedly the law has been revised so that it only applies to special programs, but then the other day an attorney told me, "That was kind of true, but the interpretation that was being given to it was that it still applied to any hospital that had a patient with that kind of diagnosis."

We believe that the consent form required for release of alcohol and drug abuse records is the same type of consent form that should be used for release of information on patients having HIV testing because that is a more stringent type of consent form than is customarily used for release of information in many other settings.

DR. WALSH: The main reason federal legislation always worries me is you have got 535 members of Congress. All you have to do is live in Washington, D.C., and go down and sit when they are marking up legislation or watch them mark it up. It represents a viewpoint of every lobbyist or every constituent of 200 million people that get in before that law comes out. It takes the entire American Bar Association to interpret the law once it is written, and that is what frightens me about getting federal laws on this. It just doesn't make any sense and never will.

CHAIRMAN WATKINS: Are there any other questions before I close out the panel? Dr. Crenshaw?

DR. CRENSHAW: Just a brief one. As a psychotherapist with also, a medical practice pertaining to sexual medicine, I have struggled a lot with insurance companies. I have found that one of the techniques used by insurance companies to avoid payment of claims, long before AIDS, was to request the detailed records before they would pay a claim. It may not be appreciated that this is another way of accessing records because I think most insurance companies are streetwise enough to know that people don't want their sexual information circulated anywhere. So, this is just a point I might bring up, that it might not occur to most people. They might not think about it. Also, with respect to mental health diagnoses, I spent a 13-year battle fighting and protecting my charts from subpoena, and if I were not so stubborn, which I am and willing to take some risks at certain times, attorneys can penetrate the mental health and the alcohol diagnoses, if they are determined.

If anyone wants to comment on either of these issues, I am open, but I wanted to include these anecdotes.

CHAIRMAN WATKINS: I would like to focus on something other than the law right now. We have a large number of professional organizations who deal with health care in the nation. Irrespective of what the laws are in the states, it seems there is a professional ethic that could be restrengthened in the minds of the American people. Maybe it is time to take a hard look at what we are doing within the health care delivery system to protect against breaches of confidentiality, and set an example for the nation. With the confusion on confidentiality, is now not the time to convene a high-level national leadership interchange between the American Medical Association, American Nurses Association, American Bar Association, American Hospital Association, American Medical Record Association, U.S. Department of Health and Human Services, CDC, state territorial health officers and so forth to address this issue very specifically? Don't try to get it broader than that. Try to say, "What can we do to reassure people with respect to confidentiality? That through the professional ethics that we have in our organizations, we are going to do our darndest to convince you that we can handle it. That we are not going to tolerate violation of our professional ethics" You can do that, irrespective of law. I realize it doesn't have the power that perhaps some tough legal backup does, but it would send a very strong signal. It might even influence state legislation or model state legislation to back you up. I would like to have some comments from each of you on something along that line. Ms. Finnegan?

MS. FINNEGAN:: I would agree with your comments that there is much that can be done within existing codes of ethics and from an administrative point of view. For example, we believe that every health care institution should orient their employees to confidentiality immediately and require them to sign a statement indicating that if they breach confidentiality they are subject to immediate termination. I think if you start out immediately upon hiring employees orienting them to the fact that your standards at that institution require them to handle all information whether it be coded or non-coded information very carefully, then you create a climate that can carry the institution's policies a long way. It is a very major effort, and I certainly would support the idea of a conference. I think there is much more that could be done in the educational programs for medical students and other health professional students to carry forward the doctrine of confidentiality.

CHAIRMAN WATKINS: Dr. Wallas?

DR. WALLAS: If I understand your suggestion, it is akin to a consensus conference in which a group of leadership organizations would get together to set standards and, also, to indicate to the nation that there is a broad-based concern about confidentiality.

CHAIRMAN WATKINS: Not so much concern, I would rather look at it the other way, as a very positive thing to reaffirm where we stand in modern technology, to reaffirm where we stand as a uniform body of professionals that we don't perhaps need a lot of laws around. We are stronger than that. Our belief is in confidentiality after 8000 years according to Dr. Lee, and so it seems to me the --

DR. LEE: I did not say that it was 8000 years.

CHAIRMAN WATKINS: Oh, with particular emphasis, because it is such a volatile issue. It seems that what we are trying to do is calm fears and take advantage of historical and ethical perspectives on this and strengthen them. The conference that was just held by the AMA was enthusiastically participated in at all levels on the education of health care providers across the board. Now, we are talking about taking on the most contentious and volatile issue. It is probably the primary obstacle to the kind of health-driven steps that you would like to take to deal with the virus through a more open and willing testing procedure. It seems to me that it is time to address this. Ms. Finnegan, I would like to take your idea and run it nationally. We must recognize that this is still an issue in the minds of those who are willing or not willing to come forward, and at least it would be a start to push ideas into the system and make confidentiality a matter of professional ethics. At least you would set some standards, and it would be very difficult then within professional organizations to accept those who violate those standards irrespective of law. Recognizing, perhaps in cases such as Mowery here, that it would be nice to be able to do something in terms of litigation.

DR. WALLAS: I think that is an excellent idea. I cannot speak for the AABB, but I suspect that they would be fully supportive of that approach and would participate.

CHAIRMAN WATKINS: Dr. Cates, do you have any views?

DR. CATES: First, under Mrs. Gebbie's guidance, the state public health officials have gotten together to discuss confidentiality as a key issue on several occasions. I certainly would support a reaffirmation of basic confidentiality principles and perhaps even a broadening of principles for all communicable diseases. Second, as Dr. Wadley aptly described, even in the absence of model laws, the STD control arena will continue its heritage of protecting confidentiality at occasional personal risk to those who take strong stands.

CHAIRMAN WATKINS: I am also dealing with the perception of the American people on the issue. After all, I

know you all do a good job in your organizations. That is not the issue. The issue now is can we convince others of your credibility to do a good job. When we have cases come up that clearly are in violation of what we all think are ethical practices, we all get upset. So, from the presentations that have come before this Commission, it is evident that there is enough of that going on to raise the question of whether by just coming together in itself we have addressed this in such a way as to make an impact on the nation as I think this Commission is doing. It seems to me the aggregate view on this issue, the fact that there seems to be a great deal of consensus among the people who have come before this Commission could well help allay some of the fears.

DR. CATES: I agree. To build on the collection of organizations you are suggesting, and to support an idea that Dr. Burke had earlier, if you as a Commission could rally the weight of the presidential image behind this principle, we would form a unified country peer pressure for concern about what confidentiality and antidiscrimination really mean.

CHAIRMAN WATKINS: Thank you very much for coming before the Commission today. We appreciate the time you have all taken. It has been helpful to the Commission, and we will proceed now with the next panel.

Panel number four, the legal aspects of testing. We have three panelists, the Honorable Kenneth W. Starr, United States Court of Appeal for the District of Columbia Circuit; Deborah Merritt, Assistant Professor of Law, University of Illinois College of Law; David Randolph Smith, Assistant Professor of Law, Vanderbilt University School of Law. Welcome to the Commission, and we will commence with a statement by Judge Starr.

JUDGE STARR: Thank you, Mr. Chairman. It is a pleasure to appear before the Commission as it goes about its important task. At the outset, I am well advised to share with the Commission a caveat that as a sitting judge, it would be inappropriate for me to set forth opinions or views on the specific legal issues raised by the testing question. My task, of necessity, will be limited to describing the state of the law. I therefore come before you only to describe and not to opine and emphatically not to advocate.

With that, permit me in the few minutes allotted to me to share a few brief thoughts about the state of the law that is more fully developed in my paper. The first and most fundamental point is that testing does indeed trigger constitutional issues when the testing is administered by or required by the government. Testing by private employers, in contrast, does not implicate the higher law of the Constitution, unless, again, it

is required by the government for the product of governmental action.

The principal constitutional question would be whether a mandatory testing program violated the fourth amendment to the United States Constitution. That basic safeguard states with majestic simplicity that the right of the people to be secure in their persons, houses, papers and effects against unreasonable searches and seizures shall not be violated. The language of the amendment is general. The words therefore call out for interpretation and that is where the judiciary comes in. As the great Chief Justice John Marshall put it, it is emphatically the province of the judicial department to say what the law is. The issue before us in the law is obviously new. The consequences of the tragedy are therefore only beginning in earnest to find their way into the courthouses across the land.

Thus it is that the principal reported case to date on the legality of a mandatory HIV testing program is, in fact, limited. That case, decided just 11 months ago, upheld a program of mandatory testing instituted by the United States State Department to expand its existing employee medical fitness program for foreign service employees seeking to qualify or to remain qualified for service abroad.

But there is a more substantial body of law in the arena of mandatory drug testing programs. Although the issues raised are obviously different, we can nonetheless expect helpful guidance in the near future from the Supreme Court which has very recently agreed to hear a case coming out of the Fifth Circuit Court of Appeals in New Orleans, upholding a mandatory drug testing program for certain Customs Service employees.

In looking then more generally to fourth amendment jurisprudence, what we see in the judicial literature is a careful focusing of the judicial eye on the core value of the fourth amendment, reasonableness. Is the governmental intrusion under all the circumstances reasonable? In making this obviously judgmental evaluation, the courts have looked to the nature of the government interest at stake, and then balanced that interest against the expectation of privacy that society is prepared to recognize as reasonable on the part of the individual. This, I hasten to add, is a societal recognition. It is the values of the community that is the question and not the individualized perhaps idiosyncratic views of a judge or a single court.

In this regard, the courts over the years have tended to be generous in upholding governmental intrusions aimed at promoting public health and safety, as opposed to intrusions carried out in the enforcement of the law. This is aptly illustrated by a Supreme Court decision at the turn of this

century upholding, against constitution challenge, a mandatory inoculation program.

The final point I would share in these opening comments is that the courts tend to look in these kinds of cases very keenly at the safeguards that surround a particular intrusion by the government. Is the intrusion as narrowly tailored as possible? Is it as limited as reasonably possible? Are interests in confidentiality taken into account? Are standards imposed to guard against wide ranging discretion on the part of officials vested with governmental power?

In closing, I would say, Mr. Chairman, that the courts have shown a special interest in whether the program under scrutiny has evidenced careful, deliberate, considered judgment of one or more of the political branches of government, as opposed to a less deliberative and perhaps less carefully crafted program, without the safeguards of the democratic process. This is, at bottom, a requirement of reasoned decisionmaking that is sensitive to the individual interests at stake. That is the path toward the higher ground of our Constitution. Thank you.

CHAIRMAN WATKINS: Thank you, Judge Starr. Ms. Merritt?

MS. MERRITT: Good afternoon. I am delighted to appear here before the President's Commission on the HIV Epidemic. Compulsory HIV testing of individuals obviously raises difficult constitutional and public policy concerns. As I have indicated in my written testimony, the most serious constitutional issues arise under the fourth amendment. Other possible constitutional claims, such as claims based on a right of privacy or on the due process clause, are largely subsumed by a fourth amendment analysis.

The fourth amendment represents a wise decision on the part of our ancestors that in a free society, more information is not always a good thing. It would be useful in any society to know which individuals are harboring contraband or carrying on criminal activities in their homes. If the police could search dwelling places and individuals at will, without warrants or probable cause, we might in fact have less crime in our society. In the same way, if we could test the entire population continuously for HIV antibodies, we might reduce somewhat transmission of the AIDS virus.

The fourth amendment, however, reminds us that health and safety are not the only important values in a free society. Health and safety are important, but those values must be balanced against the interest of individuals in maintaining their privacy and integrity against governmental intrusion. For these

reasons, the fourth amendment limits somewhat the circumstances under which the government may conduct searches of its citizens.

The fourth amendment, of course, does not forbid all searches. Privacy, like public health, is not a value that should override everything else. Hence, the fourth amendment prohibits only unreasonable searches. I have suggested in my written testimony that the courts might look at a dozen different factors to determine whether a particular testing program is reasonable. I cannot address specific programs in this brief introductory testimony but I wish to make the following three points.

First, all mandatory HIV testing programs will be subject to substantial scrutiny under the fourth amendment. HIV blood tests gather intimate medical information about an individual through a procedure that penetrates, however briefly, the individual's bodily integrity. The negative consequences of a positive test result are potentially enormous for the subject. The individual who tests positive for HIV antibodies must face the possibility of death from a dreaded disease; the disruption of his or her intimate relationships; the potential loss of jobs, friendships, and health insurance; and the possibility of social harassment.

Some of the individuals who bear these burdens moreover, will be individuals who will not have posed any threat to public health. They either will be the victims of false positive test results or individuals who, regardless of their infection, would not have engaged in any activities threatening the risk of infection to others. For all of these reasons, the courts will weigh the necessity of any mandatory testing program with great care.

Second, in order to pass muster under the fourth amendment, any testing program must treat test subjects in a dignified and humane manner, must rely upon accurate testing methods, must eliminate the possibility of arbitrary discretion in choosing test subjects, and must maintain test results in a confidential manner. Without these minimum safeguards, it is unlikely that any mandatory testing program would satisfy the fourth amendment.

Finally, beyond these minimum safeguards, mandatory testing programs are most likely to survive fourth amendment scrutiny if they further a concrete and substantial governmental interest, if they enjoy a high level of effectiveness, and if they constitute the least intrusive means of achieving the government's purpose. Testing programs aimed at low risk populations or programs that gather information about HIV status without using that information for a well articulated purpose are less likely to satisfy the fourth amendment. I would be happy to

answer your questions about specific testing programs during our general discussion period. Thank you.

CHAIRMAN WATKINS: Thank you, Ms. Merritt. Mr. Smith?

MR. SMITH: Mr. Chairman and members of the Commission, I am delighted to appear on this panel of lawyers, and I guess I would like to respond, just for a moment, just to the first point about Shakespeare's criticism of lawyers. The absolute --

DR. LEE: Did he say something good?

CHAIRMAN WATKINS: We love you as an American.

MR. SMITH: He said, the first thing we do, let us kill all the lawyers. That was Henry IV, the second part of Henry IV, however, the words were spoken by Dick the Butcher, and he was a member of Jack Cades' rebellion who sought to overthrow and institute an anarchistic system so Shakespeare, read in context, and I will produce these remarks as a supplementary filing, that the first thing that is necessary for the rise of anarchy in the individual rights is to kill all the lawyers.

The only other thing I would like to say on that regard is what de Tocqueville observed which is that there is hardly a question of importance that comes before the American public that does not involve a legal question. Lawyers, unfortunately, are in everything. So let us just talk a little bit about some of these questions from the lawyer's perspective.

The mandatory testing question I think is obviously critical. I would like to address it, though, from the police powers standpoint. As I have said in what I submitted to you, for public health, individual rights may be sacrificed if it is a legitimate exercise of the police powers, if there is a reasonable and legitimate public health risk. I think that is the real difficulty here and what you can do that will be so important is to say what is necessary for the public health and to critically examine on a cost benefit analysis basis whether testing all hospitalized patients, all persons in drug abuse clinics or all applicants for marriage licenses really is necessary when you, from the standpoint of how will that really affect the spread of the disease and what are the negative trade offs in terms of disadvantages from the public health standpoint.

The courts are going to be very interested in what the CDC has to say about this type of testing and what is startling to me is how much of the testimony, at least what has appeared in the papers, Dr. Day, etc., is really in conflict with what the recommended guidelines are for the prevention of HIV transmission, for example, in the hospitalized setting. I think that is a specific area in which widespread screening has not

been called for by the CDC and there is a case for mandatory screening for certain procedures that can be made, but that needs to be articulated and made clear.

The other point I want to make about mandatory testing is you do not solve all of your legal problems. What you generate are test results. What do you do when you get all of these test results? Well, you may get false positives which creates potential liability for negligence and negligent infliction of emotional distress and all sorts of things that are generated by false positives, particularly if you are not relying upon established protocols. If you simply do ELISA testing and you do not follow up with the Western Blot Testing you are going to have false positives and that may create liability.

The more importantly, then you get into this confidentiality problem which I think is central here, and that is, how are you going to keep this information confidential? You have generated all of this information about positive test status, positive test results and then you have a problem of public disclosure of private facts, invasion of privacy, defamation liability, medical malpractice liability if persons do not treat persons who are seropositive.

Then you also raise the question of tort liability for duty to warn. Now I know that someone is positive. Can I be sued if I do not tell their lover or spouse or foreseeable victims? Contact tracing, yes, there certainly have to be, there are questions that are going to arise and I think that confidentiality is not absolute and that one has to depart from confidentiality if a person waives it, to the insurance company. Certainly, it is waived with respect to those who are treating the patient and that waiver of confidentiality may be necessary under the Tarasoff decision to warn foreseeable victims so mandatory testing is going to generate a great deal of questions, legal problems. Even after you have solved the initial problem of its constitutionality there is a potential tort liability once you have all of these positive test results, and what are you going to do with them?

With respect to voluntary testing, I think the major concern here from the tort standpoint is informed consent. Most of the recommendations of the hospital, American Hospital Association and the Centers for Disease Control and the American Medical Association call for informed consent. I realize that the Texas Communicable Disease Statute has department from that. I think informed consent as a part of counselling is quite vital and I think that should be a recommendation of the Commission where voluntary testing is appropriate.

On duty to warn, the American Medical Association has called for specific statutes saying when do we warn, how do we

insulate liability. I do not think that is a good idea. I think it is too difficult a topic and we should leave that to the courts to be developed similarly as it has been done with respect to duty to warn with psychotherapists and psychiatric patients who pose a danger. With respect to non-compliant patients and quarantinings, I do not think we need statutes there. I think that there are going to be cases, compelling cases where persons are unable to control their behavior and pose risks. I think existing law provides the means to handle those cases and if you throw this into the legislature, I am very afraid, I am very afraid what would happen. But I think that is something that needs to be talked about.

Finally, there is the question of civil rights, and I think that goes hand in hand with confidentiality. If you say there are going to be exceptions to confidentiality and we are going to admit some cases where status should be revealed, then you ought to do something to prevent people from losing their jobs and being denied housing. Whether that is at the state level under handicapped discrimination, that needs to be addressed but I leave it to you to set the agenda on the questions. Thank you.

CHAIRMAN WATKINS: Thank you, Mr. Smith. Dr. SerVaas?

DR. SerVAAS: I guess my question is to Ms. Merritt but it could be to Mr. Smith or Judge Starr. Do you know anything about laws, state laws or federal laws, any kind of guidelines that say post-test negative counseling will be done in person and, if so, how is it different from the blood banks where there is not pre-test counseling? Do they notify people by mail or not at all if they are negative? We heard that on the positives, they do that with the physician and post-test counsel the positives.

MS. MERRITT: I do not know of any statute in any state so far that requires anybody doing counselling to do it in one form or another. Obviously the state statutes are just beginning in this area. On blood banks, I did not hear the prior testimony and I do not know other than my personal experience which had to end seven months ago when I became pregnant and was no longer eligible to give blood.

In terms of the type of counselling that one should talk about, blood banks, I think, first of all, present a very different sort of issue when talking about mandatory testing than most of the other types of statutes that we talked about here The individual interest is relatively slight and the government interest is extremely strong. In that context, for example, I see no problem with doing only one test rather than a repeat test if your only purpose is to throw out the blood. If your purpose

is to then notify the individual about the test result, you may want to do more testing.

In terms of the type of counseling, though, which was your question with these different areas, aside from the blood banks, whenever you are doing counseling, usually your purpose is to identify the people who are infected and to stop them from infecting others. In the blood bank context, it is a more narrow purpose of simply throwing out that batch of blood and not engaging in other sorts of public health counseling. Outside of blood banks, without the counseling, testing is likely to be ineffective. Testing in itself really does not really do much from a public health point of view unless you talk to the person who is positive and explain to them what the implications are for the future. That is why I say that the counseling has to be closely bound up with the testing.

Now, in terms of the negative results, in many of the contexts in which one would think about doing mandatory testing, it makes sense to counsel even when a negative result is received because those people are at high risk. The testing, for example, may be done in a drug abuse program. The testing may be done in a sexually transmitted disease program and that sort of clinic. These are people who may be at risk and who, when they go back out into the community, will be at risk again so that from the public health standpoint, maybe the counseling is important there, too.

If one starts testing broad populations, for example, the blood bank, the blood donor population, negative counseling probably can be replaced by simply public education because then we are simply dealing with a broad segment of the public. We want to reach everybody not just those who are interested in giving blood.

DR. SerVAAS: Thank you.

CHAIRMAN WATKINS: Dr. Crenshaw?

DR. CRENSHAW: Mr. Smith, I agreed with all of your comments. I thought they were very cogent with the exception of two and that I want to clarify because I was so busy chuckling at your earlier remarks I may have missed a few points. I thought I heard you say that with voluntary testing the legal ramification was informed consent. You applied the legal problems of perhaps reporting a false positive result due to an ELISA alone, the duty to warn issues and all sorts of other issues to mandatory testing only. It is my opinion they apply to both equally well and we struggled with all those problems already today.

MR. SMITH: Yes, I would agree. I probably should have made that clearer. What I meant to say is that with mandatory

testing, you still have this panoply of legal issues. Once you get positive test result with or without informed consent, you still have all of these other legal issues, but you have the additional problem of did you get --

DR. CRENSHAW: The informed consent.

MR. SMITH: --the informed consent which can lead to another problem, just the victim's finding out about the test result when he or she perhaps did not want to, whether that is actionable as a negligent infliction of emotional distress and then if they lose their job, was that caused by the test that was does without informed consent. I think there is one case where someone was tested without informed consent, probably through an insurance reporting, it was found out they lost their job and they sued under the lack of informed consent there so you do have all those issues apply.

DR. CRENSHAW: Plus the issue of those. Okay, I think that is important because we do try to sometimes put our heads in the sand about the touchy issues that you mentioned and we are forced to face them no matter which direction we head, and I think it is important that that is really clear.

You mentioned, and I will qualify it by in the best of all possible worlds that when it came to duty to warn and issues like Tarasoff and so forth, that the court should decide this. Abstractly I agree with you, but you and I both know how long the courts take to get around to doing this, and I wonder if you do not think it is practical that all of the organizations like the AMA and the APA, that are qualified to exercise opinions really need to be giving some guidance to their memberships in the interim. I assume it could be several years and the loss of a lot of lives if we just flounder.

MR. SMITH: I was responding to recommendation 16 of the report of the Council on Ethical and Judicial Affairs of the House of Delegates of the American Medical Association December 6 through 9, 1987, in which they say specific statutes must be drafted while protecting to the greatest extent possible the confidentiality of patient information to provide a method for warning unsuspected sexual partners protecting physicians from liability for failure to warn, establishing clear standards for when a physician should inform, provide clear guidelines for public health authorities. This really assumes that there can be bright lines, and the problem is what should be done with respect to a warning and what is a reasonable warning and when it is reasonable to notify just depends on a lot of things, and there are guidelines and doctors differ and there is ethical difference about when and how and who should do this.

We can debate that but I do not think you will ever cover all the issues. Foster parents, do they have a right to know that an AIDS foster child is coming into their family. I think probably so. You are going to miss some things inevitably and as Melville said, all men are enveloped in whale lines. We cannot really draw this line. I think it is wonderful to have policy statements but a statute I am afraid will either err on the side of too much disclosure or err on the side of insulating too little disclosure and I think it is perhaps better to keep it the way the Tarasoff case is and just say, look, if somebody wants to sue you and say you were unreasonable, let them prove it to a jury and get all the facts out and put the burden on them to show you were unreasonable, but have this statutory thing debated in all of our legislatures, it just troubles me.

DR. CRENSHAW: Well, we are mixing apples and oranges here. I am not talking about legislatures, I am talking about professional organizations.

MR. SMITH: I would favor that.

DR. CRENSHAW: Yes, I hear what you are saying but in all of the guidelines whether it has to do with common practices and diseases, none of our policies cover even a substantial portion of the cases and there is judgment there. The only reason I am tangling with you at all on this point is that if we left it to the legal profession to set these things, what is the fastest they could do it?

MR. SMITH: Well, --

MS. MERRITT: In 50 years?

MR. SMITH: The law moves slowly.

DR. CRENSHAW: Yes, I rest my case.

MR. SMITH: But I think you, the Commission should promulgate recommendations for the duty to warn and the duty to contact tracing as an exception to confidentiality. I think that would be very appropriate.

DR. CRENSHAW: Thank you. I repeat, I rest my case.

CHAIRMAN WATKINS: Dr. Lilly?

DR. LILLY: I am concerned about the fact that I know a fair number of people, some of them are high risk individuals who have, after consideration, decided not to be tested for HIV antibodies. I must say that all of them that I am aware of, having taken that decision decided to behave as if they were infected. On the other hand, I agree very strongly that people

should be encouraged voluntarily to be tested but given your extremely pessimistic view about the confidentiality that one can expect from testing, what do I do? What do we do?

MR. SMITH: I think the person does have the right not to be tested. However, there is a risk. I mean, they still could be sued, I suppose, for negligently transmitting the disease if they had the symptoms of the disease and had reason to know they had the disease and they sexually passed it on or passed it on through drugs. They could still have tort liability even if they had never had actually had an affirmative test because they would have reason to know they were infected. But I think the point is that people have legitimate fear of not having their antibody status known because of what is going to happen if it is found out because the realities are latency and everything else. So that is a legitimate fear and I do not think that that is elicit but once voluntary testing and contact tracing, I think you have to make an analogy to the foreseeability that people will remain active.

When Roy Cohen, they released the medical records of Roy Cohen from the National Institutes of Health in Harpers Magazine, and there are statement in his record saying that he did not wish to remain, he did not wish to follow a course of sexual abstinence and he was telling his position. In the Rock Hudson case, physicians were sued there because they knew that Mr. Hudson was being sexually active so if you posit those facts where you know people are going to remain sexually active and endanger people, this is troublesome and you have to deal with what is an appropriate response. If that deters people from becoming tested, that may argue, unfortunately, for broader mandatory testing which will be, sort of, I am not really in favor of that so the educational mission, the ethical encouragement to get people to know and act responsibly and protect them so that they will not be fearful of coming forward and being tested, that is really the hope I think.

DR. LILLY: What legal consequences of anonymous testing might follow in that sense? Is anonymous testing really anonymous? Is it unbreachable in any sense?

MR. SMITH: Well, yes. When you get tested here in Nashville at the public health authorities, and it is positive, you come in, at that point, they find out who you are I suppose and they ask about sexual contacts and they anonymously go and try to contact them so that is preserved but, and generally the public health people, unlike doctors, do not have duties to go out necessarily and warn people that they have a patient relationship with, but I think that contact tracing, the public health authorities have done it for other sexually transmitted diseases, and I think the new grants that CDC require and that

you participate in that approach so I think it is a reality for sexually transmitted AIDS.

MS. MERRITT: If I could speak to your question, too, even though it was addressed just to one. I think there is really a threefold answer to your question. One is to maintain the availability of anonymous testing and even in that context, when one does contact tracing, contact tracing itself can be confidential because the contacts do not have to be told who it was that exposed them. Some people will have had only one sexual contact and will guess, but others will not. Secondly, to have laws on confidentiality and to make those laws as clear as possible, I think I probably would differ with my colleague, Mr. Smith, in saying that a law on the duty to warn would be a good idea. The courts have been engaged in a lot of controversy over Tarasoff and it might be a good idea for the legislature to try and strike out a line at least. It will have to be interpreted by the courts later, but give people reassurance about what is protected and what is not.

And thirdly, of course, anti-discrimination laws because a lot of the things that people who are infected fear are things they should not have to fear at all, being thrown out of their apartments, being harassed at work, that sort of thing. If we can give them that assurance, perhaps people will continue to come forward. Maybe that would reassure some of the people you know.

CHAIRMAN WATKINS: Dr. Conway-Welch?

DR. CONWAY-WELCH: I would like any of the members of the panel to share some of their thoughts on an issue that bothers me. We talk about testing. We frequently link that with counselling, and there seems to be a big assumption that we have an enormous quantity of counsellors out there who are well educated and able to leap into the breach. All we have to do is find the money to pay them and we will have solved the testing/counselling problem, at least to some degree. Obviously, we know that that is not true. My personal concern comes from the fact that I know, for example, that nurses in their education, depending on the type of education they receive, have a variety of backgrounds in counselling techniques or may have none, depending on some of the curricula issues. I am wondering what legal issues there are that need to be considered with regard to counseling.

I might add that in the curricula of many medical schools, there is not a major focus on counselling skills and yet people assume that the physician would be a prime person to become involved in that effort. We certainly are in the midst of a nursing shortage. They are another logical type of person who would counsel, but we are short already of nurses. Could you

comment on legal issues surrounding the qualifications of counsellors and what problems are out there that we need to know about?

MS. MERRITT: I agree that it is a tremendous problem, and I would think that one of the most concrete recommendations this Commission could make would be to allocate the resources to training more counselors. I suppose when I think of counselors in connection with mandatory testing programs, I think of people who are perhaps social workers, perhaps nurses, who are specifically trained for that purpose. It is another issue about the government liability for poor counseling, and that is also a difficult one. I do not see the legal issues there being nearly as important as simply the social, public policy, and economic issues that we have simply got to make up our minds to allocate those resources. Governments are protected, to a large extent, by sovereign immunity, from suit by people who are dissatisfied with what the government has done. One would have to look state by state at the type of waiver the government has made of sovereign immunity and I am not an expert on that at all, but generally liability for negligence might not be a problem in that context. It would depend on the states, I suppose. I am speaking out of my depth.

DR. CONWAY-WELCH: So it is really a state issue. **MS. MERRITT:** Yes, and then obviously the Federal Government, if the Federal Government got involved in counselling, then the sovereign immunity question would be on the federal level.

MR. SMITH: I was going to say that there is a potential negligence tort action if, you can imagine the patient is told over the phone by the doctor, he is calling you up, you tested positive, come by my office, suicide. That is a case that might be brought. So there is negligent counselling. The question of who does it, I think the American Hospital Association came out in November and recommended the physician do it and sort of said that community agencies might interrupt the continuity of a patient's care and may be perceived as less personal in counselling provided by the patient's physician. I think it sort of goes hand in hand with informed consent. Whoever is getting the informed consent for assuming voluntary testing for a moment, if you had voluntary testing and you have informed consent, informed consent and then post-test counselling are really, should be considered related.

The question of, now that assumes that this is being done in a hospitalized setting. Outside of that setting, if a person goes in and is tested in some other way, I think there are some legal questions there. Again, negligence questions, and the people who do sexually transmitted diseases and inform people about the status there need to probably think about the more

severe implications of positive test result, but it is a real problem.

DR. CONWAY-WELCH: Are there not enough protections in place already for inappropriate counseling or to protect patients from the results of improper counseling. Is that already handled through other areas of liability and malpractice?

MS. MERRITT: It would be handled through the malpractice, the common law tort area, and the standard that would apply would be simply the professional standard of the counsellors, just as with the doctor the standard is: Did this fall within the standard of reasonable care of a reasonable doctor. Malpractice is judged by the standards of the profession itself. So actually those standards are already there which I suppose in a sense means one does not create more legal problems by training more counselors. In fact, if there are legal problems, they may be most acute if one is not providing adequate counseling at the beginning.

DR. CONWAY-WELCH: With all deference to my medical colleagues with whom I work very closely, the fact that we have a shortage of nurses and a supposed glut of physicians may indicate additional opportunities for folks. But I disagree with the American Hospital Association singling out a profession that my background does not have, the background in counseling that other professions do, and I am not necessarily saying even nursing does, but other professions do have more of a background in counselling. I think that is a troublesome area. I am hearing you say that from a liability point of view, a patient protection point of view that is covered by current legal statutes, etc., and that there may be a person power issue but it is not a legal issue.

MR. SMITH: Just on finances, some hospitals have officers or staff positions that are specifically involved with informed consent. This is all they do is go around and, Case Western was one of the first to put this in. Whoever that person is, the in-house counsellor who is getting informed consent would probably be the person who would have the facility to do this sort of thing in the hospitalized setting, and that I think you are right, physicians do not necessarily like informed consent so they would not like to sit down and talk about all these things either if anyone does.

DR. CONWAY-WELCH: Dr. Schafner says the definition of informed consent is if a physicians sits down in the room with a patient.

MR. SMITH: Yes.

CHAIRMAN WATKINS: Mrs. Gebbie?

MRS. GEBBIE: I think it would be helpful if we could hear a little more discussion between at least Ms. Merritt and Mr. Smith, but Judge Starr may have some comments as well on this issue of whether it is better to let something be defined by virtue of court cases or by having a statute first. I suspect their views depend in part on where we are. I get very impatient waiting for 48 court cases to sort things out and find it much tidier to work with the legislature to get a sense of something to begin with. Obviously, you disagree with that. Could you talk about that a little more?

MR. SMITH: Well, it is, the attention and balancing between civil liberties and public health are so fraught with political, I mean, we have a bill in Tennessee to test food handlers. All food handlers must be tested. That has a lot of political sway in Tennessee I suppose, and that is what happens when the bill gets into the legislature is that there are, now, the courts are not immune to this sort of politics. I do not mean to suggest for a moment that the courts are better to solve this problem but the duty to warn might be argued by some as an immunity statute where physicians do not want to have any liability for failing to warn and therefore want to insulated themselves for liability and a statute could achieve the immunizing effect.

So if the goal is to immunize people from liability then a statute, a federal statute is the best way because a federal statute can override state constitutional objections. This is something that I am sure Judge Starr can talk about but under the supremacy clause if you say physicians cannot be sued for state tort law claims involving da-dum-te-dum-de-dum-te-dum, then you have a strong argument for displacing state tort law remedies at the federal level, and if you want an immunity protection statute, a federal remedy is probably better.

What I sort of said as a way of resolving the balance between public health and civil liberties and what should you do to really solve that tension, there I think the courts may be better, and I was referring specifically to these duty to warn problems and the non-compliant patient problems. I think if you put those bills through states or for the federal legislature, you will not be happy with what comes out in the end. You may be, but it is interest group politics on both sides, and maybe the courts are a little bit less susceptible maybe.

MS. MERRITT: I think a lot of these are subjects that are good for legislative treatment. On the duty to warn in particular, I reacted on that before because the Tarasoff decision, which I am sure you have heard about in other contexts, has remained tremendously controversial. It is always subject to attack. Courts in different states have followed it

to different extents, and courts in many states have not even addressed the issue so we do not know what the rulings would be in those states. We are not completely free of legislative activity in the AIDS area. In states like California, for example, we have very strict confidentiality statutes so that doctors in that sort of state are really caught in a hard place. Are they bound by the statute, or are they bound by the Tarasoff decision? Theoretically the statute would overrule, to the extent that it is inconsistent, a judicial decision but I can understand doctors feeling uneasy about what their potential liability would be in states like that.

Also, while I agree with Mr. Smith that the legislatures sometimes make mistakes, I feel there are good things that come out of legislatures too. My home state of Illinois has taken a lot of grief in some quarters for being one of the first states to require premarital testing, and passing some other statutes, but we have some very good statutes on AIDS in Illinois. We have statutes that have allocated more funds to treating drug abuse. We have a very good confidentiality statute. We have a statute that requires mandatory testing only based on reasonable suspicion with a warrant. There are a lot of good statutes there, and that is only the first attempt by one state. Others may do better as they find these things so I certainly would not rule the legislature out of these areas.

JUDGE STARR: If I could share my parochial perspective from the judiciary, my sense is that in a wide variety of areas, the courts look with great interest to what, in fact, the legislative branch has done, and accords enormous respect to what the legislative branch has done. In a way, this boils down to how we want to govern ourselves. While the courts feel quite comfortable in carrying on in the great traditions, the centuries old tradition of leaving the common law, when there is, in fact, an identifiable public issue that raises a wide variety of public policy considerations and as to which reasonable people can differ, it seems to me that that kind of question in a democratic society lends itself more to a democratic solution through the legislative process with all of the difficulties and pitfalls of that process.

I would simply say that when the legislative process does, in fact, operate resulting in a law, the courts have shown the most enormous deference to the will of the legislature if you will, in the most sensitive areas of our constitutional life. One of my favorite examples is from the first amendment area in the Pentagon papers case. There the Supreme Court paid particular attention to the history in the Congress of the United States of the espionage laws and whether, in fact, Congress had seen fit to vest the Executive with authority to go in and seek a pre-publication ban on a newspaper. I realize that is far removed from the concerns of this Commission.

I cited by way of example that even as foundational as the first amendment is to a democratic society, the Supreme Court has been most anxious to look to Congress to see what Congress has, in fact, done. Courts frankly feel, speaking rather generally, a bit ill equipped to engage in the broad kind of balancing process that legislatures go about. I recall the observations made by now-Judge Bryer who served as an aide to Senator Kennedy for a number of years and was the principal staff architect for a number of very important pieces of legislation. He was a professor at the Harvard Law School and an immensely able man. He said that when he became a judge, he discovered one very basic difference in his professional life was he could not pick up the telephone and call someone who knew the answer. You had to rely entirely on the institutional, the very formal process of litigation.

How conducive that is to resolving broad social problems is a matter ultimately of judgment of the individual, but courts by and large feel keenly the institutional limitations of our roles.

MRS. GEBBIE: Thank you. That is very helpful. Maybe I think so because it comes closer to where I think I was deciding.

My other question goes back to this issue of mandatory testing because I think that remains a troublesome issue for lots of us. I tend in a lot of arena to look at things as a see if you try something and if that does not work, you try something a little harder or a little firmer or a little more restrictive, that is, in a sequence of steps rather than jumping into the most extreme example. To a fair number of people, mandatory testing sounds extreme and sounds like something that is apt to be tested in the courts if it goes into place in any broad way. In those court tests of mandatory testing then that might happen, would one of the considerations be whether less restrictive or voluntary kinds of programs had been tried first and found wanting to protect the public's health or would the evaluation be based on some other things? I think that was alluded to in a couple of your testimonies but I would really appreciate some further discussion of that.

MS. MERRITT: I think absolutely that would be a very important criterion. In all of the drug testing cases, which are the most analogous ones we have right now, the question of less intrusive means or least restrictive manner has been an important criterion in the courts. For example, in the drug testing cases, the courts have often asked if there is some other way the employer could tell whether or not people were taking drugs. Can you just look at the people and figure that out or is testing

really the best way? I think absolutely that would be one of the major issues in evaluating constitutionality of AIDS testing.

JUDGE STARR: I would simply add that without expressing an opinion but just in looking at the opinions that have come out to date, in the drug testing area, as Professor Merritt knows, it would be difficult to exaggerate the importance that the courts thus far have placed on the totality of the situation. It is very much, if you will, an holistic analysis. It is a very non-mechanical analysis. I think it would be a mistake to elevate any single factor in the equation and place the spotlight of importance predominantly on that factor, but it certainly is true that the courts are vitally interested in whether there are efficacious alternative means that would, in fact, warrant a lesser intrusion.

On the other hand, the courts would, it seems to me by reading the cases, be quite sensitive to a governmental statement to the effect that this is, in fact, a very efficient, effective way of achieving an important governmental interest and we have taken individual liberty interests fully into account in a variety of ways, even if there might be, in theory, a less restrictive or less intrusive, I should say, way of going about the process.

MRS. GEBBIE: That is helpful. Thank you.

CHAIRMAN WATKINS: Dr. Lee?

DR. LEE: Mr. Chairman, dealing with three witnesses like this lends an atmosphere of danger to our proceedings. It is like being in the Roman amphitheater with three lions, you know, the slightest wrong move and it is curtains.

First, a note. You made a terrifically interesting point which I have been dwelling on, and that is that, of course, Shakespeare never said anything. It is one of his characters that said these things. That is a mistake I will never make again, but from my point of view, it almost seems like we are getting anarchy with the lawyers. De Tocqueville said that we were going to disintegrate from within. One of the things that we have seen in this Commission is that drug abuse may make us disintegrate from within, and a breakdown in our system of justice will clearly make us disintegrate from within.

I have two major questions which I hope all three of you will address. First of all, fourth amendment issues seem to always revolve around reasonableness or unreasonableness. There are other vague limitations that crop up when you are talking about the fourth amendment like this business about a clear and present danger. Is there any way that you see this at an approach to the AIDS problem? Can you balance the clear and

present danger against the fourth amendment? How do you see that? Or is it just, who can?

MR. SMITH: Holistically.

DR. LEE: It is impossible? You see, that is one of the things that we have to face, though.

MS. MERRITT: No, I am not sure it is impossible. It is, of course, difficult because these are difficult issues. Maybe it is easier to talk about specific programs. We have been talking very generally about the fourth amendment and mandatory testing and it is hard if one does not focus on a particular program. Take, for example, a proposal to screen all prisoners for infection with the AIDS antibody. I would feel fairly confident in saying that, if the program has the sorts of safeguards I described before, that is, we use the standard medical protocol for testing -- the ELISA test, followed up by a confirmatory test -- if we have some provisions for confidentiality which will be very important in the prison context because it is very hard to keep things secret in prison, if we are not picking prisoners in an arbitrary manner, I suspect that the courts would uphold the constitutionality of screening prisoners.

There is a very strong deference to prisons. In the case of drug testing, the courts have shown that deference. There are special concerns about security and about safety in the prisons. The state has a special interest in protecting prisoners from being infected by others.

The only real question that I think courts would raise in the prison context when one is talking about testing is what do you plan to do with the results since obviously simply testing the prisoners does not solve the problem. The state must show exactly what it plans to do with the results. That is, does it plan to have the prisoners then put into prisons that will have more or less equal facilities? Does it plan to counsel those prisoners who are infected? Does it plan to give them condoms? What is the state's plan?

If that sort of question can be answered, I would think that kind of program, if you look at all the factors that you talked about, and I agree very much with Judge Starr that it is a very holistic approach, the courts look at a dozen or more different factors, it would be quite likely to survive review.

Other types of programs might be less likely to survive review. For example, a mandatory program testing all pregnant women for the AIDS virus. There, some of the factors tend to point the other way. We have a very intimate aspect of life protected specially by court decisions, the right to bear

children; we have a low risk population where if we are talking about all pregnant women in the country, we will have very few who are really true positives. All the problems remain of a higher number of false positives. In addition, we have a tremendously pressing question of what do we do with the results. Surely, once the woman is pregnant, the state is not going to say now you must have an abortion. I cannot, for policy or constitutional reasons, imagine any legislature saying that so then the question is what do we do? Well, we can counsel the woman, but, of course, we could offer that counseling without having the mandatory test either, and this might be a case in which the courts would look at the less restrictive means, the fact that pregnant women as a whole tend to do what their doctors ask them to do, and if we left this matter to the doctors and their patients, we probably would get as much testing.

So that is an example of how the factors might be used without knowing for sure how a court would turn out. But if you take all of these different factors and try to apply them in a particular context, it does become easier than talking in general, reasonableness terms.

DR. LEE: Judge Starr, does a fatal widespread epidemic illness represent a clear and present danger, and does that override the fourth amendment?

JUDGE STARR: I will respectfully decline to opine specifically but let me share some general thoughts on that. For one thing, I must say that the notion of clear and present danger is a very familiar one to the bench and the bar and to the public generally. We associate it with first amendment analysis. That is to say, in light of the basic protections in a democratic society envisioned by the first amendment, before there can be a prohibition, substantial curtailment of speech, there must, in fact, be a clear and present danger. That has not been the test in the fourth amendment area as to whether a governmental intrusion is justifiable or not. It is not the law, at this stage at least, that government must establish a clear and present danger in order for it to take a particular, intrusive sort of action that would constitute a fourth amendment event. In fact, the fourth amendment itself, in the part that I did not read, articulates this legal standard of probable cause which, in the law enforcement setting, every police officer on the beat is familiar with. That police officer, he or she, must have probable cause to take a particular kind of action and the like. So there is a less daunting standard than a clear and present danger.

But it might be helpful at getting at this if I shared with you very briefly a couple of examples from the courts in this closely analogous, albeit different area of drug testing. In one, the testing program was upheld, in the other, the

program was struck down. Why the difference? Although they did come out of different courts why the difference? In looking at those cases, one principal difference that emerges is that the system that was upheld by the Fifth Circuit in New Orleans was a very carefully crafted, albeit mandatory, testing program. There was a clear establishment of the government's interest. Here is why we are interested in having these test results. Here is why we need these test results, this being the Customs Service's involvement in drug enforcement. That was the basis of the Agency's interest there.

There were also safeguards in place so as to minimize the intrusion. And my colleagues have rightly said these testing programs obviously do involve intrusions. They are fourth amendment events, but there were, in fact, safeguards in place in that program so as to minimize the extent of the intrusion, the personal embarrassment and the like. It was carefully crafted.

The program in contrast that was struck down was not the result of a careful administrative process. It was a good idea that the police chief of a particular community had, and was executed in a rather intrusive and indeed rather heavy handed manner. There was no involvement by the political process which, again, the courts, and I am sounding again a slightly different chord than Professor Smith, there was no indication that the political branches, the legislative branch or the executive branch at a policy making level, had in fact sanctioned this activity, the head of the department and the like at a meaningful level. No action by the state legislature, no action by a city council. It was simply done.

Now, I do not want to suggest that action at the highest levels of the political branches is necessary to withstand fourth amendment scrutiny but I do want to emphasize that it is very helpful in this entire equation that courts will, in fact, look to.

MR. SMITH: If I could just, I think the fourth amendment question is going to be favorable to allowing testing as long as it is a reasonable exercise of police powers to prevent public health epidemic which goes to the point of looking very carefully at the medical public health risk and if it is a reasonable or potential risk, I think the courts are going to show a lot of deference.

The point that I wanted to come back to was this business of statutes or court cases, the kind of careful, multi-factorial, holistic balancing that applies to fourth amendment really ought to apply to most of these questions. When you get a statute on the books, then you have to engage in this search for legislation intent, sort of a Hemanutic,

will-of-the-wisp, what did the legislature think even though they may not have thought about it.

For example, in AIDS, in California, the Barlow case, a demonstrator in a gay rights parade bit a policeman, was arrested, said he had AIDS, and the court tried to order his test result, or his being tested. The court was handcuffed because the California legislature passed a statute saying you could not disclose test results. Well, in Tennessee, we did not have a statute and the court ordered the prisoner tested so the statute can be both a shield or a sword and in a way, the court can handle the case and balance the equities if there is a statute and then we do have to look to what our political representatives wanted to do, even though they may not have thought about the question before them. But on this question, I think that hospitalized testing for all patients between 15 and 65 has a good chance of withstanding the constitutional scrutiny. The testing of people with marriage licenses has a good chance of withstanding constitutional scrutiny, depending upon the medical health risk, and I think that is a very tough question about whether we should have such laws because those are close issues, but I think the courts probably will sustain those if I had to bet.

DR. LEE: Could I get into one other area? We heard testimony the other day about the Supreme Court decision on whether contagiousness is a part of 504, and we have this problem with the Department of Justice and the Executive and Legislative branches which do not seem to like that Supreme Court decision and there is machinery to question it. Is the Supreme Court decision the law of the land? What happens in your system when somebody does not pay any attention to it?

MR. SMITH: That is a good question for the Judge, but I just want to add one thing. The Supreme Court in the Arline case decided the question of contagiousness under Section 504 in a tuberculosis case, and wrote a footnote, as you are aware, saying we are not deciding AIDS or HIV for the reason that different facts may call for different results. The logic of the opinion would suggest, most commentators, and, in fact, was applied, I believe, by the ninth circuit in the Chalk case that persons with AIDS are handicapped because they are disabled and a person with AIDS should fall within Section 504 and most states have interpreted their handicapped statutes along that line.

The question is whether HIV positive status, mere infectivity constitutes a disability or a handicap or an impairment within the meaning of the statute. That is a legal loophole, a lawyers' argument which somebody who does not want to extend civil rights protection to HIV positive persons can seize upon, whether the United States Supreme Court will determine that HIV positive status is a handicap gets into lots of questions

about perceptions and being perceived as handicapped and reasonable minds can differ, but I do not think it is fair to say that the Supreme Court's decision in Arline decides the issue of contagiousness as a handicap in all settings because of this difference between actual impairment now versus future impairment.

JUDGE STARR: To respond to the specific question, when the Supreme Court renders an interpretation of a statute, then that is indeed the law of the land. Congress can change it, we see the movement with respect to the Grove City decision which was not a constitutional decision but rather the Supreme Court, as authoritative interpreter of the law, and in this instance, the statute, so what the court said in Arline is what this statute means. If, in fact, the executive branch is unenamored of that interpretation, if the Congress of the United States finds it not to its liking, then Congress can quickly take or it may take some time, take corrective action. I can cite a personal experience in that respect. I authored an opinion for my court, interpreting one aspect of a statute and it had quite a major consequence on a major business transaction, and it took the United States Congress 27 days to overrule my decision, not to say that I was wrong but simply to overrule to change the law. So until such time as Congress sees fit to act differently, if you will, in the rehabilitation act in Section 504, then Arline is the law of the land, but with the possible gap as to which there will, I am sure, be further litigation.

MS. MERRITT: The most important fact about Arline is that it does not decide any of the really important issues because Section 504 does not mandate treating handicapped individuals exactly like nonhandicapped individuals. It says that otherwise qualified handicapped individuals must be treated like nonhandicapped ones, and I think the Supreme Court remanded to the lower courts to develop standards on what we mean by otherwise qualified in the context of a communicable disease. But I suspect very strongly that a teacher, for example, with an active case of tuberculosis that could be communicated to children in the classroom, would not be considered otherwise qualified for the job. So I do not think there should really be too much problem with saying that people who have diseases, whether communicable or not, are handicapped and are covered by the statute. That does not really get to the important question, which is whether they are otherwise qualified. That is where the courts would take into account the public health risks.

MR. SMITH: The Supreme Court, though, did adopt the American Medical Association's recommendation on how to determine what constituted otherwise qualified and with respect to a disease and since AIDS is not an airborne disease, presumably someone in employment who was HIV positive in an office setting

would be otherwise qualified to work so if the law does apply to an HIV positive persons, it pretty much would extend its protection, but that is sort of a question that the Court did not want to address.

DR. LEE: Thank you very much.

CHAIRMAN WATKINS: Ms. Pullen.

MS. PULLEN: No questions.

CHAIRMAN WATKINS: Dr. Walsh?

DR. WALSH: Yes. I am a great believer in the last shall be best, and if I heard you all correctly, I am kind of pleased that the three of you are legal specialists and you are cautioning us against rushing headlong into recommending new, federal statutes and so on which is very close to my own heart because, for many reasons, not only philosophical but because I do not think we know enough yet about this disease and where it is going.

In the definition of mandatory testing, which is a problem for this Commission, I mentioned earlier that a term used in Hawaii of conditional testing be put on the horizon. Would there be a difference in the legal interpretation if say as part of your contractual obligation to buy insurance, you have to take an HIV test if you want to buy more than $50,000 worth or $100,000 worth? In other words, would that be considered mandatory testing or would that come more under contract law or contract law interpretation? That is one question. Want to answer that first?

MS. MERRITT: I think the question really is does it raise constitutional issues. If it is done solely by private parties, there are no constitutional issues at all whether you call it mandatory or conditional. The only time you would get a constitutional issue, either a fourth amendment issue or another constitutional issue, in the scenario you are talking about is if the state passed a law saying all insurance companies should test. If the insurance company does it, there is no constitutional issue.

DR. WALSH: Now, along the same line, what will be the fate of the people in the District of Columbia who cannot buy life insurance because the District of Columbia Council chose to pass a law emotionally really because anyone that was HIV positive could not buy life insurance without a test, even though those who wanted to buy life insurance were willing to take a test so they could purchase it. The result has been to drive all the life insurance companies out of the District of Columbia. Will that law last if somebody chooses to bring a suit?

MR. SMITH: Well, that law, that was the other side of it. That law was challenged constitutionally as a violation of the insurance company's due process rights. Now, once again, the courts did what Judge Starr has suggested and gave wide sway of deference to our publicly elected authorities with the result that there is no life insurance available in the District of Columbia. It is not altogether certain that every state, if a state constitutional challenge were brought as opposed to a federal court constitutional challenge, it is not certain that every state would say that is constitutional. But for the most part, it probably would be constitutional.

DR. WALSH: And that is not an unfair infringement of the 95 percent of the people who do not have AIDS?

MR. SMITH: I would argue it is unconstitutional and it does violate due process but I would probably apply a stricter level of judicial scrutiny that the federal courts would. The federal courts, when it comes to a due process review, are extremely deferential with economic regulation. As long as the legislature is not proven to be on drugs, they will sustain the legislation. Under, well, we just happen to defer it to the legislature. But if you start looking at, a state court, some state courts, have sort of sailed out on their own, and applied a more vigorous level of judicial scrutiny with respect to due process claims including economic due process claims, listen, you are destroying the insurance company's right to make a living and sell insurance in D. C. and you ought to show some reasonable or significant justification. The court did not get into it.

DR. WALSH: Would it have a better chance if someone who is denied the opportunity to buy insurance filed the suit and said it is not the insurance company he is worried about, it is himself and his family.

MR. SMITH: It is a more appealing case, but the legal principles --

DR. WALSH: Would be the same.

MR. SMITH: Are the same.

JUDGE STARR: I would just add, if I may, if you would permit me, that the courts have, over the years, developed the phrase rational basis. If there is a rational basis for the statute, then the courts will not strike it down on due process, substantive, if you will, due process grounds. The idea is that the courts are not to be in the business of fashioning public policy. That is for the legislature and even if the courts feel profoundly that the legislation is unwise, if there is a rational basis for it, it would be sustained.

DR. WALSH: Now, a second question, I have two or three but they are all simple ones. One of you commented, I think it was you, Ms. Merritt, that because of the threats of discrimination and the like, that information related to HIV was extremely significant and had some basis for maintaining confidentiality to a very strict degree. Was this information, in your opinion, more significant than information used to be in the test for syphilis. I mean this had the same stigma before it was treatable and the same superstitions. You know, people thought you could shake hands and get syphilis and one thing or another. Why is the statute different?

MS. MERRITT: It is not different. In fact, there are very strict confidentiality statutes with respect to testing for syphilis, and if the same sorts of statutes were adopted with respect to AIDS, they would go a long way. That is how we actually managed to combat syphilis in this country, I think, by having a combination of public health efforts. There were medical advances with a cure for syphilis, there was contact tracing, and there were very strict confidentiality statutes. In fact, the statute is so strict, there is a New York case, for example, interpreting their statute where the person who, herself, went into to be tested, wanted to have the test result released publicly because she was involved in a law suit where she was suing somebody who had raped her and she wanted to prove he had given her syphilis. They refused to release the result publicly, even at her own request, because the public policy is so strong that in order to conquer syphilis we have to have this confidentiality protection.

DR. WALSH: Yes, but if you had denied a marriage license after having the test, the confidentiality is blown, is it not?

MS. MERRITT: Not necessarily. The state does not publish the fact that it has denied you a marriage license.

DR. WALSH: But one of the two of you know, and families would know.

MS. MERRITT: Sure, and when speaking of confidentiality, I do not think that any of us mean that confidentiality would overrule, for example, a warning that a doctor would give to a patient's spouse if the patient had him or herself refused to tell the spouse. We are not talking about absolute confidentiality, but the sort of protections that prevent employers or other people -- busybodies on the street -- from knowing.

DR. WALSH: Is the anonymous testing program being carried out by CDC in 30 or 40 hospitals in any way in danger of being accused of a violation of informed consent?

MS. MERRITT: I would not think so, although I do not know much about the specifics of the program.

DR. WALSH: Well, they just picked 40 hospitals and they are doing anonymous testing of routine hospital patients.

MS. MERRITT: Oh, I am sorry. I see. I thought you meant the alternative testing.

DR. WALSH: No, I wondered whether that, I personally hope it is not threatened but I am just curious. When you talked about informed consent, whether some patient could bring a suit on that basis.

MS. MERRITT: Probably not because the samples are not identified to the individual. As I understand it, the blood is drawn for other reasons, and then we would just take a random sample of the blood and we would remove all of the identifiers and we do this solely for epidemiological --

DR. WALSH: Is there any obligation, though, on the part of those that you find are seropositive? Is there anyobligation on the part of the hospital to inform the patient that indeed he has become seropositive?

MS. MERRITT: Well, by definition the hospital cannot do that because in order to conduct this testing program without running into informed consent problems, --

DR. WALSH: Oh, I mean, then would CDC be obligated to?

MS. MERRITT: You have to have destroyed all of the identification so that there is no way.

DR. WALSH: Okay. Now, finally, my last question. You were talking about the reasonable departure from the rules of confidentiality if public health risk is involved. Could you answer my question to which I have gotten no answer all day as to what bearing would this have on the seropositive patient who knowingly rejects behavioral change and continues to behave in a promiscuous fashion? In other words, is that a reason to digress from the rules of confidentiality without informed consent?

MS. MERRITT: I would think that that would be a reason to do something, whether it is to counsel the patient further, to try and get that patient to change, or it is to contact a spouse

or another known identified person who is at risk. Or even in the extreme cases, I think Professor Smith mentioned earlier, we do have and have had in the past statutes dealing with recalcitrant patients in the tuberculosis context and in other contexts and if somebody continues to put the public health at risk and will not modify their behavior, we can even isolate that person. Now, in a lot of states right now, we do not have clear legal standards with respect to AIDS, and that is why I suggested it might be a good idea to think about those standards -- when the doctor should have a duty to warn and that sort of thing. I personally would not see any problem with that.

DR. WALSH: Do you have any comment on that?

MR. SMITH: I would agree that the first step is to encourage people to warn, etc., but if you have a non-compliant, non-cooperative patient, then civil liberty issues seem to pale with respect to the clear and present danger.

DR. WALSH: This may be one of the things that will end up in court and the rules will then be made after the fact.

MR. SMITH: Well, there probably would be a proceeding but that is probably how it should be handled because every case is --

DR. WALSH: No, I am in sympathy with that. I hate new laws if we can avoid them.

CHAIRMAN WATKINS: Dr. Crenshaw, you have a follow up question?

DR. CRENSHAW: The San Diego case you referred to about the police officer who was bitten? Just a point of interest, I was involved in that case, and eventually there was an injunction of some means by which the person who bit the police officer had to be tested against his will. However, it was against the law for the public health department to tell the police officer what the results were.

MR. SMITH: Okay, that is it. They could not release the results because of the statute.

DR. CRENSHAW: Exactly. One point of curiosity, following up on Dr. Walsh's point. You mentioned earlier, Mr. Smith, that if someone was infected, had spots, even if they had not been tested and knew that they had reason to know that they were ill and continued to have sexual partners, that would be cause for concern. Somebody who has had a few sexual partners who have become infected but someone who does not want to know and who states that they do not want to know because they do not want to confront all the changes to their life and the ethical

issues of continuing to have sex. Where does something like that fall?

MR. SMITH: Well, it is once again this amorphous, common, reasonable person of the common law. I suppose a person could continue to engage in sexual activity even though there is a possibility that they are positive without being held liable under civil tort law for negligence. And there is another problem with respect to, suppose they did infect somebody and then the person who was infected sued the infected person, there might be some defense of contributory negligence or assumption of the risk in that you did not use the safe practices, etc., but the answer it there is a moral and ethical obligation to be very concerned and find out about your status if you have reason to suspect you may be infected, and that might arise to a legal duty to where you could be sued if it was reasonable to assume that you might be infected.

There are, I do not think you can rely on the tort law however to stem the epidemic. These tort suits that come up here and there are going to do nothing to prevent the spread of AIDS. You could pass a law saying you will be liable, all persons who pass along AIDS through the use of intravenous needles can be sued in tort or, you know, that is not going to stem the spread of AIDS. I mean, it is a nice, moral slap on the hand, it is a reaction, it is a good one, but it is not going to stop the epidemic. You have got to do education and counselling and research. Those are the things that are going to solve that.

CHAIRMAN WATKINS: Dr. SerVaas, do you have a follow up question?

DR. SerVAAS: Yes. My question is to Ms. Merritt, and it has to do with a statement you made about mandatory testing. You were listing the kinds of mandatory testings that you thought maybe could be or could not be conducted without legal ramifications. While you were talking about the mandatory testing of pregnant women, you said you thought that there would not be any purpose because obviously she is already pregnant. I agree with everything but I wonder whether you would want to tell the man in your life so that he could take care of you and not become infected with the AIDS virus if you had not already infected him? Would that not be a reason?

I have another question. I am just curious to know of how you feel about the mandatory marriage license testing and whether there has been any kind of referendum or any kind of surveys in Illinois to find out what the public in Illinois thinks about it. The reason I want to tell you that is that we did do a survey of 11,000 we questioned. The question we asked was do you believe that all who apply for marriage licenses should be tested for AIDS. The answer, of 11,000 people, 90

percent said yes they did believe that. Seven percent said no and three percent had no answer. I am not telling you that I am for any kind of mandatory testing which I have gone on record always as being against but I want to know what you think. Do you have any surveys or referendums in Illinois that tell you what we the people think about testing for marriage license applicants?

MS. MERRITT: Well, to go back to your first question first, on the testing of pregnant women, it would be a reason to test pregnant women to find out if they were infected so they could tell their spouses, but it is not a reason that applies particularly to pregnant women. That would seem to be a reason to test everybody in the population and the question is whether or not it is worth doing that, given the low rate of infection in the population as a whole, the fact that you have to keep testing every six months and those sorts of questions that I am sure you have discussed before. In the pregnancy setting, that is a rationale that applies to everyone.

I will say about pregnancy that I do think that in fact doctors and patients are beginning to test solely on a private basis. I know that in my clinic, doctors have decided to test all women. They can, of course, refuse to have the test.

To move on to your second question about premarital testing, Representative Pullen is your expert on the Illinois situation since she is a member of the Illinois legislature and she could tell you much more accurately than I could what went on in the legislature, and, in fact, about polls from Illinois. I am sure that there are some, but I do not have any figures in my own mind as to what people in Illinois think about the marriage license testing.

DR. SerVAAS: I could not tell the way you explained it how you felt about it.

MS. MERRITT: About how I felt?

DR. SerVAAS: That is really what I wanted to know.

MS. MERRITT: My feelings about premarital testing are rather mixed. At first glance, it seems to be a relatively easy step to take. After all, we already draw blood in most states for syphilis. Why not test for AIDS as well? In addition, we do have a risk of transmission in marriage. It is not like food handlers and we do know that sex and also giving birth are ways of transmitting AIDS.

The problems with the premarital testing, and I am sure you may have heard some of these points before too, are first of all, the questions that people still have about the rate of false

positives. I have heard, I have looked at the medical literature and seen estimates ranging from one in every, and this is a combined false positive rate if one uses both the ELISA test and the Western Blot, the estimates for false positives range from one in every 1,250 to one in every 100,000. There is a broad range of values there. If you test 1.7 million people each year who are getting marriage licenses, then you get false positives ranging from 17 which is a relatively low number to 1,360 which is a fairly high number.

You also have a greater number of people who are in the ambiguous middle position who have a positive ELISA test. There is also work that suggests that on the first ELISA, if you test the premarital population, as many as 50 percent of the positives may be false positives who then are ruled out by the Western Blot. I sort of wonder what those people and their potential spouses think about having had one positive test and one negative test. So you have a serious problem in terms of the kinds of psychological burdens you are imposing on people who may be false positives or sort of halfway false positives who do not know what they are doing. And as I am sure you have gotten from the statisticians before, that is a greater problem when you test low risk populations than when you test high risk ones. You have not heard about that?

DR. SerVAAS: No.

MS. MERRITT: Well, the statistics, you can show it all on a blackboard but if you test the high risk population, most of the positive results will be true positives. As you test the lower risk population, a greater proportion of the positive results become false positives. I could work it out for you on a blackboard but there is not one here. That happens to be the way it works up so I think it is a troubling case for that reason.

DR. SerVAAS: I think it is troubling that we do need to educate people never to take an ELISA result and we have been given testimony from two different sources where 580,000 very low risk people were tested and not one false positive. I think we have pretty much debunked a lot of that fear of false positives but it has not caught up with all of the experts.

MS. MERRITT: One final comment about the marriage situation is that there are other alternatives other than simply going to mandatory testing. I think somebody asked before about less intrusive alternatives, and I know that there will be people in the country who will feel it is another example of government getting on their back if they are mandated to take a test. There are some states now, I think California requires all marriage applicants to read and complete themselves a questionnaire that will reveal to them whether or not they are at high risk and then counsels them both in writing on the questionnaire and orally

that if they feel in any way that they are at risk, they owe it to themselves and their partners to have a test before getting married. That sort of counseling, specific counseling which can be done even in a somewhat written form perhaps with the marriage license might be one step to try first before going to the more intrusive measure of mandated testing.

CHAIRMAN WATKINS: Thank you, Ms. Merritt. Dr. Lee?

DR. LEE: Could you clarify one point? Dr. Walsh heard something different than I heard and this is a relatively important point for us so please clarify it. He said, are you cautioning us against passing additional statutes?

DR. WALSH: Federal statutes.

DR. LEE: Federal statutes. And I thought I heard Judge Starr say that he had the greatest respect for any legislation and that it had a profound effect on how he conducted his business. This is quite important for our report and so forth. Could you clarify this?

JUDGE STARR: Well, I am not here to recommend anything. I think if I understood Dr. Walsh's question, he was suggesting do not rush head long. What I tried to convey was that the courts are keenly interested in the results of the deliberative process. It is presumed, of course, that the legislative process is a deliberative and careful process. The courts are willing to presume that. My point was that if there is, in fact, a statement in the form of law from the political branches, or a considered judgment by the executive branch at a significantly high level, then that judgment of the political branches will garner the respect of the courts. It does not necessarily mean it will eliminate constitutional concerns but it certainly will weigh heavily in the balance as a sign of the non-political branches' respect for the political process.

DR. LEE: You see, we are caught in our final report as to whether we will or will not recommend that the legislative body look at certain items. The alternative is to let it pass, disregard it.

DR. WALSH: That is not true.

DR. LEE: Well, what is the other alternative?

DR. WALSH: That is your conclusion, Burt, that is not true.

DR. LEE: What is the alternative?

DR. WALSH: That is not true. The alternative is to observe what has happened at state legislative efforts and make efforts to determine what the success has been, what the challenges have been, what controls of successes have resulted, before you rush head long into federal legislation. Federal legislation is much more difficult to modify or remove once passed, and has much greater implication I think. So I do think there are alternatives. I just do not feel that as conscientious as we have been in our hearings, that in nine months on a subject this complex, we are yet in a position to recommend federal limiting legislation or federal legislation of any kind. That is all.

MR. SMITH: I think, if I may just offer one point, the notion of state legislatures as being a laboratory in the experimental process in working things through is one of the major strains in the law for allowing state legislatures to experiment and try to work things out before federal legislation. They have been trying to pass federal product liability legislation for years and it has been defeated. There are all kinds of, and medical malpractice legislation at the federal level, there are certain very significant advantages to federal legislation that overrides and supersedes contrary to state law and is a supremacy clause point.

So, for example, if you really decide as strongly that one or two particular things just had to be uniform and had to be set and had to be moved on now, then federal legislation would be appropriate. One of the issues is a question about employment and housing and applying the handicapped laws specifically to persons who have AIDS or HIV status, and federal legislation there would, for example, after the Arline decision, Tennessee amended its state statute to exclude from the coverage of handicapped communicable diseases. They just said no. Under our law, under our state employment discrimination law, a handicap, the term communicable diseases is not a handicap and they directly went against the Arline opinion so you are having a lot of shaking out but the larger question of a statutory solution to these problems is that when you get into state tort law and how to handle these balancing problems, federal, it is different from state, although statutes themselves have advantages. You have to sort of ask if it is going to federal legislation or is it going to be statutes at the state level and there is a little difference there. But I might be in favor of certain things at the federal level but on the whole, a lot of these things do not need necessarily statutes.

DR. LEE: One of the things that repeatedly comes up for us, though, is that this is not a state problem. It is a national problem. AIDS walks. It is an international problem so that just like your state liability stuff and state drug laws and state discrimination laws, etc., etc., do have their limitations

and this many, many, many witnesses have, if there is one thing that I have come away with, is why does your President not do something, what does your government not do something. This is the type of other side of the coin. I understand Dr. Walsh's opinion but the other side of the coin has been expressed here vehemently.

MR. SMITH: Well, as Publius said, delay is hateful but promotes wisdom.

CHAIRMAN WATKINS: I have asked the Executive Director to clarify one point for the record because I am a little bit confused on what was said.

MS. GAULT: On a number of issues, this Commission is going to have to make recommendations about whether there should be changes to state statutes or federal statutes and so it is important that this panel's relevant testimony not be misrepresented. I would therefore like to go through the list of these issues so that this panel's positions are made clear. If you do not feel comfortable responding right now, you may respond in writing.

The first is federal laws on anti-discrimination against those who are seropositive. The second is some type of federal law on confidentiality or some type of federal law encouraging states to do something in the area of confidentiality. The third is a federal law affecting federal funds for states which did or did not have contact tracing laws. This is an issue that we will have to face at some point soon. The fourth is some type of federal law, perhaps a withholding of funds, which did or did not encourage states to enact criminal statutes related to the transmission of HIV.

All of these are issues that we will have to either take an affirmative position on or a negative position on and I think it would be helpful for us to get your position in writing on these particular issues.

JUDGE STARR: Well, I can be very brief and say again, it is not my position or would not be appropriate for me to make any recommendations of any kind.

MR. SMITH: I think that I would say that with respect to the last, withholding funding from states that did not pass criminal statutes. I think there you are talking about a carrot and stick approach of federal incentive, using the spending power to encourage state legislation on criminal statutes. I think that the states are already moving in this direction and do not need a lot of encouragement and that is a marginal benefit in curing the epidemic.

With respect to contact tracing, I think that is pretty much already in place in a number of ways, and if federal legislation is necessary to encourage contact tracing, so be it, but I question whether it is really necessary because I think states for the most part, as I say, under the CDC grants, sexually transmitted disease grants, they have got to do it anyway so you have got to decide whether it is really necessary.

On confidentiality, AIDS test results are confidential. They are part of the chart, they are part of the file. They are confidential. Whether you should have any special rules regarding HIV status, I do not think so. I do not think you need that. With respect to penalties for disclosure and an additional federal remedy for invasion of privacy or something of that sort, I think state laws are already there. If it is really found wanting, and maybe a federal law there. The one area that you do need some guidance on is this gap in Section 504 and gap in state employment and housing laws where civil rights is a gap and there are not state laws that are good in that area, and that would be the one area where there might be a need so that one is worth considering.

CHAIRMAN WATKINS: Would you put that, Mr. Smith, in the context of the Mowery case in East Tennessee, the latter statement you just made. Where would you see it going there?

MR. SMITH: A federal statute prohibiting discrimination?

CHAIRMAN WATKINS: No. I am talking about the Dwayne Mowery case here in Eastern Tennessee.

MR. SMITH: The student?

CHAIRMAN WATKINS: Right. Where would you put that? That is up to the state, as I understand, and this is one state that does not seem to have --

MR. SMITH: Our laws are not particularly helpful there, although I think under the education laws, you might have been, well, I think the state medical records laws and breach of confidentiality, if it could be proven that his medical status was released by school officials under the education law, you might be able to state a claim, but we would have a problem under our state laws there. I think you would, in order to remedy and protect that fellow, that young boy and others like him, you would need to have a stricter state confidentiality law, a specific cause of action which may or may not be needed at the federal level.

CHAIRMAN WATKINS: Do you sense that there is a proclivity in Tennessee to move in that direction as a result of the lessons learned out of this case?

MR. SMITH: Yes, I think there is. But the Tennessee state legislature, after the Arline case, the first thing they did was say, well, the federal, the United States Supreme Court says that communicable diseases fall within the definition of handicapped. We say no, and it is debatable whether our amended state employment discrimination statute would not apply to AIDS but I think that a federal law that set up just as Section 504 reads, to apply that to HIV status would clarify the law, and then secondly, if you had a specific statute, I think isn't it Representative Waxman has a statute.

CHAIRMAN WATKINS: So you are recommending to the Commission that perhaps there needs to be a clarification.

MR. SMITH: Yes, I do think there needs to be a clarification on Section 504 and AIDS and HIV. That is number one because the courts are divided on this, and there really is some dissent on that legally and a recommendation would recognize the need for that legislation and with respect to confidentiality, if a doctor discloses confidential information without a privilege, there would be liability under state tort law, but a federal remedy I think would be very strong, effective and clear and would set a tone but I think number one, for the Mowery case in Tennessee, you have to have discrimination.

DR. WALSH: Jim, may I ask a question please?

CHAIRMAN WATKINS: I would like to have Ms. Merritt answer.

DR. WALSH: All right, when she is finished, I would like to ask a question, too, of you I mean.

CHAIRMAN WATKINS: Ms. Merritt, would you answer?

MS. MERRITT: Sure. You are asking for my opinion as to whether I think it would be a good idea to pass these laws, not whether or not they are constitutional because I do not see any particular constitutional problems.

MS. GAULT: Well, it had been represented that you were opposed to any kind of federal laws.

MS. MERRITT: My feelings on the laws you suggest are, on the last two you mentioned, the carrot and stick approach with respect to criminal laws and contact tracing, I think I agree with Professor Smith there that that is an area that has always been very much a state domain, public health, contact tracing,

criminal laws for people who expose others knowingly to a contagious disease. I think the states are also acting there, either under their existing laws or with new ones, quite rapidly to deal with that problem. I have just written a long article about federalism and how important it is even today to maintain a role for the states, and I think that is one area in which we can safely leave the role to the states.

On the other two statutes, I do see more role for federal involvement. Confidentiality, to begin with, I think is perhaps one of the most important steps that anyone can take to try to stem this epidemic because it is a way of encouraging voluntary testing which in the end is probably the way we will get most people to be tested. Even if we enacted mandatory testing for everyone tomorrow, it would be a nightmare to put it into effect and to really do it.

We are going to have to rely to some extent somewhere on voluntary testing and confidentiality is the key to that, and if we have some states that are moving in that direction but not others, this is an area in which national uniformity could help a lot. It is something that requires a lot of thought, how we are going to draft that statute, and one would want to look at what states have done and it is possible we are not even ready today, we need to think about it for a few more months, but that is an area for federal involvement.

Similarly, on discrimination, I think that might be an area for federal involvement. It certainly has been in other civil rights areas, from discrimination against racial minorities to the aged to women to people with handicaps. And again, that would be a significant step towards controlling the epidemic because of the effect it would have on people's willingness to come forward and be tested voluntarily and might fit in well with that the states are doing in terms of contact tracing and other sorts of public health protections. The question you will have to face there is do you take the approach of Title VII which is to have a federal anti-discrimination law that applies to almost everyone except for small employers who are specifically excepted or do you take the approach of the discrimination against the handicapped, the Rehabilitation Act, which applies only to people who receive federal funds, and is a much more limited kind of statute. The reason that was done, I think, with the Rehabilitation Act was a sense of caution. It was also done with respect to school children because education is traditionally a state domain and there was a sense of moving cautiously there.

It obviously, however, does not go very far in terms of relieving the problem if the only anti-discrimination law on the federal level applies only to those who receive federal funds. A much stronger step would be to take the Title VII approach which would apply to all employers with exceptions and in the AIDS case

perhaps there is not even a good reason for exceptions for smaller employers.

CHAIRMAN WATKINS: Are you recommending that the latter be something that we, the Commission, consider?

MS. MERRITT: I would recommend considering that. Again, with discrimination laws, one would need to look at what the states have done for suggestions. The states are marvelous resources in this country -- Brandeis called them the marvelous laboratories of research. There may be language in the state tatutes that would be useful. It obviously deserves a lot of thought, but those are the two areas in which federal involvement would be acceptable.

CHAIRMAN WATKINS: Thank you. Dr. Walsh?

DR. WALSH: The question that I just wanted to raise, you do understand, we do have to sometimes wash our dirty linen in public because of the Sunshine Law, and I was not aware that we were mandated to give opinions on the four suggested laws that were suggested by Polly. I do not know where that came from in the mandate, nor have I ever seen it in the mandate. I did not mean to say that we should not consider in any way whether a federal remedy on anything may be helpful or may be sought but I think that even in those areas where Mrs. Merritt has indicated we should consider legislation, she has made patently clear that this is something that is going to take considerable time and research. I am concerned as to whether this Commission has the skill or the time to do such a thing and rather than do it badly, my own inclination was to avoid it, that is all. And I do not see anything in any mandate that we had that specified that we had to have answers to the four points you raised.

CHAIRMAN WATKINS: Well, of course, we do have to make recommendations to the President so that he may give advice to his Cabinet members on legal matters relating to the HIV. This is our charter. Whether we comment specifically with recommendations or whether we provide enough information so that advice can be given on legal matters is the issue.

DR. WALSH: That is all right. That is the only point I am making here.

CHAIRMAN WATKINS: We are going to close out now. I would like to have the final question with Ms. Merritt. You gave us a very nice insight into one very specific testing program involving prisons that you were postulating as a possible scenario that would be legally unobjectionable. We have had strong recommendations with respect to testing on entry into a hospital or other similar environment for certain kinds of medical treatment, either to protect those conducting very

intrusive operations or in the best interests of the patient in terms of the health care that can be provided. Would you also think that mandatory testing for HIV in specific non-emergency cases where local medical, competent medical authority would state is in the best interest of the patient or clearly in the best interest of the attending health care providers would be legally unobjectionable? I want to get quite specific as you wanted to be specific. Would you discuss that, from the same context you did in the prison case?

MS. MERRITT: Sure. Let me just run through briefly the constitutional factors, the arguments that one might make in favor of such a program, mandating testing for hospital patients. First of all, one already does much lab work in the hospital so it is not perhaps an additional intrusion.

CHAIRMAN WATKINS: I am not asking you for all patients necessarily.

MS. MERRITT: Right. But of some subset. There is some possibility of transmission if we are talking about surgery or other sorts of invasive procedures, and arguably there is some diminished expectation of privacy which is a factor we have not talked about here yet today but courts do take into account in the hospital setting because the patient is voluntarily going into the hospital. It is also a non-criminal setting which tends to weigh in favor of constitutionality. We are not going to punish the person if they are positive.

The arguments that would weigh against the constitutionality, obviously we have all the heavy burdens that we always have when we deal with mandatory testing of anyone. Hospitalization for many people is not really a choice. It is an emergency or it is something that needs to be done, not an elective procedure. There may, in fact, be a high proportion of false positives depending on the particular population we are testing. If we are testing adults generally rather than simply drug users or some group like that. There is a big question about what steps exactly the hospital will take if the patient tests positive. I do not imagine that we want to then tell the hospital they have the right to refuse to treat the patient. I assume we want to protect medical care for the patient so it is a question then of what exactly, why the hospital is, how they are going to use this information. It may be that as a practical matter, doctors and nurses cannot treat all patients as if they are infected and will take different steps with respect to patients who are shown to be infected.

Those kinds of factors are what the courts would weigh in deciding constitutionality. My suspicion is that the courts would find it constitutional to mandate that. My question is whether or not that is a law that is necessary because doctors

have such a strong bargaining position with respect to their patients, this seems to me precisely an area in which hospitals can be left to their own devices.

CHAIRMAN WATKINS: Let me just add that the context would be where there has been an inability to obtain that permission from the patient. We were told in general that the patient-doctor relationship is such that the individual will come forward when it is found clearly in his or her best interest to allow that test to take place. I am referring to the case where that test was disallowed by the individual. Do you proceed with the care? I think that came up in the San Francisco General case from Dr. Lorraine Day. She would proceed with it, it was difficult for me to see the difference between that and using the proper protective procedures under all circumstances but nevertheless, I am just trying to deal with that.

Also, considering possible downstream litigation, suppose you provided an alternate procedure because you did not get that permission and did not want to conduct the invasive procedure that an orthopedic surgeon might have to go through under certain circumstances? Would there then be liability on the doctor for not providing the correct procedure? In other words, I am just trying to explore a little more the legal considerations related to mandatory HIV testing on entry into a hospital.

MS. MERRITT: Well, again, it is a question of who is mandating the testing. The point I was making a minute ago is that I believe that probably if the government mandated the testing.

CHAIRMAN WATKINS: No, the doctor I would think.

MS. MERRITT: Okay, that is what I was saying, is that the government probably could do that but probably does not need to. Hospitals could adopt their own internal rules that they will not accept a patient who is not willing to be tested for AIDS or as a somewhat less restrictive alternative, the hospitals could adopt a rule as my obstetrics clinic did, that everyone will be tested if they agree to it, if somebody refuses then they are assumed to be positive and are treated in that manner. Doctors have, I think, a fairly high bargaining position with respect to their patients. Despite all the talk about patients' rights, patients have to get into the hospital and will tend to go along with whatever rules are there.

MR. SMITH: Mr. Chairman, may I respond to that just briefly?

CHAIRMAN WATKINS: Yes.

MR. SMITH: I think there is a case, narrow category, and you have picked a very narrow area where one can make a case where universal precautions may not be so persuasive where a specific surgical procedure involves, can be done a different way more safely to those in the OR and consent would make a difference in how you would do the procedure. The CDC guidelines talk about that but they come out and say, get an informed consent, this narrow area. The effort to expand that narrow area to get around the universal precautions and to broaden testing of all patients, all surgical patients, I think you have to sort of raise an eyebrow at that, and ask, is the purpose really a concern to do the surgery differently and better to serve the patient or is the concern really to prevent infection and to not treat the patient or to deliver or to refer or to avoid. The comments of Dr. Day really are at odds with the statement that a physician may not ethically refuse to treat a patient when an epidemic prevails, a physician must continue his labors without regard to the risk of his own health. There is a medical ethics question about that little narrow area, but I think in certain cases, narrow area of cases with respect to certain procedures, it may be advisable to have a mandatory test done where it is really necessary and efficient on the cost benefit. It is a very narrow area, and to sort of expand that to all surgical patients and justify non-treatment is --

CHAIRMAN WATKINS: Well, I am certainly not proposing that. I wish we had had the wisdom of you here, it was germane to the discussion yesterday and I think it is important to clarify. Anyway, I do not want you all to leave with the feeling that we do not think law abiding citizenry is a fundamental underpinning of our society and if we had all the lawyers like you three, then we would feel a lot better about the nation. So let us leave it on that note, and we will close now. In closing these hearings, I would like to thank all of our witnesses, not only these but their predecessors for presenting the complex and difficult issues of testing, ethics and discrimination clearly and articulately over these past three days. They have been extremely valuable hearings. You have raised enormously important issues for our future response to the epidemic and offered some options for humane solutions. The Commission will maintain a continuing dialogue with all of our witnesses as we would like with you to follow-up on questions that we were unable to ask you today.

I would also like to thank my fellow commissioners here for their patience and dedicated attention to these intensive days of testimony. They have been some of the most intensive we have held yet. So thank you very much, and thank you, Dr. Conway-Welch, who is not with us right now. She and the members of the Vanderbilt Stadium group here with security force and so forth, have been very generous in allowing us to be at this very special place for these hearings. With those comments, we will adjourn the hearings. Thank you.

(WHEREUPON THE HEARINGS WERE ADJOURNED.)