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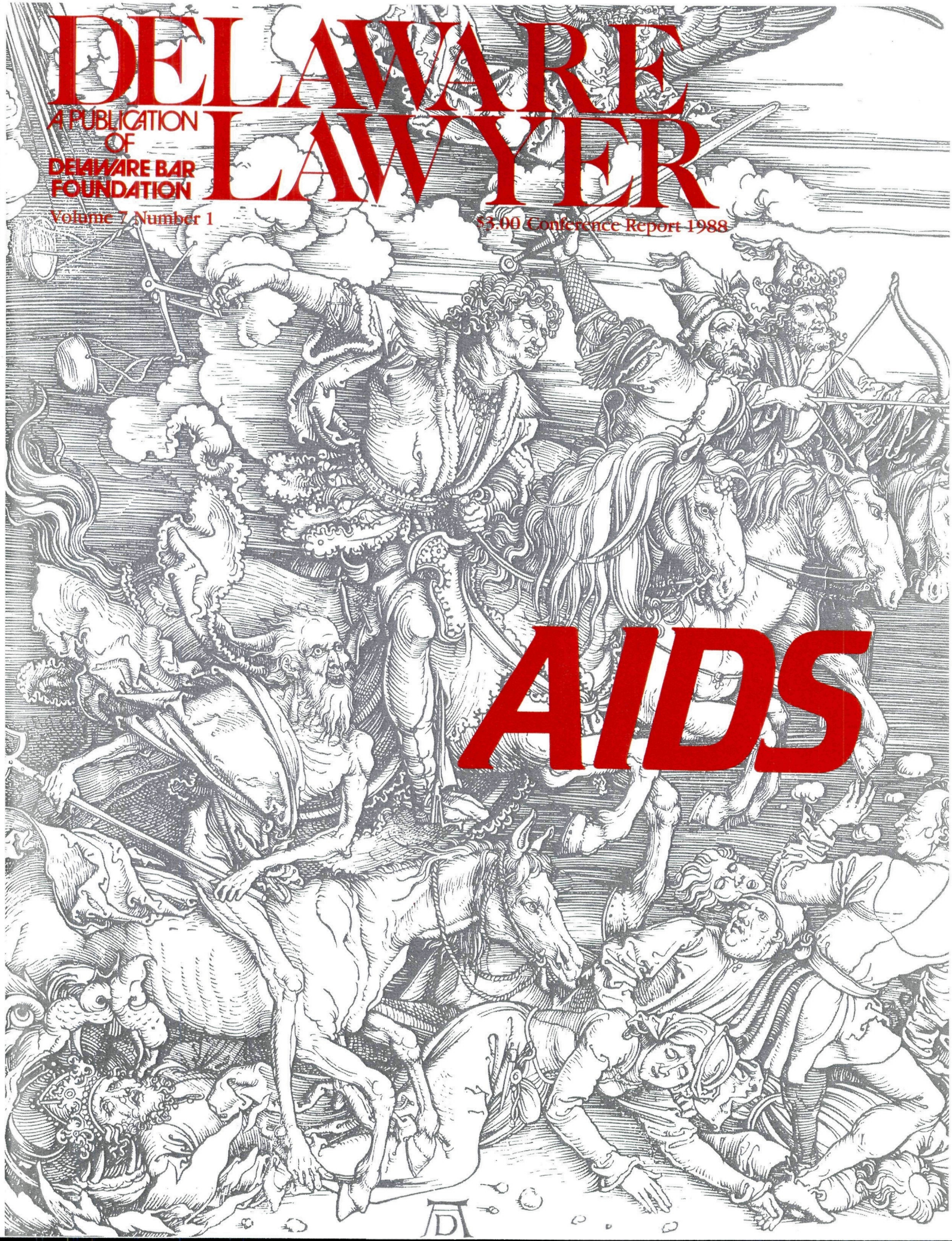

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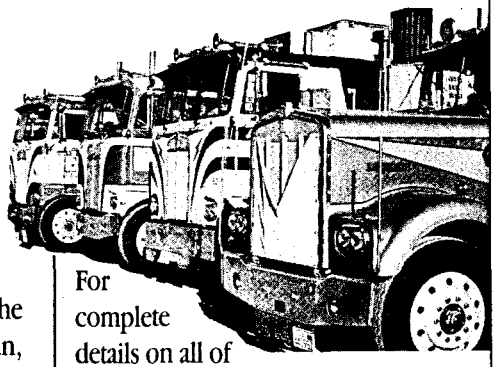

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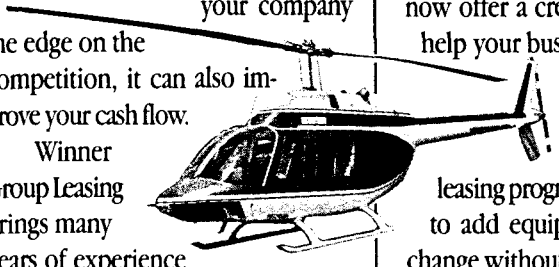

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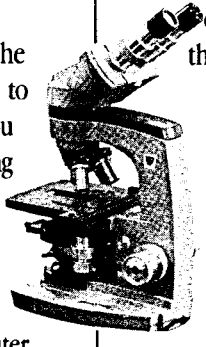

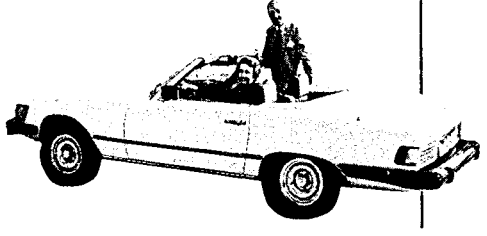

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Governor Michael N. Castle addressed a combined audience of legislators, health care professionals, social workers and members of the general public at the Professional Conference on AIDS on April 16, 1988.

Remarks by Governor Michael N. Castle

I am very pleased to have the opportunity to discuss this important issue with you today.

Let me begin by commending the Delaware State Bar Association, the Delaware Dental Society, and the Medical Society of Delaware for organizing this conference.

For the past several years, the state has been deeply involved and committed to addressing the serious issues posed by Acquired Immune Deficiency Syndrome, or AIDS.

As you will no doubt hear later today, agencies within the state government have been working to understand, to educate people about, and to combat this terrible killer.

On their behalf, welcome to the fight.

The professionals represented by this conference have the ability to make a great deal of difference in educating people and helping to stop the spread of AIDS in Delaware.

I hope that, as you educate yourselves about AIDS, you will discover ways to educate and help your clients and patients.

By doing so, we can at least treat and cure the plague of misinformation about AIDS.

As I said, the state has been involved in this effort for several years and I should like to take a few minutes to describe the record of what has been accomplished.

It is a good record, a strong record, and in some ways Delaware is far ahead of all but a handful of other states.

But first I want to define the issue of AIDS—from the state's perspective.

This is necessary because the public perception of AIDS has been evolving almost since it began to affect significant numbers of people in America.

Where once it seemed to affect only homosexuals and a small number of ethnic groups, today it affects homosexuals and heterosexuals alike; it affects women as well as men; no social or ethnic group is immune.

In fact, the single largest at-risk population today is not homosexuals, but illegal intravenous drug users.

It is also, to a considerable degree, a disease affecting prostitutes.

Having said that, let me make an important point: *Our attitude about the problem, our determination to solve it once and for all, must not be colored by any personal or social view of the groups involved.*

AIDS is a *medical* problem, and society and the state must view it as such.

But it is also a highly charged emotional issue. It is a disease that kills all its victims—sparing none. It is potentially as dangerous and destructive of life and society as any plague in the Middle Ages. It snuffs out young lives—tragically.

ABOUT THIS SPECIAL ISSUE

This is a first for two publications, a joint issue of *DELAWARE LAWYER* and *DELAWARE MEDICAL JOURNAL*. We find a symbolic fitness in a collaboration parallel to a professional alliance to confront the great health and social catastrophe of our time.

In late 1987 representatives of the Bar Association, the Dental Association, and the Medical Society convened to plan a Professional Conference on AIDS. On April 16 of this year an audience of 300 convened at the University of Delaware's Clayton Hall to hear the views of distinguished surgeons, dentists, lawyers, and scientists. The conference attracted far more than members of the three committed professions. Prominent legislators, health care workers, social workers, and highly articulate members of the general public came to learn and contribute to the cause of AIDS enlightenment. Much of the content of this issue is drawn from presentations made at the conference.

In July of this year The American College of Legal Medicine sponsored a brilliant two day AIDS symposium in Arlington, Virginia. It is our good fortune to publish some of the material presented there.

If there is a single message to be drawn from these endeavors it is this. The most important preventative against the spread of a plague for which there now exists no cure is education. We dedicate this joint issue to that proposition. *Fiat lux!*

Bill Wiggin and I recently attended a conference on AIDS sponsored by the American College of Legal Medicine. We were so impressed with the program that we persuaded the sponsors to allow us to publish one of the presentations in this issue.

There were two things I learned at the conference that impressed me greatly. The first was the response to a question I asked C. Everett Koop, the Surgeon General: Was there any "good news" with regards to AIDS? He replied that intense research into retroviruses would likely assist in the solution of other medical problems. I had hoped for something more, some encouragement about the spread of the disease. I thought he might say that heightened public awareness had resulted in a dramatic decrease in the rate of new cases, or that the incidence of IV drug abuse was declining. He didn't say what I'd hoped, because I don't think those things are happening. The educational messages, while important, are not necessarily reaching the people most at risk.

The second thing about the program that struck me was a discussion of AIDS dementia. It presents itself in cases where people are HIV positive and may not be aware of it. More important, they may not have any physical symptoms attributable to the disease. Consequently, the dementia is very difficult to foresee or to diagnose. It manifests itself in a gradual subtle deterioration of judgment. The implications are frightening. As a Superior Court Judge, I am concerned that undiagnosed AIDS dementia might be the root of a defendant's illegal conduct, or that it might affect a defendant's ability to participate in the presentation of a defense. In industry, employers have to concern themselves with those who occupy sensitive positions where the lives of others may be jeopardized by mistakes of judgment. The obvious examples are railroad conductors, pilots, and plant operators, to name but a few. AIDS dementia represents yet another complication in an already complex illness.

A recurring theme in this publication is the need to strike the difficult balance between the legitimate need to protect society and the need to protect our hard won and precious civil rights. In 1988 we are making amends to the Americans of Japanese descent who were wrongfully detained in concentration camps during World War II. Yet we hear suggestions that everybody be tested and that those who are HIV positive be shipped off for the good of the society. I don't believe any such suggestions will ever be seriously considered, but the fact that they are made warns us of the need to be vigilant in protecting the civil rights of each citizen at every step along the way, knowing, as we do, that the impact of the disease on our society will grow much greater in the decade ahead and knowing, too, that as the incidence increases along with the attendant costs, society's anger and frustration will increase.

(Continued on page 7)

Where once it seemed to affect only homosexuals and a small number of ethnic groups, today it affects homosexuals and heterosexuals alike; it affects women as well as men; no social or ethnic group is immune.

To date, AIDS has claimed 50 lives out of the estimated 120 known cases in Delaware, and we believe that 4,000 Delaware residents are infected with the virus. By 1991, it is predicted that the total number of AIDS victims here—including those who will have succumbed to the disease—will exceed 1,000 cases.

As we have learned that AIDS can strike anyone, and as our knowledge of the pathology of AIDS has grown—and with it our understanding that it is a changing, elusive killer—the potential for fear has grown. Thus those who convey information to the public about AIDS—whether they are in state government, in the private sector, or in the media—must exercise exceptional care. AIDS is a matter of great concern to people; and it is our job to educate them, not frighten them. Let me take a few minutes to tell you about the state's efforts. They are significant, and in a number of ways innovative.

AIDS Advisory Task Force

The AIDS Advisory Task Force was formed two years ago under the auspices of the state Division of Public Health. Membership in the task force represents virtually every group with an interest in the issue—the medical profession, the Gay and Lesbian Alliance, and state agencies.

Last September the task force issued its first report, recommending a number of steps at both the community and governmental levels.

The recommendations covered:

- Development of public policies.
- Education programs.
- Voluntary testing and counseling.
- And treatment of AIDS victims.

Because at least four cabinet-level departments must deal with various aspects of AIDS, it was proposed through the Human Services Cabinet Council, which has the responsibility for coordinating interagency programs, that

(Continued on page 7)

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Governor Castle's Remarks
(continued)

each department address those recommendations with policies specific to their own needs.

In addition, the Office of State Personnel was asked to develop general policies related to the state as an employer—including hiring policies and policies related to employee/client interactions.

The result is that today we have comprehensive policies and sound practices in place, with a strong emphasis on prevention and education.

Health and Social Services

Through the Division of Public Health, the Department of Health and Social Services has taken responsibility for developing and disseminating health policies about AIDS; for providing roughly 3,000 voluntary testing sessions a year—we are able to provide testing within a week of the request in New Castle County, within two weeks in Kent and Sussex counties; for providing public awareness and education programs for about 1,000 people a month; management of over 50 active AIDS cases per month; and coordination of all related AIDS activities.

That means fielding over 600 calls monthly and conducting roughly one meeting a day, five days a week with groups from throughout the community which are interested in learning more about AIDS.

In addition, the department's Division of Alcohol, Drug Abuse and Mental Health requires its contractors to provide clients with information about the AIDS risk factor associated with IV drug use. If we are going to stop the tragic spread of AIDS, we must make drug users understand the risk they are taking.

Public Instruction

The Department of Public Instruction has developed a model mandatory education curriculum and materials for kindergarten through twelth grade—designed to give students important facts about AIDS and its prevention. We have developed guidelines for bus drivers and school personnel regarding the handling of body fluids. We have in place policies regarding the admission and attendance of students infected with AIDS.

(Continued on next page)

Susan C. Del Pesco

Martin J. Cosgrove

It was especially gratifying for the Bar Association to have had the opportunity to work with the Dental and Medical Societies of this State in presenting the AIDS conference last April. My most sincere thanks to the interprofessional committee which worked together to make the conference a reality.

I am confident that this publication, which embodies much of the meeting, will be valuable to all who take the time to read it.

Susan C. Del Pesco

This issue of *Delaware Medical Journal* departs from our usual format of learned articles addressed exclusively to the medical profession. It is a collaboration among doctors, dentists, and lawyers in which the expert knowledge and distinct viewpoints of three professions are brought to bear on a social problem that defies the abilities of any isolated group of experts to solve.

AIDS, of course, is first and foremost a medical problem, as Governor Castle wisely observes in his introductory remarks at page 4. The great advantage of the April 16 Conference, from which most of the articles in this issue were drawn, was the opportunity it gave topflight medical and dental experts like Doctors Day, Redfield, and Cioffi, to inform lawyers, legislators, and the intelligent lay public about the current state of scientific knowledge, without which the combined effort to control AIDS cannot succeed. I believe that it was no less informative for members of our profession to hear of the legal, economic, and social concerns that must go into any humane and effective equation for responding to this major threat to our well-being as individuals and as a nation. I am delighted to see the professions united in a common cause.

Martin J. Cosgrove, M.D.
President, Medical Society of Delaware

Governor Castle's Remarks
(continued)

Services for Children, Youth and their Families

The Department of Services for Children, Youth and their Families has developed policies regarding the care of foster children who test positive to the AIDS virus. In addition, the Children's Bureau is under contract to recruit foster parents for children with serious health problems including AIDS, and the Bureau is developing a plan for identifying and then providing additional social services needed by children and families with AIDS.

Correction

AIDS is a serious problem in our nation's prisons, and the Department of Correction in Delaware has made once voluntary AIDS education classes madatory for inmates so that they understand how AIDS spreads through homosexual contacts and IV drug use. We have provided classes for all female prisoners and more than ten percent of male prisoners. We provide voluntary testing for inmates (currently 14 are known to be HIV positive). And we are developing an AIDS education program for correctional officers.

The Next Step

Since we believe that, for at least the next five years, the number of AIDS cases in Delaware will double annually, the state is already proceeding with the next steps to fight this disease.

In addition to almost $86,000 in state funds directed towards AIDS programs during the current fiscal year, we have received over $330,000 in federal funds for prevention efforts this year. The budget I have proposed would increase state funding; additionally, we are seeking—with a strong degree of optimism about our chances of success—double the current federal funding the next fiscal year. This new funding would allow us to add nine people to the ten already providing counseling and testing, education, and case tracking.

- We are already at work determining how the new AIDS cases will affect our ability to handle the caseload.
- And we are in the midst of planning alternative care systems for AIDS patients.

As you no doubt know, it has been proposed that a privately run care facility for AIDS patients be established on state property, and my first reaction to the proposal was positive.

- The Division of Mental Health is developing an estimate of the increased need for AIDS prevention and education programs made necessary as more drug users seek help.
- The Department of Public Instruction is conducting a follow-up survey to make sure that the AIDS education program is being fully implemented, and DPI is forming a crisis team which would go into action if a Delaware student is found to have AIDS.
- The Department of Correction is presently determining how an increased AIDS population will affect both the operation—and the cost of operation—of our prisons.

Obviously, the growing number of IV drug users with AIDS will affect our decisions about future programs. I am asking Secretary Eichlier to develop an estimate of new IV-drug-use-related cases, and to develop a comprehensive plan to deal with these cases.

As I said earlier, our knowledge of AIDS keeps changing, as does the profile of the disease and its victims. Given this state's limited role in dealing with AIDS (the states cannot be expected to undertake any sort of research projects), we must maintain our flexibility and keep finding new and more effective ways to make our education and prevention programs successful. The efforts of the state *must* be supplemented by efforts by groups like yours, by conferences like this one. Until recently, much of the responsibility for educating, testing, counseling and helping was borne by the Delaware Lesbian and Gay Health Advocates. They have done an exceptional job of promoting understanding and helping AIDS victims. Out of this conference, I hope, will come a commitment by Delaware legal and medical community to do the same thing. ■

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Early Detection: The Role of the Dentist

Dr. Gerald Cioffi

I should like to start from a clinical perspective and look at the word itself—AIDS. It's a good descriptive term. It's an acquired immune deficiency syndrome. Those are all very important points. How is it acquired? I think we're all now well aware that it is acquired by infection with the HIV virus. Immune deficiency is the hallmark of this illness. What separates it from other illnesses and syndromes is the severe immune deficiency that can be a part of this illness. The last word is very important as well: *syndrome.* The word tells us that we are not looking at a disease. AIDS is *not* a disease; it's an *illness* encompassing a great number of diseases. When we put particular combinations of diseases together in a single patient and couple that with the presence of the HIV virus we have fulfilled the definition of a patient with AIDS.

I began treating AIDS patients in the service expecting to see the lesion or the disease of AIDS, but I didn't find it. What I found instead was a multiplicity of diseases wrapped up in a package. And I think that's a very important point, often overlooked in our approach to this illness. AIDS is a combination of diseases and we have to look at patient management from that perspective.

Dr. Winslow mentioned during his remarks that many patients, once they acquire immune deficiency as a portion of this illness, succumb and become victims of multiple emergent secondary infections from organisms already present in their bodies. I want to discuss the role of the dentist in the treatment of this patient population.

One patient, a young man in his mid 20s, came to the dental clinic for treatment of a gum condition, a gingival condition. He had a particular condition that we call ANUG or acute necrotizing ulcerative gingivitis or periodontitis. It was very refractory to treatment despite all standard therapy. *He did not get well.* This was back in 1983.

We began to look for reasons why an otherwise normal, healthy person was not responding to a pathogen that all of us would usually handle very easily. The answer lay in immune deficiency. This particular case was my first clinical experience of making an original diagnosis from dental findings of HIV infection and immune deficiency. I have found since that time that it's been a very common experience in my practice. In fact, many of the earliest signs and symptoms of immune deficiency will occur in the oral cavity. And for a very good reason — the greatest microbiotic challenge to the human body is through the oral cavity. Since the earliest, most subtle changes in immune deficiency will occur in the oral cavity, I have found that the dental profession is in a very good position to make early diagnoses and original diagnoses of this infection. This has become a very common clinical experience. Now when we look at certain types of infection in an otherwise healthy individual not on other medications, we must entertain the possible diagnosis of immune deficiency. I find myself in daily practice in the position where it is not merely appropriate but obligatory that I be able to rule out immune deficiency. Accordingly, there will often be reason and need for the dentist to order an antibody screen for HIV infection.

Now many of the conditions I encounter are not uncommon to the family of patients who are immune deficient, because of radiation, immunotoxic drugs, chemotherapy for various neoplasias, genetic or developmental deficiency, or viral infection. The common latent manifestations of the herpes class of viruses is a good example. They are very common in the immune deficient patient. There is a dramatic similarity between all the classes of immune deficient patients and in particular within the class in the acquired immune deficiency syndrome. Unfortunately, once patients have begun to manifest immune deficiency there is very little that we can do for them at this time. They are very refractory to treatment for both their oral and their systemic manifestations and they require chronic therapy. We are getting better in supporting some of the concomitant diseases *because we're getting them sooner.* That is a very, very important point in the treatment of this illness. From my point of view as a clinician, I'd very much like to see testing — because I know that from a therapeutic standpoint if I don't get into the picture early in the game the patient is going to have a very difficult time with the management of his complications, which are predictable and unfortunately irreversible.

I was very glad to hear Governor Castle observe that this is a *medical* problem. In the late 70s and early 80s we treated it as every kind of problem but a medical one. It is a sexually transmittable blood borne viral infection. Any kind of policy or legislation that deals with this issue should begin with that recognition and focus. The role of the infectious disease department in the medical institutions is pivotal. This group of patients *belongs* with the infectious disease clinic, *belongs* with the infectious disease specialist. It's difficult to manage infectious diseases. I think that we're going to conquer many of the mistakes that we made early, many of the misconceptions, and many of the prejudices about this particular illness when we finally come to grips with it as an infectious disease, because that is what we're facing.

I'd like to make another important point. All the conditions and all the diseases we encounter in AIDS patients can be acquired in other ways, and other patient populations can manifest the same diseases. The point is that today you have to be diagnostically and clinically attuned to recognize what was not the case ten or fifteen years ago: Immune deficiency is now becoming one of the more common ways that patients acquire these diseases.

The herpes classes of virus are very important in this patient population, and indeed in all populations of immune depressed patients. We all have these viruses. They're mostly childhood diseases. We carry them latently and harmlessly for life because we have competent immune systems to hold them back. When those systems break down then we have recurrent infections. With immune depression we find that a normal cold sore, which many people have occasionally, produces an overly dramatic inappropriate response, which suggests and leads to immune depression. When I use barrier techniques with my immune depressed patients, it's for a different reason from what is commonly thought. I use barrier techniques and isolations to protect the *patient,* who is now immune deficient. Common microbiota in the practice and from my staff are now a very big threat to the patient.

For example during a normal routine dental examination office visit I treated a patient who had a very subtle pigmented, slightly discolored lesion on the roof of the mouth. "Mr. Jones, you've got a small pigmented area in the palate." Examination, biopsy, and testing lead to a diagnoses of HIV infection, intraoral Kaposi's scarcoma and a patient well into severe immune deficiency. Intraoral lesions are often the first constitutional clinically evident sign of the illness. For example, white hairy leukoplakia is becoming a very useful clinical marker for the progression of the illness. Patients who have white hairy leukoplakia as part of their syndrome have a much more rapid rate of development of the full blown AIDS syndrome. We must remember that the AIDS portion of the illness is the end of the spectrum. Patients with this particular intraoral manifestation predictably get sicker faster and have a much more rampant

(Continued on next page)

Gerald A. Cioffi, a Commander in the United States Navy Dental Corps, is a graduate of the University of Pennsylvania School of Dental Medicine. He also holds an M.S. degree in education from the School of Graduate Education of the same University. He is a consultant at the Naval Hospital in Jacksonville, Florida, where he heads the Department of Oral Medicine. Dr. Cioffi is also a well known speaker at continuing education programs. His remarks are drawn from his address to the Professional Conference on AIDS.

Early Detection
(continued)

run of their illness than patients who do not have hairy leukoplakia. We now have a clinical marker that can be predictive of patient outcome. A colleague in the neighboring clinic called me and said that his patient had an unusual lesion on the side of his tongue. One look at this lesion of candidiasis from my clinical standpoint and I was very suspicious of immune deficiency. The HIV test was positive.

I have a difficult time understanding the arguments over testing. I first started seeing AIDS patients in 1983 at Bethesda Naval Hospital and have been seeing them regularly since that time. In that five years I have never had any difficulty or any refusal by a patient to take the test. I sometimes think that we sit on the side and make up ideas about this patient population without ever sitting down and talking to somebody who has the illness. The patients are very appreciative to receive treatment and very much concerned about their health. After consultation I've never had any problem or even any hesitation on the patient's part to get the appropriate workup. It has never been a problem.

Another point that I want to make is the importance of the association of the dental and medical teams. When we are doing dentistry on the medically compromised patient, the dentistry is medicine. When it comes to management of this patient population, if we begin divided we will end up together. These patients *must* have joint management. The course of the illness leads to multiple, unavoidable hospital admissions and chronic management. There is no one-time fix for these patients. And there has to be constant communication between the specialists and between the professions in the management of these patients. You will very shortly find yourselves being drawn together because you simply can't adequately manage the patient if you don't. So you can't begin by trying to divide the treatment team and then all of a sudden find yourself in a clinical situation where you must hurriedly go out and find a dentist who can work with the team. It has been our experience that you make out much better and the patient makes out tremendously better if you begin with the team approach. These patients need the attention of multiple specialists and you need to have these people together in one place with a protocol, a clinic, and a facility that knows how to get things done in a very timely manner. For me, that's a very practical approach and I'm sure I will be criticized for maybe not taking into consideration all the social and legal issues, but I have a bias toward treatment of the patient.

When we first got into this business we sat down and tried to decide how to best balance all the social factors, political factors, and medical factors, and then we drew up a set of rules. We began to learn almost immediately that the system we had set up crippled the hospital and we couldn't treat the patients. That began a process of rediscussion and reaccommodation. Now there is no such problem. We have gotten through the issue and I hope you will too, because it is absolutely inappropriate for a health care professional to treat a patient

without full access to his medical history. That's not in the patient's interest or the health care professional's. In the management of a multifaceted infectious disease you need to know the complete clinical picture. That was a stumbling block in the beginning and it led to inappropriate treatment. That is why we're now back to the point of doing for this particular patient population what we do with *all* our infectious disease patients. It *is* a medical problem.

There are some *truly* unique things about this. For example, once this patient population acquires their immune deficiency, *mortality is 100 percent.* Unfortunate but true at this time. They become part of the terminally ill population and as in the case of those suffering from inoperable tumors, incurable cancers, and other terminal illnesses, these patients have some very special problems: denial, high rates of suicide, anger, acceptance, accommodation, the tremendous financial burden, and problems of access to care for a long term chronic illness. In addition to the common problems of the terminally ill, the AIDS patients face stigma. It is socially acceptable to die from cancer or leukemia, but it's not socially acceptable to die from AIDS. So terminal sexually transmittable diseases present an additional factor not present in non-infectious diseases. They are important issues and they need to be addressed.

The critical period in this patient population is* before *they get sick and I think we're just on the brink of realizing that investing large amounts of money and effort at the end stage of the disease is inappropriate and nonproductive.

The emphasis on treatment is shifting to the latent period between infection and the time when the immune system starts to go. We have very little success in reversing the immune deficiency. We are learning, step by step, that it is critical to identify the patient early and to try to prevent the decomposition or the faulty mechanism of the immune system from breaking down. The critical period in this patient population is *before* they get sick and I think we're just on the brink of realizing that investing large amounts of money and effort at the end stage of the disease is inappropriate and nonproductive. That makes early detection extremely important and that, I think, is where the role of dentistry is: early detection and identification of these patients in order to begin initial therapy. AZT, one of the more promising drugs, tries in a sense to reconstitute the immune system. But you can't reconstitute a system that has vanished. Accordingly I think we're going to see that we need to make testing accessible, easy, and fast.

Bracing for the Long Haul

We do have to recognize that once we get into this business, there's no backing out. Once we open a clinic and begin to treat a patient population, this is not something we're going to do for three years or five years. This is a long haul proposition. Whatever process

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Early Detection
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evolves in the state of Delaware, I hope from the experience that I've gone through, that I can persuade you to look as far ahead as you can and to design a system that you can live with, realizing that it will be in place for a very long time. The prospect for eliminating a sexually transmittable disease in our population once it's been introduced is virtually zero. This new illness is going to be a permanent part of pathology that calls for a little different thinking.

It has been our policy that this illness is a medical problem, an infectious disease. Servicemen who are found to have it are not disciplined. They are treated medically.

It has been our policy that this illness is a medical problem, an infectious disease. Servicemen who are found to have it are not disciplined. They are treated medically. They are to be treated, medically retired, and cared for by the government. What happened unexpectedly when we announced that policy was an inundation of enlistments. This patient population is very much aware of their problems, of the costs, and of the problem of access to care. If you serve 90 days of active duty you are a veteran, and the government then has to assume care for you. Many people were attempting desperately to get into the federal service because they had no idea how they were going to be able to provide care for themselves. Accordingly I want to point out to you that one of the unavoidable consequences of designing a system is that it will have an impact on attracting or deterring an influx of patients. That is both a political problem and a social problem — and an economic problem.

I want to make a final point. I think there is no difficulty in treating this patient population. I do feel that inevitably what will happen as a natural consequence and a natural course of clinic medicine is that these patients will be drawn to centers that have multidisciplinary approaches and are staffed to handle infectious disease. And that will happen because the access to care will be quicker, the care more thorough, and the follow-up more appropriate. And the patients will do much better. ■

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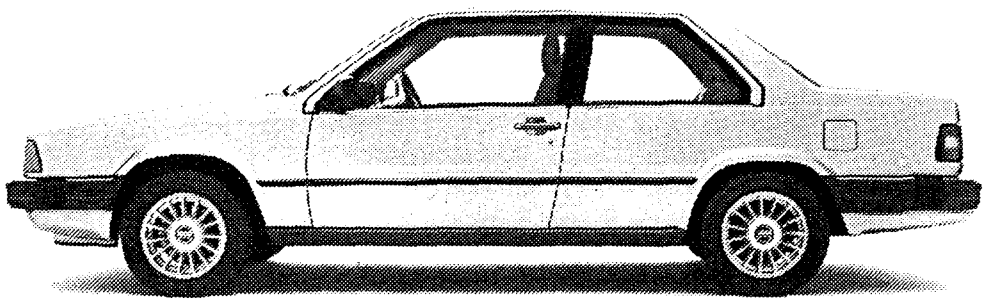

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The Researcher's Initiative

Robert R. Redfield

Dr. Robert Redfield, since 1986 Section Chief, Retrovirology at the Walter Reed Army Institute of Research, worked with Dr. Robert Gallo in discovering HIV. He has been responsible for AIDS laboratory research at Walter Reed and acted in the clinical treatment of AIDS patients at that institution.

The following is drawn from his remarks at the Professional Conference on AIDS held last April.

It is from my perspective as a doctor, as a researcher and as someone concerned about public health that I speak today. I want to go through some of the aspects of the clinical disease to make several points that I think are important in understanding the nature of this epidemic and where it is today. I shall also express my own opinions as a physician and a scientist concerned with public health as to how a medical community should respond to this epidemic.

When AIDS was first recognized it was a mysterious syndrome, an aggregate of signs and symptoms without an etiology. To the credit of the public health service in three short years it was no longer a mysterious *syndrome* but a *disease*, that is to say a disorder of bodily functions with a defined etiology. In 1984 we recognized that AIDS, the syndrome, was actually the end-stage clinical consequence of an infectious disease caused by a virus known as HIV. And now in 1988 we know probably more about the clinical pathogenesis and the clinical manifestation of this disease than we do of any other in clinical medicine.

In my opinion "AIDS" is really an anachronism we can really no longer afford to focus on in the medical community. We need to address HIV infection and the whole spectrum of illness it causes. HIV is a *retrovirus*. The power of a retrovirus and the reason that this epidemic is spreading so rapidly comes from a very important biological property of these viruses. When many viral diseases infect the cell or the host they replicate. There is an immune response to them, they are ridded, and the individual is then immune to them. When a retrovirus enters a cell, it actually becomes part of the genetic information of the cell in order to reproduce itself. What that means at the clinical level is that once a retrovirus infects a human being, it's really part of him for the rest of his life. A self-limited retrovirus infection is not consistent with the biological properties of these viruses. When they infect a human host they become part of the genetic information of that individual for life. We have understood that biological property from the beginning and it is very important in understanding the magnitude of this epidemic and how it is spreading throughout the world.

We also understand that when a retrovirus becomes part of the genetic information there is a period of time before there is an immune response: the presence of antibody directed against this virus. It's a marker that the individual is in fact infected with the virus itself. Back in 1984 when many people used to say that antibodies to the AIDS virus meant that you had been *exposed* to the AIDS virus, to those of us trained in retrovirology the presence of antibodies really meant that you were *infected* with the retrovirus. I think that in 1988 we all recognize that. Since 1984 we've had the ability to diagnose HIV infection, that is to say that an individual is infected with the virus *for life*.

We also know that the AIDS virus causes a disorder of a bodily function, the immune system. The T-4 cell which is the center of the immune system, or the quarterback of the immune system, is the primary target of the AIDS virus. The virus replicates in that cell and causes premature death. But the virus actually causes an immune defect throughout the entire immune system. Early in the disease, it causes abnormalities in the B cell system, the cells that make antibodies for your body's defenses. Clearly this virus causes disorder there. We've come to know that

the virus replicates very well in monocytes, in macrophages and tissue cells such as Langerhans cells, but from a clinical perspective the most important part of this disease is that it causes the premature destruction of the helper cell, a slow chronic process in the human host.

Once we understood the etiology and the central pathogenic event, the premature destruction of T cells, we tried to form a systematic way to look at this as a continuum. One can actually divide it into six stages of illness that are graded on the degree of immunologic dysfunction. It is very helpful in the clinical management of patients and we continue to use it four or five years after we developed it in our practice of medicine. It is also helpful in trying to understand the natural history of this infection.

If you look at the stages of illness there actually is a correlation between the destruction of T cells and the different stages of disease. The T cell number correlates with the clinical stage of disease. There's a gradual destruction of T cells and the clinical consequences are defects in ability to regulate infections at the level of skin, defects of protecting and regulating infections at the level of the mucous membranes, and finally defects at the systemic level where patients develop opportunistic infections.

One patient taught us very early that this virus infection takes a very long time from the initial infection to the time that an individual actually develops the clinical disease and dies. A young man who became infected in the summer to fall of 1980 had an acute mononucleosis-like syndrome, which, in retrospect, was probably the acute retrovirus syndrome. He developed chronic lymphadenopathy, which was well documented over the next three years with multiple lymph node biopsies. He then came to Walter Reed at a time when we were looking for patients with this new AIDS-like illness. We recognized that what these patients appeared to have was low T cells, and so, when we saw patients with lymphadenopathy we automatically worked them up for their T cell system. (We had an arbitrary definition of "AIDS related complex," which was less than 400 T helper cells and chronic lymphadenopathy for greater than three months.) Over time the patient developed what we call stage 4 disease—persistent defects of hypersensitivity, and then stage 5, which would be complete anergy for greater than three months. For 38 months this patient felt totally healthy. He was running 3 or 4 miles a day. You would have said that all of a sudden he developed AIDS. In reality if you had been following him from an immunological point of view and following what this virus was destroying, the T cell system, you would have predicted the progressive destruction of his immune system. He then developed cryptococcal meningitis and he died at 49 months of follow-up. For 68 months this man, classified as healthy, had a subclinical HIV infection, a clearly developed progressive disease.

In 1985 a San Francisco study said that only 10 percent of people that had a healthy adenopathy developed AIDS. This is consistent with our study. If you started at Walter Reed Stage 2 (which is chronic lymphadenopathy) and you followed for three years, only ten percent developed AIDS and only five percent actually died. But 75 percent were sicker in terms of their immunological function. Everybody became sicker in terms of immunological function. For example, if you started at Walter Reed Stage 3, 29 percent developed AIDS; at Walter Reed Stage 4, 71 percent. Or if you're one of the "healthy" with less than 400 T helper cells, 100 percent developed AIDS. This gives you an understanding of the natural history of infection: it is a *progressive* fatal disease that gradually destroys the T cell immune system in a majority, if not all, infected individuals.

There were five patients in the Walter Reed Stage 2 class who did not progress—their mean T cell count dropped from 875 to 525 in the follow-up period. So although (arbitrarily) they did not progress to Stage 3 disease they clearly suffered a significant destruction of the T cell systems.

Early on the virus replicates. Gradually it seems to be controlled to a degree. If you try to isolate virus from Walter Reed Stage 2 or 3 patients, in only 15 to 20 percent can you actually get the virus out, using crude techniques—(that's

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not to imply that if we don't try to use very special techniques we can't grow the virus)— but gradually over time the amount of virus in the individual host seems to go up. This is contrary to what many people believed two or three years ago. In patients toward the end of the illness, it's very easy to isolate the virus and there's a larger quantity of virus in patients as they develop more and more symptomatic disease. Many say, "there's no reason to know if I'm infected now, because I'm in a stable relationship." But over time there is a dynamic infectivity with the AIDS virus so that people are less infectious early in the disease when they have Walter Reed Stage 2 or 3 diseases. Later they become much more infectious. Accordingly a majority of those infected now are the least infectious they are going to be and they would benefit from an opportunity of knowing if they are infected or not. The immune system does respond to the virus and regulates and controls the infection. Indeed, every protective immune response that we know in infectious diseases has been demonstrated in HIV infection. I think that nature does have a normal immune response to this virus. The only problem is that this virus isn't like the others: it becomes part of the genetic information of the immune system itself and it gradually picks away until it destroys the immune system. I believe that in the next ten years or so, we will begin to understand this natural response and be able to mimic it, and use that as an effective intervention strategy in dealing with HIV infection. Many people consider that somewhat hypothetical at this point, but I think that's something we will accomplish.

As clinicians, we can clearly understand there is no mystery about the pathogenesis of this infection in the human host: it is a progressively fatal disease in a majority if not all of those infected.

It is a sexually transmitted disease. It is also transmitted by blood and blood products, but I'm going to discuss sexual transmission because I think that's the important role of transmission in this country today.

In 1985 vaginal-genital intercourse was proclaimed by many to be safe sexual practice. It was said that if one stayed away from unsafe sexual practices (e.g. anal intercourse), one could avoid infection. It was shown, however, in one study that 13 out of 16 in the study practicing what was considered safe vaginal-genital intercourse infected their partners. That's a highly efficient mode of transmission by recurrent sexual contact. The study also emphasized that condoms can reduce the risk of transmission. Only two of 12 individuals who used condoms every time infected their partners. I use the word "only" sarcastically, because I don't think that a 17 percent failure rate in the case of a fatal, sexually transmitted disease is reassuring.

Many people think the condom is the centerpiece of the public health effort to control AIDS. The FDA won't license the condom for birth control. Why? Because the condom fails 5 to 15 percent of the

time. I think that we shouldn't assume that the condom is going to prevent the spread of a teeny little virus any better than it does a fairly large sperm cell that only can make a successful impregnation three or four days a month. So my position medically is that the condom has just too high a failure rate to be accepted as an optimal medical strategy or for us in the public health perspective to say this is the best we can do. On the other hand, I want people that do what I think is medically ill-advised or from a public health perspective ill-advised, to reduce the consequences of their action by wearing condoms. But I don't want them to feel good about it. I don't want them to think that they're doing what I think is right medically.

When we see patients who have Walter Reed Stage 1 or 2 disease and evaluate their spouses, only around 16 percent of their spouses are infected. But if they're at stage 5 or 6 disease it's on the order of around 56 to 60 percent. Studies of hemophiliacs, which used to be used to say that heterosexual risk was overestimated, now show that as the T cells go down below 200 in the male hemophiliacs the women are becoming infected. Actually there is a very nice relationship between degree of immunodeficiency and the ability to transmit this virus. That again tells us that we have a great opportunity: most Americans are less infectious to their partners now than they ever will be again, if we in the medical community, the legal community, and the legislative community can somehow figure out a way to get across to people the idea that they would *like* to know this information.

This is my simple message: it's a sexually transmitted disease. Any of you who are at risk for a sexually transmitted disease are at risk for the AIDS virus infection. Any of you that are never at risk for a sexually transmitted disease will not be at risk for the AIDS virus. Your children who are at risk for a sexually transmitted disease will probably be at risk for the AIDS virus, and those of your children who will never be at risk for a sexually transmitted disease, won't be. Twenty percent of adults by the age of 30 have seen Herpes Simplex II. By the age of 30, 40 to 60 percent of blacks have seen Herpes Simplex II. It's not because blacks or caucasians are promiscuous, it is because they slept with someone who had Herpes Simplex II. The AIDS virus will be no different.

I want my children to know whether their sexual partners are infected with the AIDS virus. If people want to have multiple sexual partners, or be homosexual, then they're not at risk for the AIDS virus as long as their partners are not infected. And I think that from a medical position, as a doctor, that's the position I try to teach: from a medical perspective people need to know whether their sexual partners are infected.

Heterosexuals at Risk

Masters and Johnson published a book that looked at heterosexuals who have had over 30 different sexual partners in the last five years. In the city of New York, ten percent of the women were infected with the AIDS virus and eight percent of the men. People say that just couldn't be true or those are very active heterosexual people. That's right. That's what Masters and Johnson looked at - very active heterosexual people. Heterosexuals are clearly at risk. They're at risk if they sleep with those who are infected with the AIDS virus. They're not at risk if they sleep with those who are not infected.

There is only one risk group: human beings who have sex, share blood or blood products, or were born to parents with the AIDS virus. The whole notion of risk groups classification is totally inappropriate now, because it implies to young people that there's a risk group and there's a *not* risk group. I don't mind as long as we define the risk group as human beings who have sexual, parental, or perinatal exposure to the virus. The virus won't be generated spontaneously in the bedrooms of America. It's only going to occur in people who are exposed to it, but it's not a disease of gay men or drug addicts or hemophiliacs. It's a disease that people acquire because they're exposed to others carrying it.

Misplaced Emphases

Many people have said today that we need to stop talking about AIDS, *per se*. I agree. We need to recognize from the natural history of this infection, that it takes on the order of eight to twelve years from the time you're infected to the time you develop AIDS. The AIDS cases in Delaware today are people that

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were infected in the 1970s, the late Carter years, maybe the *early* Carter years. The epidemiology of AIDS today (homosexual men and drug addicts) tells us nothing about how this virus is being transmitted. It tells us how the virus was being transmitted back in the late '70s. I am glad that someone is recording the historical perspective of this epidemic. But I don't want to see that done at the expense of not knowing where the epidemic is today. And the reality is that in many parts of the country we don't know where the epidemic is. We need to shift our focus from AIDS to HIV infection, from "risk groups" to exposure to the virus.

We've had the ability to make an accurate diagnosis through screening and confirmation tests since 1984. It can be done with a greater degree of sensitivity and specificity than we have in any other test in clinical medicine.

The Department of Defense program for young civilian applicants who wanted to join the military service incorporated an analysis for HIV infection into the medical exam. I have a great deal of pride in the way the Department of Defense has handled this—as a medical problem. When you want to join the armed forces, you're evaluated for your medical fitness for duty. HIV infection is considered to make you unfit for active duty for a 20-year military career. We do a screening (ELISA). If it's reactive we do a Western Blot. If it's positive by very specific criteria we obtain a second specimen. Why? When you're running 100,000 to 200,000 specimens a month it's much more likely to have a clerical error than a technical one. In my lab we found clerical errors in around 3 per thousand of the hepatitis B. serologies. We couldn't tolerate that for HIV infection. We require a second sample and if that sample is also positive the subject is informed that he is infected with HIV.

This is where the epidemic is among young people who want to join the service. You should remember that young men and women who want to join the service have to graduate from high school, they can have no records of felonies, and they must sign a statement saying they're not gay and that they don't use drugs. We select against some of the "higher risk behaviors" that people associate with HIV infection. On

the other hand, the military is probably made up of lower socio-economic groups. But over all, 1.5 per thousand of the young people who want to join the service are infected with the AIDS virus. We must put that in perspective. In San Francisco in 1975, less than one in one thousand gay men were infected; by 1985, 500 per thousand. How did that happen? It didn't happen because they were gay. It didn't happen because of anal intercourse. It happened because they had sex with people infected with the AIDS virus. It's very simple, very straightforward. Right now, 1.5 per thousand of the young people who want to serve their country are infected with the AIDS virus, a higher rate than obtained among gay men in 1975. Furthermore, there is an age related curve: among 25 year olds, it's 3 per thousand.

You in Delaware may think you don't rank high in the AIDS cases of America, but I can tell you in all the large scale studies that we've done through serological survey, Delaware ranks in the top five for prevalence of HIV infection.

You in Delaware may think you don't rank high in the AIDS cases of America, but I can tell you in all the large scale studies that we've done through serological survey, Delaware ranks in the top five for prevalence of HIV infection. Number one is New York where it's almost ½ percent of all men and women who want to join the service. Maryland, my state, ranks number two, New Jersey number three, and Delaware kind of sits in the middle and usually ranks fourth or fifth, ahead of California, ahead of Texas, and ahead of Florida, where many people think this epidemic is focal. Now when I go across the Mississippi, everyone tells me it's never going to happen in Montana, because people in Montana are different from those people who live on the East coast. I tell them that they have an opportunity to make an impact and use their knowledge, because I think it's going to happen in Montana. (I don't think Montana people are that different from those of us on the East coast.) When I talk to people on the East coast I tell them what our studies on Africa show. They reply, "Well, that's never going to happen in America because we people on the East coast are different from those Africans." I don't think we're that different from "those Africans," having been there and met them. This is where the epidemic is, and your state is in the middle of it.

Let's look at the Nation's capital. One in 200 teenagers from the District of Columbia who have graduated from high school, and who don't have felony records, are infected with the AIDS virus. The capital of the AIDS epidemic in young people who want to join the service is New York. We found that two percent of all male applicants and 1.8 percent of all female applicants from Manhattan were infected. In the New York metropolitan area it didn't matter if you were black or white, man or woman: your risk of infection depended upon whether you were 18 or 25. If you were 18 it was three per thousand; if you were 25 it was three percent. When the New York Commissioner of Health says he's surprised that one out of 43 women from the Bronx who elected to give birth to babies in the month of November, that one in 61 women from the city, and one in 112 women statewide were infected, it should come as no surprise. This epidemic has been moving in the young people in New York City for quite some time now.

You read in the papers that the epidemic is "stable." Not true. Again, I'm not worried about the epidemic in 40 to 60 year olds. I'm worried about 15 to 30 year olds, because that's where sexually transmitted diseases tend to be a problem. If you plot by age group the first two million people who elected to join the service, you can get an annual estimated incidence of what HIV infection is from one year to the next. That's what we did with our analysis of the military data of civilian applicants. We can now see the likelihood of infection from year to year. We have found that there is a 40 percent greater likelihood that a black or white man from a lower AIDS incidence area will be infected the second year over the first year. A doubling time of less than three years in young black and white men from low endemic areas would probably include Delaware and most of the United States. The situation of black women is even

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more tragic. Most of the incidence cases I see right now both at Walter Reed and in my practice are black females. They're the most rapidly growing group in an endemic area. There's a 120 percent greater likelihood they're infected the second year over the first year. On the national level, the doubling time in black women who want to join the service right now is on the order of one year. I don't think it's because these women are black. I don't think it's because they're women. I think it's because they're being exposed to people who have the AIDS virus. I don't consider it a stable epidemic when black females are doubling in one year or when males and females, or males from around the United States are doubling in less than three years.

Since 1984 the medical community has had the opportunity to interrupt ignorant transmission among their patients. I think a lot of patients are going to be upset when they find that that right has been denied them because the medical community hasn't provided the leadership to establish early diagnosis of HIV infection.

In Praise of Knowledge

We have had a very aggressive clinical program in the military since 1984. I'm proud that the members of the armed forces and particularly the army, are provided the opportunity to receive medical care based on knowledge. I also think that soldiers should have the opportunity to stop ignorant transmission. Since 1984 the medical community has had the opportunity to interrupt ignorant transmission among their patients. I think a lot of patients are going to be upset when they find that that right has been denied them because the medical community hasn't provided the leadership to establish early diagnosis of HIV infection. All soldiers have the opportunity to be informed if they have been unknowingly exposed to it. One thing unique about the military is that we can practice medicine based on knowledge, independent of social and political pressures.

This is the medical agenda I should like to leave with you. HIV infection is no different from any other disease, and the principles of medicine should be practiced here. We strive for early diagnosis and we provide optimal care based on knowledge. We need to interrupt ignorant transmission and we physicians should be providing the leadership of our national response to a national crisis. We need to work with our legislators and, our lawyers, but medical people must provide the leadership for a medical problem. I say this, we are dealing with a *treatable* disease. Most people with HIV infection today are being denied optimal treatment because they don't even know they are infected. I can stop the leading cause of death, pneumococcal pneumonia, but I can't stop it if I don't know my patients are infected. I can optimize my medical care based on knowledge, but I can't do it if I don't know my patients are infected. I can actually interrupt ignorant transmission to their friends and families but I can't do it if I don't know they're infected. And unlike Dr. Day, I would not say just that the physicians have the *right* to know their patients are infected. My point is that physicians have the *responsibility* to know if their patients are infected, so that they can provide the medical care for which their patients look to them.

... medical people must provide the leadership for a medical problem. I say this, we are dealing with a treatable disease. Most people with HIV infection today are being denied optimal treatment because they don't even know they are infected. I can stop the leading cause of death, pneumococcal pneumonia, but I can't stop it if I don't know my patients are infected.

The Testing Issue

There are two approaches to medical link/test link education. One is what I call "volunteer testing with routine ignorance," and the other "routine testing with voluntary ignorance." Both are

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voluntary. I would rather put the routineness on what I think is medically correct: the early diagnosis of HIV infection. People should know and their doctors should help them know if they're infected. The argument against routine testing with voluntary ignorance stresses the stigma of disclosure. But is there more stigma when I have to go to a gay mens' health center and give the hidden code to find out if I'm HIV infected or if my doctor routinely did it and everybody knew? We have put the stigma on the person who knows. We should put it on the person who doesn't. Is it discriminatory to provide this knowledge to people who are already concerned enough that they come forward and seek and ask you to help them or they go to anonymous clinics? Or is it less discriminatory to provide an equal opportunity for *all* our patients? When you consider that this epidemic is moving rapidly now in the young black heterosexual population, you realize that our program today is very discriminatory. Education is critical. We have a program that's been in place for several years whereby people can come forward if they think they're at risk and get tested at anonymous test sites. They get educated. I'd rather educate *everybody.* Routine testing in a medical setting is a way to provide education to all, except to those who have been educated to a point where they don't want to know, because they're concerned. And then I'll try to educate them as to why their ignorance is hazardous to their health.

We think it's a good idea for people who are going to get married to know if they're marrying people with the AIDS virus. In the only state that's done premarital testing, one in 2,000 people has been found to be infected.

People have argued against premarital testing. And again, I think they miss the point. I think that this country has to create an environment in which everybody who is infected knows it in order to get optimal care and stop ignorant transmission. Everybody in this state needs to know about the AIDS virus and what it means, and their role in the epidemic. We think it's a good idea for people who are going to get married to know if they're marrying people with the AIDS virus. In the only state that's done premarital testing, one in 2,000 people has been found to be infected. People say that's not cost effective. I think it's pretty cost effective to be able to tell those one in 2,000 people that have a fatal virus so that they may not infect partners they're about to marry. The other argument that I would also use: What is the public health effort to control the epidemic among the American family of the future? One is to say, "It's not going to happen." The other is to encourage young men and

women who are about to get married, since they are going to have recurring contact, to know whether this virus is going to be part of their relationship. It's a powerful educational tool and it only costs $6.00.

I can't prove these things, so I write them as assumptions because every time I'm in a panel discussion I am asked to prove them and I can't. I cannot prove that knowledge is better than ignorance. But I assume it. I cannot prove that compassion is better than vengeance. I have been asked to prove it. I can't. And I cannot prove that respect is better than fear, but I think these principles are the principles behind any medical, legal, legislative, public health policy that we should have in dealing with this epidemic. We should not assume that ignorance is better than knowledge, or that vengeance is better than compassion, or fear is better than respect.

We know all about this disease. We have all the tools we need to deal with it. We have a number of alibis that say we can't use these tools. It's obviously my position that no matter how excellent the alibis, we know enough now to make a major impact on this epidemic among the young people in our country. We just have to have the courage and will to use it. We in the medical community need to work with our lawyer friends and legislators to come up with a program that will begin to utilize the opportunity, not the burden, that the scientific community has given us to watch this virus become endemic in the human species.

In reality the AIDS epidemic that I'm trying to stop is the AIDS epidemic of the 21st century. The crisis now is not the AIDS epidemic at the end of *this* century. That's already happened. We will make no impact on the AIDS epidemic in the State of Delaware for the next ten years, except for newborn babies. The impact we're going to make is in the AIDS epidemic of the 21st century. We know a lot about this progressive uniformly fatal disease. Our focus should be on the virus and, if the epidemic of this century has happened, we need to get together to form the policies to deal with the epidemic of the next. ■

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Considerations and Potential Pitfalls in Lab Tests for AIDS

Cyril H. Wecht

The use of laboratory testing in establishing a diagnosis of AIDS and ARC has become increasingly important in the last three years. Since the initial commercial introduction of testing kits in 1985, there has been a great deal of controversy surrounding the proper use of these procedures. Many questions have been raised about the sensitivity and specificity of the various commercial kits that are in use. Each innovative development that increases the ability of testing to identify previously undetectable levels of the AIDS virus antibody is hailed by its developers as a new benchmark reference method, one that will allow us to define the true scope of the infection.[1,2] Indeed, are we following correct procedure by screening only for the HIV-1 virus? Do we need to concern ourselves with the recently identified HIV-2 as a potential source of infection, a somewhat less virulent virus described by Dr. Peter Piot, a Belgian AIDS researcher, at the recently concluded Stockholm conference?[3]

As the debate on various legal and ethical issues continues, we as medical professionals are faced with the reality and necessity of performing AIDS testing and interpreting the results with test methods that are less than perfect in an attempt to provide realistic estimates of the true nature and extent of the disease.

The most recent CDC criteria for AIDS case definition partially categorize individuals on the basis of laboratory test results.[4,5,6] I should like to define and discuss the problems associated with the laboratory performance of AIDS tests.

Terms Related to AIDS Testing

FALSE POSITIVE: A positive test result is obtained in the absence of the AIDS virus. This results in an individual's being incorrectly categorized as having the antibody to the AIDS virus when it is absent. This generally results from a lack of specificity in the test system.

FALSE NEGATIVE: A negative result is obtained in the presence of the antibody to the AIDS virus. This results in an individual's being incorrectly classified as virus free when he does indeed have virus present. This can result basically because of one of two reasons:

1. The individual being tested has not developed detectable levels of antibody, i.e., the levels of circulating antibody are too low for the test kit to detect.

2. The test method being used lacks sufficient sensitivity to detect circulating antibody levels, even though they are present in sufficient quantities.

TRUE POSITIVE: A positive test result is obtained on a patient that has the antibody to the AIDS virus.

TRUE NEGATIVE: A negative test result is obtained on a patient that lacks the antibody to the AIDS virus.

REPRODUCIBLY REACTIVE: When a specimen is found to exhibit a positive result upon initial testing, it must be retested. If it is found to be reactive a second time, it is classified as reproducibly reactive.

SENSITIVITY: This is the ability of the test procedure to identify the AIDS antibody in those possessing the disease. Ideally, sensitivity should be 100%, i.e., if 100 patients with AIDS are tested, 100 positive test results will be obtained.

SPECIFICITY: The test procedure will correctly classify as negative all individuals who do not have the AIDS antibody. As with sensitivity, specificity should be 100%, i.e., if 100 individuals who are disease free are tested, 100 negative test results will be obtained.

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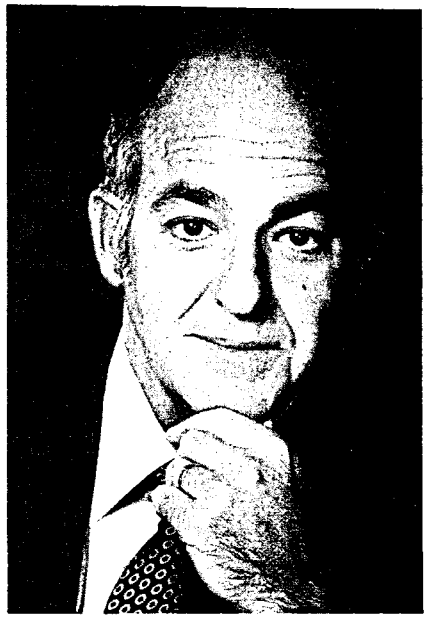

Cyril Wecht brings the disciplines and expert knowledge of both the medical and legal professions to the discussion we are privileged to publish here. Dr. Wecht is today Adjunct Associate Professor of Epidemiology, University of Pittsburgh Graduate School of Public Health and Adjunct Professor of Law at Duquesne University of Law. He is a member of the Pennsylvania Bar and holds medical licenses in Pennsylvania, California, and Maryland. He is also the author of an exceptionally large body of medical-legal literature.

Dr. Wecht's remarks were delivered in July at an AIDS conference in Arlington, Virginia sponsored by the American College of Legal Medicine.

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(continued)

PREDICTIVE VALUE: This is an overall measure of a test method's ability to correctly classify diseased individuals as possessing the AIDS antibody and disease free individuals as lacking the AIDS antibody. An ideal AIDS test would be 100% sensitive and 100% specific and would have a predictive value of 1.00.

The most commonly used method of testing for the AIDS virus antibody is the Enzyme Immunoassay (EIA or ELISA) technique. Of 698 laboratories reporting data to the American Association of Blood Banks and the College of American Pathologists, 610 or 87.4% use an ELISA method. Six ELISA test manufacturers are reported. A total of 88 laboratories reported performing Western Blot testing for the AIDS virus antibody.

Each of the six manufacturers addresses the limitations of its particular test procedure in an attempt to make users aware of the precise purpose of the test results that have been generated. These limitations are very consistent from manufacturer to manufacturer. For example, EIA procedure and the interpretation of results must be closely followed when testing serum and plasma specimens for the presence of antibody to HIV.

The primary use of the HIV antibody test is to screen blood and plasma donations so that units containing antibody can be identified and eliminated or restricted to further manufacturing into non-injectable products. It is inappropriate to use this test as a screen for AIDS or as a screen for members of groups at increased risk for AIDS in the general population. The presence of HIV antibody is *not* a diagnosis of AIDS. Individual blood and plasma donors who are repeatedly reactive for HIV antibody should be referred for medical evaluation, which may include additional testing such as antibody detection by the Western Blot technique, if that has not been done at the collecting facility.

A negative test result does not exclude the possibility of exposure to or infection with HIV.

False positive test results can be expected with a test kit of this nature. The proportion of reactives that are falsely reactive will depend on the sensitivity and specificity of the test kit and on the prevalence of HIV antibody in the population to be screened.[7]

The prevalence of HIV antibody in random donors is not known, but the higher the prevalence of HIV antibody in a population, the lower the proportion of falsely reactive samples.

All estimates that are made of sensitivity and specificity are based on estimated prevalence rates. If these prevalence rates are in error, significant deviations in the false positive rates for all manufacturers may be found.

The use of the EIA or ELISA methods for the detection of antibodies is a well-established technique in the clinical laboratory, and one that presents no unique technical problems. As with all laboratory testing procedures, the general rules of good quality control apply. Complete and detailed records of all testing must be maintained. These should document all procedural steps

used in reaching a final test result. All waterbaths used for incubation should have temperatures checked with each use, and all optical density readings should be recorded for both positive and negative controls and test specimens. All spectrophotometric equipment should be properly maintained, and written records of periodic wavelength checks and maintenance functions should be available. The specific details of the manufacturer's procedure should be followed exactly. Deviation from the written protocols can significantly influence final test results. The results of all testing should be reviewed by the supervising pathologist, and this review should be done with each testing run performed. Interpretive guidelines should be strictly adhered to, and repeats should be done as per the manufacturer's suggestions. If these guidelines are adhered to, the technical performance of the HIV antibody testing should present no unexpected difficulties in the laboratory. It should be stressed that all commercially licensed procedures have undergone the same FDA review criteria.

Once kit selection procedures have been completed, one should carefully review all protocols relating to infection control and contaminated waste disposal. While it is an infrequent occurrence, cases have been reported that would seem to indicate that exposure and subsequent infection have resulted from accidental laboratory exposure.[8] It will be necessary to establish appropriate training and education programs for all staff members who may come into contact with potentially hazardous materials. Training programs should not be limited to the laboratory staff only. Others within the organization can contact potentially infectious material and may be at risk. The need to address these issues involves not only good laboratory practice, but is also mandated by OSHA. On October 30, 1987, the U.S. Departments of Labor and Health and Human Services published in the Federal Register and mailed to over 500,000 employers a Joint Advisory Notice entitled "Protection Against Occupational Exposure to Hepatitis B Virus (HBV) and Human Immunodeficiency Virus (HIV)". It advised employers that they were responsible for the following:

1. Provide training and education programs for staff with potential exposure.
2. Adopt appropriate sanitation control procedures.
3. Develop standard operating procedures to reduce exposure.
4. Provide appropriate personal protective equipment.
5. Provide testing and other medical services to employees that may have been exposed.
6. Maintain a system of record keeping to document compliance with the above listed.[9]

The notice further announced that OSHA was beginning a program of enforcement, including inspections, to enforce its existing general regulations and statutory provisions regarding the duty of an employer to provide a safe and healthy work environment. Recent inspections conducted by OSHA of health care facilities have resulted in actions being taken against the employers. Fines that have ranged up to $5,000.00 have been levied in several cases.[10]

With the initiation of testing protocols, the laboratory assumes a major role as the provider of information to the medical practitioners requesting the HIV antibody testing. It is perhaps in this area that the greatest risks for liability are found. The pathologist must ensure that the requesting practitioner is aware of the meaning of the HIV antibody test. Failure to provide the practitioner with this information could result in the erroneous interpretation of data. Every attempt should be made to discuss the issues of sensitivity and specificity. A full understanding of these issues can significantly alter the information that is presented to a patient with either a positive or negative test result. One should be prepared to recommend the appropriate follow-up studies that would be needed to confirm or rule out a diagnosis of AIDS. Western Blot techniques are strongly suggested as a confirmation technique for the initial EIA positive findings.[11]

A newly developed test has been recommended as a replacement of the Western Blot test. The HIVAGEN test for HIV antibodies is a dramatic improvement over the Western Blot procedure and will soon replace it as the standard confirmation test for the detection of antibodies to the human immunodeficiency virus, a top AIDS researcher announced recently.

Everyone involved with HIV testing recognizes the shortcomings of the

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Western Blot assay. This test was selected for use because it was the only confirmatory test available in March of 1985 when widespread HIV testing of the nation's blood supply was initiated. However, the Western Blot is labor intensive, nearly impossible to standardize and clearly unsuitable for mass screening ventures.

A major problem with current testing procedures is indeterminate results on confirmatory testing. All positive results with the screening ELISA must be confirmed with another test, but the Western Blot has a 10 to 15% indeterminate rate.

These indeterminate results must be resolved by further testing. Superficially, this does not appear to be a major medical problem. However, it poses many serious difficulties.

What does an indeterminate result mean to a specific patient? What about a couple planning to marry who must obtain HIV testing beforehand as is now required by some states? Imagine the anguish of this couple faced with an indeterminate test result, particularly one that may take weeks or months to resolve.

This year approximately 29 million AIDS tests will be performed in the United States. Of these, about 500,000 will appear reactive on the initial screening and require confirmatory testing.

Using the Western Blot technology in confirmatory testing, approximately 75,000 results will be indeterminate and several thousand false-positive. This means 75,000 people will be told, "We don't know whether or not you have been infected by the AIDS virus." Even worse, some people will be told they are infected when, in fact, they are not.

HIVAGEN uses an ELISA technology —the same laboratory technology used in the successful AIDS antibody screen. Because of this approach, HIVAGEN is objective and automated as opposed to the subjective and manual Western Blot procedure.

Most important, HIVAGEN uses genetically engineered ELISA capture antigens. The capture antigens attract and bind the AIDS antibodies in the assay. The highly purified genetically engineered capture antigens give HIVAGEN a high degree of accuracy and reliability. The Western Blot has limited accuracy because the capture antigens it uses are from disrupted virus particles and are only partially purified and therefore contain human cell remnants that can interfere with the assay.

The diagnostic protocol for AIDS antibody testing is a two-step process—a screening test and a confirmatory test. If the screening test is reactive, a second screening test is performed to determine if the specimen is repeatedly reactive. The screening tests are highly sensitive in order to eliminate false-negative results. The screening tests are so sensitive, they may lead to reactive results in certain people who do not have the AIDS antibodies, e.g., lupus patients or women who have had multiple pregnancies.

Because of this, all repeatedly reactive screening tests have been confirmed using a confirmatory test—the Western Blot—which is far more specific than the screening tests and usually eliminates most false-positive results.

However, the Western Blot has several major limitations. First, the Western Blot is not a standardized test. With over 1,200 laboratories performing the Western Blot in the United States, there is a wide range in the quality of laboratory results. Second, the Western Blot is manual and requires subjective interpretation by highly skilled laboratory technicians. Third, nonspecific bands frequently appear in the test strips. As a result of these major limitations there are still some false-positive results.

In clinical trials of blood donated by healthy (AIDS-free) individuals, HIVAGEN produced no false-positive results. The Western Blot false-positive rate was 0 to 5% depending on who was doing the test and the type of Western Blot used.

In addition, HIVAGEN reduced the number of indeterminate results by 77% — 4.2% for HIVAGEN vs. 18% for a licensed Western Blot procedure.

In a series of over 1,200 individuals known positive for the AIDS antibody, HIVAGEN produced no false-negative results. HIVAGEN reduced the number of indeterminate results, this time by 84% — 2.5% vs. 15.6%.[12]

Informed Consent

The laboratory should aid in the development of informed consent documents to be used by all practitioners that have requested HIV antibody testing on a patient. The joint development of these documents will protect both the practitioner and the laboratory.

The laboratory must address the issue of confidentiality of records and results when testing for the HIV antibody. Confidentiality of all laboratory records is a given; however, in the case of HIV testing, one would be well advised to take additional measures to preserve patient confidentiality. It would not be inappropriate to consider placing the actual testing logs and patient records in separate files. Access to these files should be restricted on a need-to-know basis.

The laboratory would do well to consider the potential for liability involved with general screening programs that may be proposed by various groups. It has been generally held that these screening programs (particularly of low risk employee groups) are an inappropriate use for the HIV antibody test. While the financial rewards of this type of testing program may appear to be very attractive, the potential for misuse and misinterpretation of the results weigh heavily in favor of not becoming involved. There is an increasing trend in the insurance industry to require HIV antibody screening as part of routine application procedures for life insurance, due in part to the losses that have been suffered. It has been estimated that the total dollar payout for AIDS-related death, disability, and treatment claims in 1986 was approximately $292 million.[13] The potential for litigious actions being brought against the testing laboratories is not insignificant.

The laboratory has a responsibility to report the results of positive HIV antibody tests to the appropriate public health agencies. Failure to report the results of these tests could result in fines and jail sentences. Similarly, the laboratory's failure to report a positive HIV antibody may create liability to third persons where it can be shown that if such a report had been filed, the third party could have obtained medical treatment that would have decreased pain and suffering and possibly prolonged life. This may prove to be the case where public health regulations provide for contact tracing of sexual partners of persons with AIDS. The people traced via this route could then be informed of available medical treatment and proper personal health care. This would thus decrease their likelihood of developing AIDS, or at least allow them to minimize the risks associated with possible opportunistic infections, etc.[14]

Specific Recommendations and Suggested Policies

1. No testing should be performed without verification of informed consent.
2. Oral requests for HIV antibody testing should not be accepted. Only those requests that can be shown to have originated with appropriate informed consent should be accepted for analysis.
3. These documents should be maintained by the requesting clinician. The laboratory should receive verification that bears the signature of the physician, but not the signature of the patient.

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4. Whenever and wherever practical, patient identification should be accomplished without the use of names. It is suggested that special request forms be developed that provide the laboratory staff with only alpha numeric code numbers.

5. All records bearing identifiable patient information should be maintained in locked files. Access should be restricted and on a need-to-know basis only. Access logs should be maintained and periodically reviewed.

6. The laboratory should provide the practitioner with necessary documents to ensure compliance with public health reporting regulations. Complete all information by code number and instruct the attending physician to provide patient specific data.

7. Review with the clinician the specific information needed for insurance claim processing. This should be reviewed with the patient, along with the specific meaning of the release of information statements that accompany most insurance forms. The patient should then decide if insurance billing is appropriate for this particular test.

8. All documents associated with insurance claim processing should be maintained under lock and key as in (5) above.

9. Develop and maintain strict staff educational guidelines to comply with the OSHA standards. Document your compliance in writing. Maintain these records.

10. Decide in advance specific procedures that will be taken in the event that an accidental exposure occurs to a staff member. In the event of an exposure, document all steps taken and all procedures carried out. Maintain these records indefinitely.

11. Establish strict sanitation and waste disposal policies in writing. Monitor these on an ongoing basis to ensure compliance.

12. Monitor the ongoing performance of the actual assay. Monitoring should be internal (i.e., rates of false positives versus true positives, etc.), external (through peer group comparisons using survey material), and through published performance reviews in the literature. Do not hesitate to revise procedures and make changes when they become necessary.

Summary and Conclusions

The laboratory testing for HIV antibody presents a unique set of challenges for the laboratory professional. These challenges have evolved from two separate sources.

The technical challenge of selecting, evaluating, and identifying the optimal testing methods by which the medical community at large can begin to identify the true nature and scope of the disease process. We are dealing with an imperfect test method. The prevalence rate in the population at large has yet to be fully defined. Rates of false positives and false negatives are given as statistical best estimates based on estimates of prevalence rates. We are facing increasing pressures from individuals and groups to screen large segments of the population. These same individuals and groups have not taken the time to review the very basic scientific and statistical data, which indicate that mass screening of the population at large is inappropriate. Until such time as the available testing methods are improved, and the rates of false positive and false negative tests are decreased, the dilemma will persist.

We also face the challenge of education. We are deluged with new information daily. We must digest this information and provide it to our fellow practitioners in a usable format. The concepts of specificity, sensitivity, and predictive value are not new to the laboratory field. They have been in use for many years. Unfortunately, they have been used too little outside the laboratory. With the onset of the AIDS epidemic, they have been catapulted to a sudden role of prominence. We have a responsibility to teach and educate both our fellow professionals and the public what these test results mean. When and where is it appropriate to test? These are questions that must be addressed.

The performance of these tests can subject the laboratory to an increased risk of litigation. We have a responsibility to ensure that we take appropriate steps to limit this risk. Never have staff training and education been as important. It is only through continuing and intensive efforts to maintain the absolute highest standards of testing accuracy and integrity that we can limit these risks.

The legal issues remain to be fully defined. Legislative actions are pending that will help clarify some of the issues of confidentiality, but these await final action. In the meantime, we must take appropriate steps to ensure that we limit our own liability. At the same time, we have an ethical responsibility to protect the rights of our patients. We must each take whatever small steps we can to enlarge the existing knowledge base about the disease. ■

[1]"New Test Developed to Detect HIV Early, Accurately", AMA Newsletter, May 27, 1988, p.8.

[2]"Commercial Test Nears for Hidden AIDS Virus", *New York Times*, June 8, 1988, p. 8.

[3]"Largest AIDS Parley Ends in Stockholm", *New York Times*, June 17, 1988, p. 10.

[4]Centers for Disease Control (CDC): "Classification System for Human T-Lymphotropic Virus Type III/Lymphadenopathy-Associated Virus", MMWR: 35, 1986, pp. 334-339.

[5]Centers for Disease Control (CDC): "Classification System for Human Immunodeficiency Virus (HIV) Infection in Children Under 13 Years of Age", MMWR:35, 1986, pp. 334-339.

[6]Centers for Disease Control (CDC): "Revision of the CDC Surveillance Case Definition for Acquired Immunodeficiency Syndrome", MMWR:36 (suppl.), 1987, pp. 1s-16s.

[7]Abbott Laboratories Diagnositic Division: "Human T-Lymphotropic Virus Type III Abbott HTLV III EIA", 1987, pp. 1-13.

[8]Center for Disease Control (CDC): "Update: Human Immunodeficiency Virus Infection in Health Care Workers Exposed to Blood of Infected Patients", Vol. 36, No. 16, 19, as appearing in JAMA, Vol. 257, No. 22, pp. 3032-3039.

[9]52 Fed. Reg. 41, 818 (October 30, 1987).

[10]Hermann, Donald H.J.: "Liability Related to Diagnosis and Transmission of AIDS", Law, Medicine and Health Care, Vol. 15, Summer-1987, pp. 36-45.

[11]"Serological Diagnosis of Human Immunodeficiency Virus Infection by Western Blot Testing", JAMA, Vol. 260, No. 5, Aug. 5, 1988, pp. 674-679.

[12]"Clinical Laboratory Update", Smith Kline Bio-Science Laboratories, Vol. 1, No. 3, May/June 1988, p. 1.

[13]"Insurance Companies Pay $292 Million for AIDS", Pennsylvania Medicine, February 1988, p. 24.

[14]"Partner Notification for Preventing Human Immunodeficiency Virus (HIV) Infection — Colorado, Idaho, South Carolina, Virginia", Leads from the MMWR, JAMA, Vol. 260, No. 5, Aug. 5, 1988, pp. 613-615.

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The Informed Professional: Another View of HIV Testing

An Interview with Dr. Lorraine Day

The report of the Delaware Division of Public Health's AIDS Advisory Task Force announces with the cozy insouciance of an armchair General that health care workers "intimately exposed to bodily fluids of patients, [are] at extremely low risk for AIDS." Report, page 4. The prospect to those in the trenches is somewhat less cheery.

One of the speakers at the Professional Conference last April, Dr. Lorraine J. Day, practices an exceptionally sanguinary kind of surgery at San Francisco General Hospital: she is an orthopaedic surgeon.

"We are covered with blood constantly when taking care of trauma patients. It's not uncommon to take care of a patient who bleeds fifty or sixty units and generally all over us. The most blood replacement I've even given to a patient that I've taken care of was 247 units. That blood goes into the patient and bleeds back out again. Many times after long cases, before we were aware of the risk, I had blood all the way through my underwear on to my skin, all over my abdomen, all over my legs. I've had to put my legs into the shower to wash the blood off. This is how life really is in the orthopaedic operating room in a trauma hospital."

Remember that Dr. Day practices in San Francisco, where the incidence of HIV infection is extremely high. Since she operates regularly on patients carrying the virus, she feels herself at risk. Exposed daily and for long stretches to large amounts of blood in such a community, Dr. Day is skeptical of the orthodoxy quoted above from the Task Force Report.

Her credentials make her an impressive dissenter: in addition to serving as Chief of the Department of Orthopaedic Surgery at her hospital, she is an Associate Professor at the University of California School of Medicine. Her intelligent and courageous determination not to accept on faith or authority the assertion that her risk is minimal has earned her much opprobrium: resentment of her message may arise from a fear of discrimination, which prompts many to resist anything remotely suggesting isolation, segregation, or lazaret mentality.

Dr. Day has encountered hostility in the community she serves, and she met it again in Delaware. (See "Plague Politics" *infra.*) Since her views are the product of a superior intellect at work on an accumulation of first hand experience, they're entitled to be heard, no matter how distasteful they may be to those who for ideological purposes minimize the danger to health care professionals.

Until early October last year Dr. Day and her colleagues believed that AIDS was not very contagious and that they were not at risk. There had been eight hundred needle sticks with AIDS blood at the hospital where she practices and no one had contracted the disease. Then she learned of a health worker who had originally tested negative for HIV infection, and who had no other risk factors. After a single accidental needle stick the worker turned antibody positive within six weeks. Faced with this alarming development, she met with all of the Chiefs of Service at the hospital, who agreed with her that routine voluntary testing of surgical patients was reasonable, and such testing began. She also took the position that she had an obligation to be tested herself. (If she should be positive, sustain a cut in the operating room, and bleed into a patient, the patient's infection would be her moral responsibility.) She is highly critical of doctors who refuse to be tested. She sees the present crisis as the occasion for reciprocal candor between health care worker and patient in the interest of informed precaution on behalf of anyone at risk in a surgical setting. She was tested and encouraged her staff to be. At that time the Chiefs of Services agreed that this was a rational thing to do. When this information hit the newspapers, there was an uproar, and many of her previous supporters backed down and disagreed with the position they had previously endorsed.

Dr. Day asked a pointed question about the received wisdom that the risk to health care workers is low. Low in comparison to what? Hospitals take extraordinary and elaborate precautions to protect people who handle fluoroscopy or x-rays in the operating room. Yet Dr. Day knows of no one who has sickened or died from the effects of these procedures for the last fifty years. If the "low risk" is about one in 800, (800 needle sticks before contracting an incurable infection) how should hospital workers react to the prospect of being electrocuted only once in 800 uses of sophisticated electronic equipment in the surgical setting? So high a prospect of lethal exposure would hardly be countenanced in the most slovenly medical setting.

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The news got worse: in January 1988 Dr. Day learned of a laboratory maintenance man who contracted the virus. The initial response was to question his lifestyle, but he denied his exposure to any of the conventional risk factors. He had always worked with protective gloves. His virus was subtyped and found to be exactly the same type used in the laboratory.

The bad news continues to accumulate: a study in the Journal of Investigative Dermatology observes: *"The previous assumption that HIV infection can exclusively occur by the entry of virus through wounds in the skin and mucous membranes into the blood can no longer be considered valid. Our results suggest that the Langerhans cells in the skin and mucous membrane are primary target cells for sexually transmitted HIV infection."*

To Dr. Day this suggests points of entry in the eye, the mouth, the vaginal tract, the rectal tract, or the skin *without a cut or any wound.* She is understandably distressed that she cannot require that patients be tested, even though she must operate on them and risk exposure to their blood.

"We can stop drunk drivers in California and check them for sobriety. If they get caught it has major implications for them, sometimes their jobs and their social status. The Supreme Court has decided that the public good is greater than the disadvantage of the individual. And yet, we have people out there who can kill others with their disease, but we cannot routinely test them. It is said that the consequences of a false-positive test are too great to warrant routine testing. Nonetheless, ten million blood donors and two million military recruits have been tested and they seem to have handled the possibility of false-positive results."

The Fallacy of Universal Precaution

To get around the politically hot potato of testing, many in the medical establishment take the position that it is unnecessary to know the HIV status of each patient, because precautions can be taken in every case. Dr. Day doesn't buy this. "You can't play the Super Bowl every Sunday. There is no way you can

continue with that high level of anxiety every time you operate. The idea of using universal precautions is very high sounding but it's not realistic." She describes the almost unmanageable complexity of splash shields, inadequate supplies of properly sized surgical gloves, cumbersome knee boots (two pairs — they aren't water proof), surgical masks insufficient to filter out

Sparing the Feelings of the Lethal

During the question and answer period at the Professional Conference a woman identifying herself as a lawyer from Philadelphia expressed concern for health care workers who don't have the same options as doctors.

Dr. Day's response: "I know that nurses and others in the hospital are at risk. When you're taking care of any patient with a contagious disease it is routine to take precautions. Two to three years ago at San Francisco General Hospital a number of nurses wanted to wear masks and gloves when they took care of AIDS patients. They were told they could not do this because it hurt the delicate psyches of the AIDS patients and that they would feel they were unclean. The nurses continued to wear gloves and masks and they were called on the carpet, taken down to the Civil Service Commission, and penalized." This is surely the height of goofy solicitude. Health care workers are engaged to practice effective medicine. They aren't on the contagion firing line (we apologize to Emily Dickinson) to help fainting robins back to their nests again.

aerosolized particles capable of carrying the virus, and a panoply of Star Wars contraptions that make it difficult for a surgeon to breathe or to hear what is being said to him. Major precautions like these are for the identifiably contagious (if you're allowed to identify).

Dr. Day is a eloquent spokesman for medicine first, ideology second.

"We have to go back to basics. The fear of becoming called bigots has caused us to lose our common sense. It's unfortunate that AIDS has been politicized. If it had started out as a truly medical disease and not a political one, we would have routine testing. During the polio epidemic, no polio patient wanted to keep secret from his doctor that he had the disease. If a polio patient was contagious and required an operation, major precautions could be taken, because all concerned knew what they were dealing with.

It is a sad time when we in the medical profession cannot voice our opinions. We must get this disease under control. We must save all lives. Gay, straight, minority, majority. The way to do it is to have routine testing of anyone who needs testing. We must put a lot of resources towards preventing the disease, as well as treating it. Until then we shall do nothing but keep our heads in the sand."

A lot of other people seem to share Dr. Day's concern. It is estimated that by the mid-1990's when the AIDS epidemic is scheduled to reach a rolling boil there may be a shortage of half a million nurses, and applications to medical schools are already falling off. This is hardly surprising. It is one thing to expect health care workers to be altruistic in the assumption of understood risks; it is quite another to demand of them a suicidal commitment to noble ignorance.

Ellen Goodman, the nationally syndicated columnist, who has also interviewed Dr. Day, made a shrewd observation, "If we are going to trust health care professionals to treat the sick, part of that trust is to give them privileged information, the tools of their job." ■

Psychiatric and Psychological Aspects of AIDS

David E. Raskin, M.D.

Acquired Immune Deficiency Syndrome is defined by a disturbance in cell mediated immunity (one mechanism the body has available to combat infection). The incidence of this disorder has steadily increased through the 80s. High risk groups include homosexual and bisexual men, intravenous drug abusers, hemophiliacs, children of high risk parents, and female sexual partners of men with AIDS. There have been some reports of female to male transmission. Transmission usually occurs through bodily fluids and usually as the result of, a.) sexual contact, b.) blood transfusion, c.) The use of syringes contaminated with the virus, d.) or transmission from mothers to newborns.

The onset of AIDS is often signaled by the development of Kaposi's sarcoma, lymphomas, or opportunistic infections. Kaposi's sarcoma is a malignant tumor. Lymphoma is a tumor of lymphatic tissues. Opportunistic infections are those induced by organisms incapable of causing disease in a normal person but able to produce infections in a less resistant or injured host. Initial symptoms usually include, cough, shortness of breath, fatigue, diarrhea, weight loss or lymphadenopathy (swollen lymph nodes). Occasionally, the diagnosis of AIDS is made in a patient in whom depressive illnesses predate these physical illnesses. It is now apparent that there are psychiatric manifestations of AIDS, and there have been several papers reporting them.

Obsessional Symptoms Relating to Fears About Developing AIDS[1]

The Worried Well

Members of high risk groups concerned about developing AIDS encounter considerable emotional distress. Their symptoms range from obsessional worries to anxiety and panic attacks, and acute hypochondriasis (fear of illness). At times, these symptoms can reach the level of being dysfunctional and require psychiatric intervention. Psychiatrists have even treated individuals not in high risk groups who, because of a single sexual indiscretion, become obsessed with the fear of developing AIDS and who consult physicians repeatedly and request repeated testing as a way to reassure themselves that they have not been exposed to the AIDS virus.

Psychiatric Symptoms in People Diagnosed as having been Exposed to the AIDS Virus

The first set of symptoms are those that follow the disclosure that a patient has been exposed to the AIDS virus. As with other chronic diseases, the patient first expresses denial and disbelief. This is followed by depression or symptoms of anxiety. Thoughts of suicide are common. Suicidal behavior is more probable in AIDS patients with a history of documented personality disorders.

The second major variety of psychiatric symptoms are those relating to the direct effect of the AIDS virus on brain function.[2] Approximately 30 to 40 percent of patients with AIDS show symptoms of central nervous system impairment. Eighty percent (80%) demonstrate postmortem neuropathological abnormalities. The most common form of central nervous system dysfunction is a diffuse encephalopathy. Encephalopathy means a disease of the brain. Symptoms include malaise, lethargy, anorexia, and diarrhea, resulting in significant weight loss. Over weeks or months, the patient then develops symptoms of dementia including a slowing of thought processes and motor movements, incontinence, confusion, and in some cases, hallucinations and delusions. Initially, AIDS patients with dementia appear to be psychologically depressed with an observed reduction in normal emotional response, impaired memory, concentration problems, and social withdrawal. This can lead to seizures, mutism, and coma. In all probability, an encephalitis (inflamation of the brain) is involved, but the precise neuropathological mechanisms are not yet clearly understood. Since psychiatric response to AIDS and central nervous system dysfunction as a result of AIDS are so common, it is incumbent upon physicians to have AIDS patients routinely evaluated psychiatrically. Depression and suicide risk need to be assessed. Supportive psychotherapy, medication, or both, need to be provided. One must always keep in mind the potential for the central nervous system involvement and the development of dementia.

It is interesting to note that family support systems are beginning to develop in response to the catastrophic effects of AIDS on families, spouses, and significant others.[3]

Medical/Legal Issues

AIDS has presented medical specialists, psychiatrists included, dilemmas in terms of confidentiality. The American Psychiatric Association (APA) AIDS policy[4] indicates that physicians have an ethical obligation to guarantee privacy and confidentiality. If, however, the physician determines that the patient is continuing to put others at risk of infection, the APA feels it is ethically permissable for the physician to override confidentiality and notify those at risk. This is in accord with the psychiatrist's general duty to protect as defined in the *Tarasoff*[5] case[6]. The APA believes further that it is ethical for a psychiatrist to report to an appropriate public health agency the names of patients who are determined by convincing clinical information to be HIV infected (HIV positive means a person has been exposed to the Human Immune

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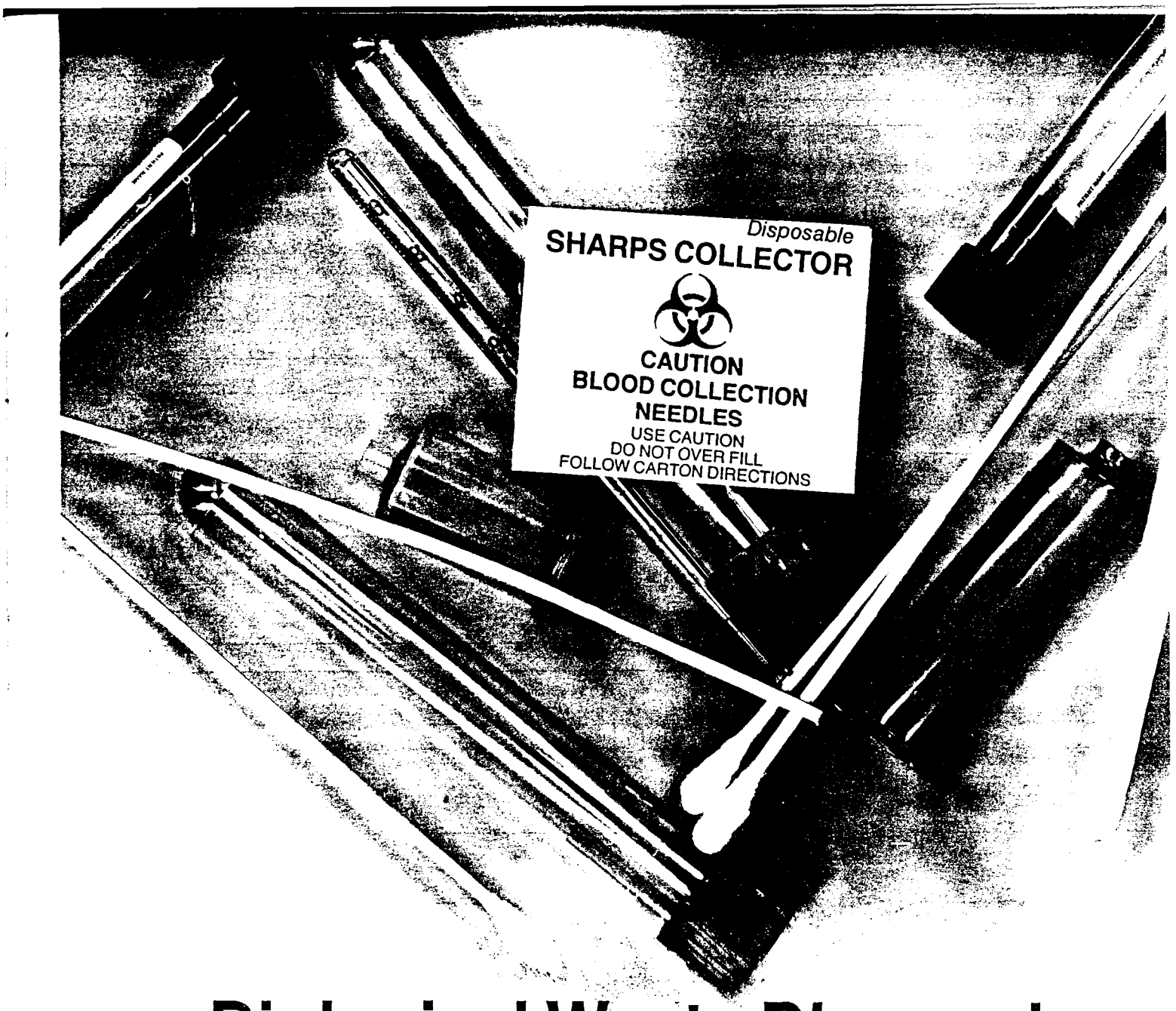

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Psychiatric and Psychological Aspects
(continued)

Deficiency Virus) and who the doctor feels are endangering others.

Demands for psychiatric hospitalization of HIV-positive persons, who engage in promiscuous activity or intravenous needle sharing may be expected.[7] Are such uses of commitment legitimate? Many facilities are unable to meet the medical needs of a symptomatic AIDS patient or even to protect their own patients from being infected by a promiscuous carrier. These questions and issues undoubtedly will be addressed in the next few years. ■

[1] Psychiatric Aspects of AIDS, by Faulstich, M., *American Journal of Psychiatry, 1987:* 144-551-6.

[2] Neuropsychiatric Aspects of Acquired Immune Deficiency Syndrome, by Loewenstein, R.J., and Sharfstein, S.S., *International Journal of Psychiatry and Medicine,* 1984: 13: 255-60.

[3] Support Group Helps Mothers Share Grief. Families of AIDS Patients Learn to Ease Pain, by Sari Straver, *American Medical News,* January 22/29, 1988; 3, 18-21.

[4] AIDS Policy: Confidentiality and Disclosure, *Psychiatric News,* January 15, 1988.

[5] *Tarasoff vs. Regents of University of California,* 131 Cal. Rptr. 14, 551 P2d 334 at page 347.

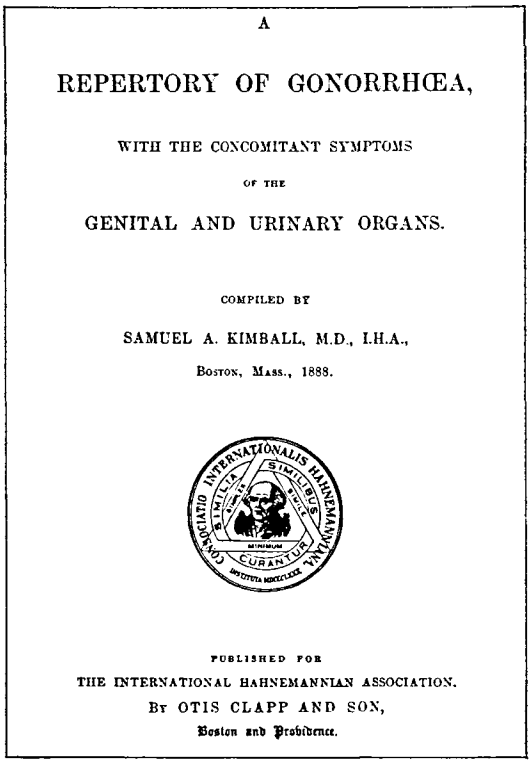
[6] Forensic Psychiatry and Psychology, Case Law Summary & Analysis Series, *Duty to Warn,* Joseph T. Smith, M.D., J.D., Steven B. Disbing, J.D., PsyD.

[7] AIDS, Psychiatry and the Law, by Paul S. Appelbaum, M.D., *Hospital & Community Psychiatry,* January, 1988; Vol. 39, No. 1, p. 13-14.

David Raskin, Chairman of the Department of Psychiatry at the Medical Center of Delaware, comes formidably well equipped to speak on the issues addressed in his accompanying article. He is not only an extremely distinguished psychiatrist; he has applied his skills to the examination and treatment of many patients suffering from AIDS.

To name but a few of his professional accomplishments, we note that he is Clinical Professor of the Department of Psychiatry and Human Behavior at Jefferson Medical College, in Philadelphia, and the Psychiatric Consultant for Correctional Facilities in Delaware. For the last sixteen years he has been an Examiner of the American Board of Psychiatry & Neurology. His many learned articles have appeared over the years in prominent medical and psychiatric journals. His recent initiative in combining medical and legal disciplines for the education of both professions in a continuing medical-legal education program, "The Insanity Defense", was enthusiastically received by doctors and lawyers alike.

Plague Politics



A

REPERTORY OF GONORRHŒA,

WITH THE CONCOMITANT SYMPTOMS

OF THE

GENITAL AND URINARY ORGANS.

COMPILED BY

SAMUEL A. KIMBALL, M.D., I.H.A.,

BOSTON, MASS., 1888.

PUBLISHED FOR

THE INTERNATIONAL HAHNEMANNIAN ASSOCIATION.

BY OTIS CLAPP AND SON,

Boston and Providence.

Sick through sin?

Mrs. Patrick Campbell, an English actress who flourished in the first quarter of this century, was at the height of her blunt powers of self-expression when an Edwardian sex scandal reduced London society to a state of lubricious hysteria. Mrs. Campbell dismissed the brouhaha with a civilized yawn: "Does it really matter what people do, so long as they don't do it in the streets and frighten the horses?"

The sentiment is decent. It endorses the right of privacy while upholding the claims of decorum. But it may become a dangerous sentiment to the extent that the notion of a right of privacy is pervertedly transformed into the power to kill by stealth. It is the purpose of this discussion not to urge the undermining of civil liberties, but to suggest a climate in which personal freedom and essential knowledge may coexist.

Behaving Badly Under Fire

For some years we have known that AIDS is a terrible threat to mankind. We have also learned that we should become fully informed about AIDS in its every aspect and that we should act decisively in accordance with that knowledge. Many, however, have been less interested in the pursuit of truth than in maintaining ideological purity. At the opposite ends of a political spectrum religionists of the far right and sexual minorities (and the officials who look to those very different constituencies for retention of office) have engaged in turfmanship and displays of indignation to the detriment of public health.

A few years ago I disposed of my father's medical library on the theory that several hundred out of date textbooks on urology had limited appeal for the general reader. I could not, however, resist saving a splendid oddity entitled "A Repertory of Gonorrhoea" by Samuel A. Kimball, M.D. (The principal charm of this otherwise useless volume — it was printed in 1888 — is the author's inspired choice of a publisher: the fine old Boston firm of Otis Clapp & Son.) Dipping into this peculiar treasure recently, I was startled by the durability of its Victorian point of view. The preface speaks of "the noble work of curing the sick, *"even if they are sick through sin."* (Italics supplied.) The same zest for moralistic responses to medical issues is in full flower today. All too frequently members of the religious far right equate AIDS with divine retribution. Although they speak perfunctorily about love and forgiveness, their core attitude towards the victims of AIDS appears to be patronization, laced with Old Testament wrath.

At the other end of that spectrum is politicized gayhood, which has suffered much to attain security in a lifestyle it now sees threatened by a linkage in public perception between AIDS and minority sexual preference. And, like the religious right, that minority is no stranger to folly in the defense of principle. In San Francisco, that Mecca of variegated love life, sensible public health measures intended largely for the protection of homosexuals have been angrily spurned by gay leaders as acts of covert homophobia. Apparently gays can be just as self destructively silly as their opponents.

Naturally this kind of doctrinaire wrongheadedness also prevails among the politically sensitive members of the United States Congress. It has been reported that the respected Henry Waxman, Chair of the House Subcommittee on Health and the Environment, has gotten into hell's own tangle in trying to craft useful AIDS legislation, beset by a fellow Committee member insistent upon making it plain that the United States government endorses neither homosexuality nor drug addition.

The misuse of the AIDS issue reached a new low in Chicago recently, according to the *New York Times* of Tuesday, July 26. A virulently antisemitic black activist, not surprisingly fired from the office of the Mayor, has declared "the AIDS epidemic is a result of doctors, especially Jewish ones, who inject AIDS into blacks". The *Times* account continues: this charmer now works for the Reverend Louis Farrakhan, who heartily endorses his allegations.

The Prudence of Concealment

In his article elsewhere in this issue Dr. Gerald Cioffi points out that it is "socially acceptable" to die of any of a number of afflictions, but *not* of AIDS, and Professor Furrow tells a cautionary horror story of a young man whose HIV positive diagnosis was leaked, costing him his job, his medical insurance, and his home.

The initial equation of AIDS and homosexuality has stirred up a frightening degree of hostility to gays, including violence to the point of murder. A decision of the United States Supreme Court has exacerbated this state of affairs by upholding statutory condemnation of minority sexual preference. *Bowers vs. Hardwick, et al,* 106 S. Ct. 2841 (1986). Instead of extending the *Griswold vs. Connecticut* right of privacy to all dis-

(Continued on next page)

creet consensual behavior (not in the streets and not frightening the horses) a majority of the Court embraced a traditionalist approach, stressing "crimes against nature" and the long history of the sodomy laws. *Bowers*, which does not even refer to AIDS, validates in half the jurisdictions in the Republic the criminalization of activity widely associated with AIDS. Concealment of infection thus becomes a sensible, if ignoble, course of conduct.

This is no place to examine *Bowers* as Constitutional adjudication. It is enough to recognize that this controversial decision of a sharply divided Court has not materially contributed to being open about a menace that cannot be confronted in the dark. Had Bowers gone the other way, declaring once and for all the right to conduct one's private life insulated from the censure of boudoir busybodies, our task would surely have been easier.

The Delaware Response

Seemingly resistant to the prejudices and pet lunacies described above, Delaware leadership in the AIDS crisis has been strong. At the April Professional Conference the Governor stated a continued resolve to deal with AIDS as a *medical* problem. The Attorney General has earned high marks for his handling of the Alfred I. duPont Institute dustup, and his office has kept itself remarkably well informed about the many legal developments in AIDS confronting us for the first time. (See David Lyons's article, *supra.*) But none of these encouraging signs should lull us into the belief that we in Delaware are immune to special interest digressions from effective response to the epidemic.

In September 1987 the AIDS Advisory Task Force of the Delaware Division of Public Health issued a lengthy report. It was later supplemented by a majority report on the issue of HIV testing, and a vigorous dissent from members of the medical community. Both appear in an appendix in this issue.

The Report, the work of a broad-based group of professional and community representatives, is an honorable achievement, distinguished by courteous deference to the prickly sensibilities of every imaginable concerned minority, racial or sexual. (Sometimes to bizarre effect: on page 11 the Report refers to "persons within the prostitution industry", a category that may raise a few eyebrows at the Chamber of Commerce.)

Perhaps the most significant features of the Report are a kind of muted hostility to HIV antibody testing and a gratuitous intrusion of sexual minority preachments.

"Because AIDS first affected the gay population in the United States, we have already seen lag time between the first manifestations of this disease and the recognition that we face a very serious public health problem. In other words, had the disease first struck the heterosexual community, the alarms might have been raised earlier, and more attention might have been given to education, research, and treatment." Task Force Report at page iii.

This is irrelevant to the problem at hand, which is to contain a plague. We should not be expending our energies on recriminations over the perceived inadequencies of our earlier response. But gay leaders, not unrepresented in the formulation of the Report, appear to demand simultaneously the glamour of martyrdom and the security of uncritical endorsement. Given the emotional climate surrounding AIDS, this deserves a good deal of sympathetic understanding. But the contamination by special interest agenda of Task Force deliberations has lead to a less than satisfactory piece of compromise legislation on HIV testing. See Lyons discussion at page 75.

Yes, even in enlightened Delaware* there is a pervasive tendency to put social priorities above sound medicine. At the Professional Conference in April Doctors Cioffi, Day, and Redfield argued eloquently for widespread and early HIV testing, not merely for the protection of the uninfected but for the provision of informed medical care to the infected at a time when they could still benefit from therapy. Their presentations of painful truths outraged several of those in attendance. One addressed a savage attack on Dr. Day to the authorities of the San Francisco Hospital where she practices and teaches orthopaedic surgery. (Shoot the messenger!) Another, learning of plans to show a videotape of the Conference to a group of policemen, persuaded the program moderator to dispense with the medical portion of the tape because it was "off the wall", which of course it most emphatically was not. It now appears that unpalatable truths are up against something uncomfortably close to prior restraint.

**The General Assembly has indeed acted responsibly. Handicap legislation (House Bill 135) is now law and should eliminate much discrimination against the infected.*

Giving Life a Chance

At the July symposium sponsored by the American College of Legal Medicine one speaker said it all in a few well chosen words. Here is an extremely accomplished doctor, Dr. Lonnie Bristow of the American Medical Association, telling lawyers and legislators what he as a medical specialist needs in stopping a plague:

"Discrimination triggered by the fear of AIDS may increase the risk of the spread of AIDS because those at risk may not come forward for testing and counseling. Therefore, discrimination threatens not only those who are infected, but the rest of society as well."

Consider the source of these wise words. This is not gay propaganda. This is not the extravagance of a hypersensitive civil libertarian. It is the informed assessment of one qualified to deal with a problem that is above all else a medical one. It appears that doctors and lawyers have united in fostering this emergence of dazzling common sense. Former President Robert MacCrate of the American Bar Association has spoken out strongly against discrimination as it bears on the AIDS crisis.

What are the prospects for common sense triumphant? Well, in the long run, when things get bad enough, common sense has a wonderful way of reasserting itself in the face of ideology and prejudice. The Task Force Minority Report on the issue of HIV testing correctly asserts that the time has come to stigmatize the discriminators instead of the sufferers. Despite (or perhaps because of) the shadows cast by *Bowers vs. Hardwick*, we need to adopt the most stringent antidiscriminatory measures. Those at risk must feel safe in informing themselves and, if infected, in pursuing competent medical help.

I am confident in the triumph of sanity. It will not be the first occasion that our free society has shown the strength to abandon preconceptions in order to grapple with unpleasant truths and to succeed in so doing. ■

William E. Wiggin

Informed Consent and Confidentiality Regarding HIV Related Tests

(Final informed consent/confidentiality legislative recommendations from State's AIDS Advisory Task Force)

Section 1. Definitions

1. **AIDS** - Acquired Immunodeficiency Syndrome

2. **HIV** - the human immunodeficiency virus identified as the causative agent of AIDS.

3. **HIV related test** - a test for the antibody or antigen to HIV.

4. **Health facility** - a hospital, nursing home, clinic, blood bank, blood center, sperm bank, laboratory, or other health care institution.

5. **Health care provider** - any nurse, physician, dentist and other dental worker, optometrist, podiatrist, chiropractor, laboratory and blood bank technologist and technician, phlebotomist, dialysis personnel, emergency health care provider (including any paramedic, emergency medical technician, law enforcement personnel, or firefighter), and others whose activities involve contact with patients, their blood or corpses.

6. **Legal guardian** - a person appointed by a court to assume legal authority for another who has been found incompetent or, in the case of a minor, a person who has legal custody of the child.

7. **Person** - any natural person, partnership, association, joint venture, trust, public or private corporation, or health facility.

8. **Release of test results** - a written authorization for disclosure of HIV related test results which is signed, dated and which specifies to whom disclosure is authorized and the time period during which the release is to be effective.

Section 2. Informed consent.

A. No health facility, health care provider, or other person shall test or shall cause by any means to have tested, any specimen of any patient for HIV related tests, without the informed consent of the subject of the test or the subject's legal guardian. A health care provider shall ensure that informed consent has been received prior to ordering testing by a laboratory or other facility.

B. Informed consent to an HIV related test shall consist of a voluntary agreement executed by the subject of the test or the subject's legal guardian. If the agreement is oral, the facts pertaining thereto must be documented by customary practice. Informed consent shall consist of at least the following:

(1) an explanation of the test, including its purpose, potential uses, limitations, and the meaning of its results;

(2) an explanation of the procedures to be followed, including that the test is voluntary, that consent may be withdrawn, and the extent and limitations of the manner in which the results will be confidential;

(3) an explanation of the nature of AIDS and other manifestations of HIV infection and the relationship between the test result and those diseases; and

(4) information about behaviors known to pose risks for transmission of HIV infection.

C. Notwithstanding Section 2A, the provisions of Sections 2A and 2B do not apply when

(1) knowledge of such test results are necessary for medical diagnostic purposes to provide appropriate emergency care or treatment and the subject of the test is unable to grant or withhold consent;

(2) the testing is done for the purposes of research, provided that the test is performed in a manner by which the identity of the test subject is not known and may not be retrieved by the researcher.

(3) a health care provider or health care facility procures, processes, distributes or uses (i) blood, (ii) a human body part donated for a purpose specified under the Uniform Anatomical Gift Act, or (iii) semen provided prior to the effective date of this Act for the purpose of artificial insemination, and such test is necessary to assure the medical acceptability of such gift or semen for the purposes intended.

(4) necessary to control the transmission of HIV infection as may be allowed pursuant to 16 Del. C. Chapter 7 et. seq. as it relates to sexually transmitted diseases, or 11 Del. C. Section 6523 (b) as it relates to the Department of Corrections.

(5) testing is ordered by a court of competent jurisdiction within the confines of civil or criminal litigation where the results of an HIV related test of a party, or a person in the custody or under the legal control of another party, is relevant to the ultimate issue of culpability and/or liability. Said order shall be issued in compliance with the following provisions:

(i) No court of this State shall issue such order unless the court finds that there is a compelling need for such test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for testing and disclosure of the test results against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters future testing or which may lead to discrimination.

(ii) Pleadings pertaining to ordering of an HIV related test shall substitute a pseudonym for the true name of the subject of the test. The true name shall be communicated confidentially, in documents not filed with the court.

(iii) Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party.

(iv) Court proceedings as to disclosure of test results so ordered shall be conducted *in camera* unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

D. Any person on whom an HIV related test was performed without first having obtained informed consent pursuant to Section 2C(1), 2C(4) and 2C(5) shall be given notice promptly, personally and confidentially that a test sample was taken and the results of such test may be obtained upon request.

E. At the time of learning the test result, the subject of the test or the subject's legal guardian shall be provided with counseling for coping with the emo-

(Continued on next page)

tional consequences of learning the result, for understanding the interpretation of the test result, for understanding measures for preventing infection to others, and to urge the voluntary notification of sexual and needle sharing partners of the risk of infection.

F. Notwithstanding any other provision of law, a minor 12 years of age or older may consent or refuse consent to be a subject of HIV related testing and to counseling relevant to the test. The consent or refusal of the minor shall be valid and binding as if the minor had achieved his or her majority, and shall not be voidable, nor subject to later disaffirmance, because of minority.

Section 3. Confidentiality.

A. No person may disclose or be compelled to disclose the identity of any person upon whom an HIV related test is performed, or the results of such test in a manner which permits identification of the subject of the test, except to the following persons:

(1) The subject of the test or the subject's legal guardian.

(2) Any person who secures a legally effective release of test results executed by the subject of the test or the subject's legal guardian.

(3) An authorized agent or employee of a health facility or health care provider if the health facility or health care provider itself is authorized to obtain the test results, the agent or employee provides patient care or handles or processes specimens of body fluids or tissues, and the agent or employee has a medical need to know such information to provide health care to the patient.

(4) Health care providers providing medical care to the subject of the test, when knowledge of the test results is necessary to provide appropriate emergency care or treatment.

(5) When part of official report to the Division of Public Health as may be required by regulation.

(6) A health facility or health care provider which procures, processes, distributes or uses: (i) blood, (ii) a human body part from a deceased person donated for a purpose specified under the Uniform Anatomical Gift Act; or (iii) semen provided prior to the effective date of this Act for the purpose of artificial insemination.

(7) Health facility staff committees or accreditation or oversight review organizations which are conducting program monitoring, program evaluation or service reviews.

(8) Pursuant to 16 Del. C. Section 901 et. seq. as it relates to investigation of child abuse.

(9) Pursuant to 16 Del. C. Section 7 et. seq. as it relates to sexually transmitted diseases and their control.

(10) A person allowed access to said record by a court order which is issued in compliance with the following provisions:

(i) No court of this State shall issue such order unless the court finds that the person seeking the test results has demonstrated a compelling need for the test results which cannot be accommodated by other means. In assessing compelling need, the court shall weigh the need for disclosure against the privacy interest of the test subject and the public interest which may be disserved by disclosure which deters future testing or which may lead to discrimination.

(ii) Pleadings pertaining to disclosure of test results shall substitute a pseudonym for the true name of the subject of the test. The disclosure to the parties of the subject's true name shall be communicated confidentially, in documents not filed with the court.

(iii) Before granting any such order, the court shall provide the individual whose test result is in question with notice and a reasonable opportunity to participate in the proceedings if he or she is not already a party.

(iv) Court proceedings as to disclosure of test results shall be conducted *in camera* unless the subject of the test agrees to a hearing in open court or unless the court determines that a public hearing is necessary to the public interest and the proper administration of justice.

(v) Upon the issuance of an order to disclose test results, the court shall impose appropriate safeguards against unauthorized disclosure, which shall specify the persons who may have access to the information, the purposes for which the information shall be used, and appropriate prohibitions on future disclosures.

B. No person to whom the results of an HIV related test have been disclosed pursuant to Section 3A may disclose the test results to another person except as authorized by Section 3A.

C. The provisions in this section shall not interfere with the transmission of information as may be necessary to obtain third-party payment for medical care related to HIV infection or with the documentation of cause of death on death certificates.

Section 4. Remedies and Penalties.

A. Intentional or reckless violations of Sections 2 or 3 shall constitute a misdemeanor.

B. Any person aggrieved by a violation of this Act shall have a right of action in the Superior Court and may recover for each violation:

(1) Against any person who negligently violates a provision of this Act, liquidated damages of $_____ or actual damages, whichever is greater.

(2) Against any person who intentionally or recklessly violates a provision of this Act, liquidated damages of $_____ or actual damages, whichever is greater.

(3) Reasonable attorney fee.

(4) Such other relief, including an injunction, as the court may deem appropriate.

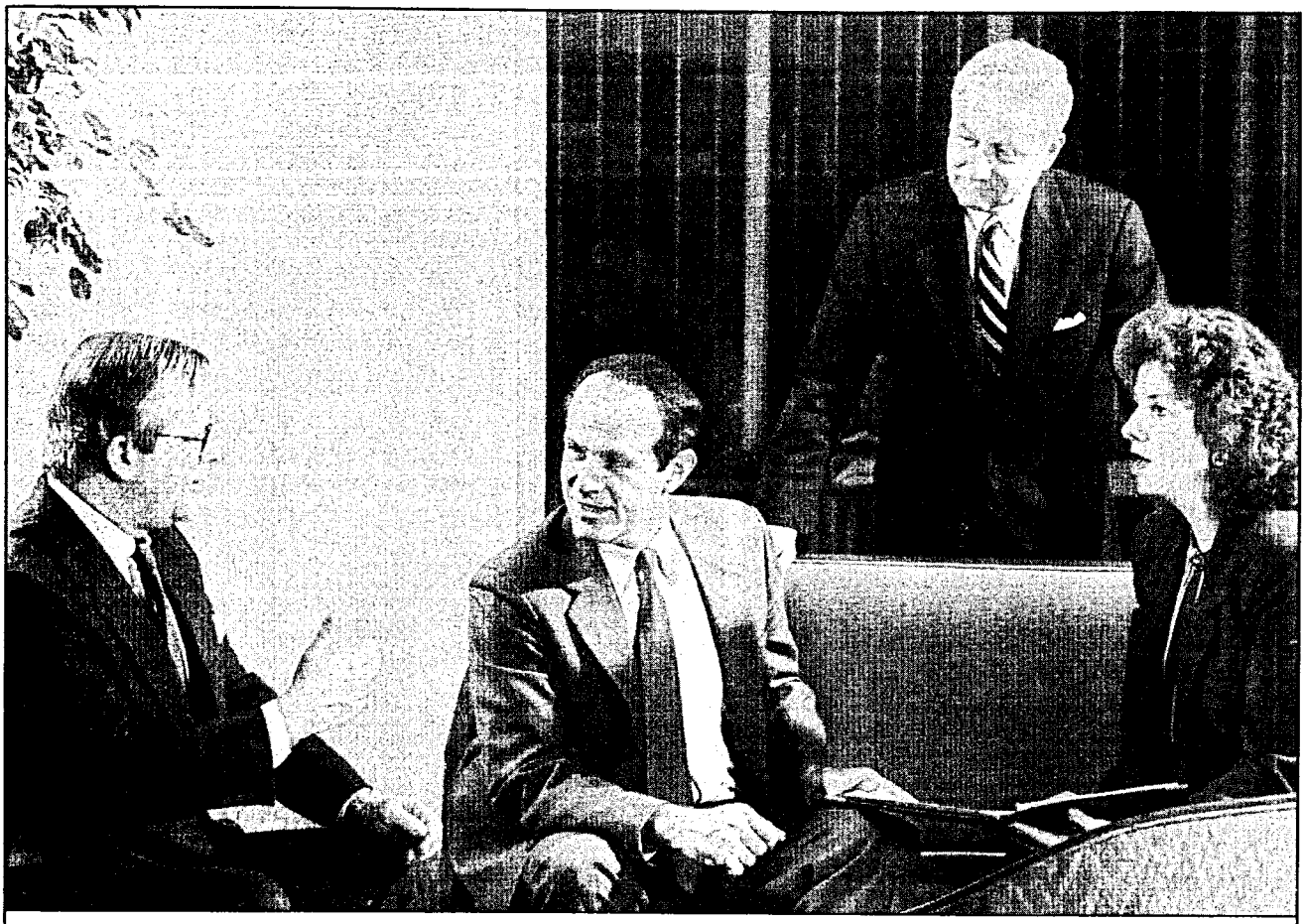
(5) Any action under this Act is barred unless the action is commenced within three years after the cause of action accrues. A cause of action will accrue when the injured party becomes aware of an unauthorized disclosure pursuant to Section 3, or that an HIV related test has been conducted without informed consent pursuant to Section 2.

C. When considering the state of mind of a person alleged to have violated a provision of this Act, reference shall be had to 11 Del. C. Section 231 which specifies definitions relating to state of mind.

D. The Attorney General may maintain a civil action to enforce this Act in which the court may order any relief authorized by Section 4B.

E. Nothing in this Act shall be construed to impose civil liability or criminal sanction for disclosure of an HIV related test result in accordance with any reporting requirement by the Division of Public Health.

(See page 81 for Minority Report)



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Delawareness
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A Commitment to Hope
Intellect, Capital, and Social Responsibility

John F. Maguire

The importance of the resources of private enterprise in the war against disease is insufficiently recognized, but in the case of AIDS they may turn out to be dispositive. Tracking the virus and confronting it is capital intensive business. To Delawareans it should be of particular interest that the DuPont Company, the state's chief employer and largest chemical manufacturer, has a major commitment to health science.

John F. Maguire, the Sales and Marketing Manager, North America/South America of the DuPont Medical Products Department, spoke at the Professional Conference, describing the DuPont initiative. The following is drawn from his remarks.

I would like to thank the Delaware State Bar Association, the Delaware State Dental Society and the Medical Society of Delaware for giving me a chance to share with you a little of what DuPont has been doing in the area of AIDS.

As of March, 1988, more than 53,000 Americans have been diagnosed with AIDS. Nearly 12,000 of these are under age 30. More than 20,000 of these have already died of AIDS. It is estimated that 1.5 million Americans carry the virus. The latest information is that 75 percent of them will develop the disease within six years of infection. The Surgeon General estimates that in just three more years, there will be 270,000 cases of AIDS in the U.S., with 179,000 deaths. The cost of providing healthcare to the people afflicted with AIDS will be between 8 billion and 16 billion dollars by 1991.

As I see it there are five major concerns with AIDS. They are 1) Understanding and preventing the methods of transmission, 2) Developing ways to detect and diagnose infection and disease, 3) Providing health care professionals with ways to counsel and monitor infected persons, 4) Developing a treatment or cure for people with AIDS, and 5) Finding a way to prevent the disease. The DuPont Company is active in each of these efforts.

Understanding and Preventing Methods of Transmission

It became clear in 1984, after the cause of AIDS was discovered by Doctors Robert Gallo at the National Cancer Institute and Luc Montagnier at the Pasteur Institute, that AIDS was being spread in three primary ways—through direct contact with contaminated blood and blood products, through sexual contact with infected persons, and from infected mother to newborn infant. To prevent transmission the first thing needed was a test to detect the presence of AIDS contaminated blood. DuPont, working with our partner, Biotech Research Laboratories, was one of five companies to be granted a license by the government to develop and commercialize a test that could detect the presence of antibodies to the human immunodeficiency virus. We received approval to market such a test late in 1985. These screening tests were designed for one major purpose—to make certain AIDS contaminated blood would be kept out of the nation's blood supply. About 1200 people to date have been diagnosed with AIDS as a result of receiving transfused blood containing the AIDS virus. However, since testing of all donated blood began in 1985, we have effectively controlled blood transfusions as a method of transmission. Today, the DuPont HIV screening test is being used at blood centers around the world. This success is the result of providing our customers with a test that worked extremely well, and then supporting them with systems and procedures to help provide their communities with safe blood.

While the purpose of these screening tests was to keep the blood safe, it was clear very early on that these tests were also being used to test people. Since the purpose of the tests was to eliminate transmission of the disease through transfusion, they were intentionally designed to be highly sensitive, as to preclude false negative results. However, to achieve this high level of sensitivity, the tests can result in false positives. From a blood safety standpoint that really doesn't matter, because if there is any indication that the blood is contaminated, it is discarded. However, it is not acceptable to notify people that they might be infected when they are not. To deal with that, DuPont and Biotech Research Labs

have developed another kind of test called the Western Blot. This product addresses the second concern—*Developing ways to detect and assist in the diagnosis of HIV infected people.* While the diagnosis of AIDS is a clinical procedure, involving the manifestation of symptoms such as Pneumocystis Pneumonia, the beginning of that process is to determine that one has developed antibodies to the AIDS virus. Once a person has been found to be antibody positive by the screening test a Western Blot test is run. The results of a Western Blot are not only more definitive, but they are also more descriptive. Instead of yielding a mere yes or no to the presence of antibodies to the AIDS virus, which is the information gained from a screening test, the Western Blot gives specific information about the individual antibodies and their quantity, which are directed against the various parts of the structure of the virus. To date, the Biotech/DuPont Western Blot kit is the first and only confirmatory test that has been licensed by the FDA.

The Western Blot can also address the third concern—*providing physicians with better information to counsel and monitor infected individuals.* The Western Blot is not only useful in confirming the presence of infection; it may well be helpful in predicting when a healthy person who has antibodies to the AIDS virus, may develop symptoms of disease.

Another product developed by DuPont which can be used to determine the stage of disease and effectiveness of therapy is the P24 Core Antigen test. This test is capable of detecting the presence of the AIDS virus itself rather than antibodies to the virus. Researchers are now using this test to watch what is happening to those who are healthy but antibody positive. The Western Blot shows the level and kind of *antibodies*, the Antigen tests the level of *virus.* The predictive value of these tests derives from their capacity to monitor the decreasing amount of antibodies and the corresponding increasing amounts of virus.

Other tests under development at DuPont include a genetically engineered or recombinant test that is manufactured without using any live virus. This test is not only safer to manufacture, it appears to be even more sensitive and specific than the existing virus based screening tests. We are currently selling this new test in Europe. We are also in the process of evaluating a rapid, visual, manual test for AIDS antibodies. Called Hivchek, this matchbook size test is designed to be used without laboratory equipment, can withstand extreme climate conditions, and doesn't require highly skilled technicians. We believe this kind of test will be particularly useful for developing nations, especially those in Central Africa where AIDS is still being transmitted through blood transfusions. We are also developing a screening test for a new variety of the AIDS virus, called HIV-2. While HIV-2 is not believed to be present in the United States, if and when it arrives, we hope to be ready with a screening test.

(Continued on next page)

Commitment to Hope
(continued)

DuPont has also developed a screening test for another retrovirus—HTLV-1. While not nearly as well known as HIV, this virus has a lot of similarities to the AIDS virus. This virus can be spread the same way as AIDS, and can lead to serious disease, such as adult T-cell Leukemia, and ultimately death. We expect the FDA to license our HTLV-1 antibody test this year, and for blood centers to begin screening for HTLV-1 antibodies soon thereafter.

Our next concern is *developing ways to treat or cure AIDS.* Last year DuPont entered into an agreement with H.E.M. Research of Rockville, Maryland, which had developed a drug called Ampligen. Initially, it was thought Ampligen might be effective in treating certain kinds of cancer. An early clinical trial in England showed reason to hope that Ampligen might well be effective in treating people with ARC (AIDS Related Complex), which at this time is its only indication. DuPont and H.E.M. joined forces earlier this year, and today expanded clinical trials are underway at six different hospitals in the U.S. including Hanneman, to determine if Ampligen will be effective in treating ARC. While we do not expect definitive results for another few months, we are hopeful that Ampligen may well be an effective treatment for ARC patients. If clinical trials progress at the current rate, we expect availability in late '88 or early '89.

Finding Ways to Prevent the Disease

Although DuPont is not directly involved in developing a vaccine for AIDS, the company is contributing to research. Before an effective vaccine can be developed, we will need to increase our understanding of the virus and the way it works. It may surprise many to learn that the AIDS virus was first sequenced right here in Delaware at the DuPont Experimental Station. The unraveling of the genetic code of HIV took a team of DuPont researchers, working with Dr. Robert Gallo at The National Cancer Institute, nearly a year. Earlier this year DuPont introduced an automated DNA sequencing system, called the Genesis 2000, that could have done the job in about a week. Since that initial effort to sequence the AIDS virus,

our researchers have continued work to build on the growing body of knowledge necessary to the development of an effective vaccine.

Finally, DuPont is committed to supporting the research community at large with products designed to assist basic AIDS reasearch. I don't know of any other company that offers researchers the range and depth of products to unravel the AIDS mystery. In all, we have available some 40 different research products being used by AIDS reserachers around the world. These include such sophisticated products as DNA or RNA probes, monoclonal antibodies, a new centrifuge that is particularly useful in viral research, and much more.

DuPont is very serious in its efforts to contribute to improved health care. In 1987 the corporation spent about a quarter of a billion dollars in health care research. Those monies are being invested in finding ways to diagnose or treat such diseases as cancer, heart disease, arthritis, Altzheimer's Disease, and others. However, a significant portion of these efforts and financial resources during 1987 and the past five years have been devoted to AIDS. We have every reason to believe the kind of commitment we made in materials research 50 years ago that led to Nylon and Teflon will produce equally important contributions in solving the AIDS crisis as well as in health care in general.

AIDS is a disease that people can learn to avoid. While we must continue to find better ways to detect and treat this disease, we must also help people to understand what they can do to protect themselves and their loved ones. To that end, we have prepared and are making widely available a pamphlet titled "Understanding AIDS." This pamphlet is not only available to DuPont personnel but to the general public. There is a toll free number, 800-441-7515 that anyone can call to get this pamphlet.

I look forward to the day when we can all meet together again, and look at what those of us in industry, government, and the medical community have done together to beat AIDS. ■

John F. McGuire, a graduate of Harvard with degrees in Chemistry and Business Administration, held positions in Products and Marketing with New England Nuclear Corp. of Boston, Massachusetts. When DuPont acquired New England Nuclear, he became National Sales Manager of the Specialty Diagnostics Division of the DuPont Medical Products Department. Today he is the Sales and Marketing Manager, North America/South America of that Division. Mr. McGuire's remarks were delivered at the Professional Conference on AIDS.

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AIDS: Designing a Balanced Legislative Response

Barry Ray Furrow

AIDS is a medical problem, a legal problem, a public health problem—but it is first of all an individual's problem. No professional specialty can lay sole claim to the territory. Professional collaboration is essential. Lawyers, doctors and scientists must forge a close working relationship in coping with AIDS. Just as lawyers must learn to think in terms of rates of testing error, clinical trials, and disease vectors, so physicians and scientists need to become familiar with the power of the law and its limits. Just as we have not found a medical magic bullet for AIDS, so we do not have a legal tool that enforces behavior modification overnight.

Law, policy, science and medicine blend in the crucible of AIDS-generated responses. In the face of scientific uncertainty, legal responses piggyback on medical knowledge and epidemiological discovery. Precipitous legal reactions are dangerous until we better understand the risks of the disease, its scope, and the limits of our ability to test for it and treat it.

I. The Temptations.

A. The temptation for non lawyers and legislators, and for lawyers as well, is to view the law as a weapon in a Clint Eastwood movie. We pass a law, we act, and the problem is eliminated. The easy fix, invoking the ready arsenal of legal tools, is tempting to the legislator. It is never that easy, and with AIDS even less so.

B. The temptation has been to view the AIDS problem as largely limited to a stigmatized minority. But it is rapidly becoming a heterosexual problem. As of February 1987, 30,000 Americans have been diagnosed as having AIDS. Perhaps five to ten times that number have AIDS related complex (ARC). The Public Health Service estimates that 270,000 Americans will develop AIDS by 1991. Since this projection is based on the number already infected with HIV, it does not take into account those likely to be infected in the future. 73% of those diagnosed with AIDS have been gay men, and this has fostered a backlash in the form of discrimination and violence. Sexual practices in the general population will now endanger increasing numbers of heterosexuals.

C. The temptation to overreact is likely, ironically, as we acknowledge that the AIDS problem now transcends sexual orientation. People's careers and rights may be unfairly impaired. As Benjamin Schatz of the AIDS Civil Rights Project has written:

People who have or are perceived to be at risk for AIDS have been fired from their jobs, evicted from their homes, refused services by businesses and government agencies, and denied visitation provileges with their children. Doctors have been evicted from their offices for treating people with AIDS, while other medical personnel have refused to offer treatment. Discrimination may persist even after death; some funeral homes have refused to accommodate the bodies of people who have died from the disease. Schatz, "The AIDS Insurance Crisis: Underwriting or Overreaching?", 100 *Harv. L. Rev.* 1782, 1784 (1987).

D. The temptation exists to use available and important tools such as the ELISA test overzealously in the misplaced optimism that such tests are more accurate than in fact they are in pinpointing the locus and magnitude of the problem in all potentially affected population groups. Standardization in testing is a problem, as is the error rate in smaller laboratories with less skilled technicians. Variation among laboratories in test characteristics can lead to unacceptably high false positive test results.

See Meyer and Pauker, "Screening for HIV: Can We Afford the False Positive Rate?" 317 *N. Eng. J. Med.* 238 (1987) ("hasty and indiscriminate screening for antibody to HIV is imprudent and potentially dangerous . . ."); Barry, Cleary, and Fineberg, "Screening for HIV Infection: Risks, Benefits and the

(Continued on next page)

Barry Ray Furrow, a graduate of Harvard College and Harvard Law School, is a professor at the Widener University School of Law, Delaware Campus. He was previously a professor at the University of Detroit School of Law and the Director of the Health Law Center at that University. He has taught and written extensively on health law, law and medicine, and law and science. Professor Furrow was one of the speakers at the Professional Conference on AIDS.

Burden of Proof," 14 *Law, Medicine & Health Care* 259 (1987) (burden of proof on necessity for HIV screening should rest with those proposing to test).

We live in an imperfect world, in which confidences are often violated, employees retaliate, acquaintances shun, landlords evict. We are all afraid of AIDS and the possibility of our exposure to it. For many of us, its current prevalence in populations that we may find unattractive—gays, drug users—makes the disease even more socially uncomfortable. As a result, the act of testing for AIDS carries significant risks for the person tested. Tests can have adverse consequences even if the result is accurate; if the result is incorrect, the consequences can be truly destructive. Let me quote an example from a recent article in the *Journal of the American Medical Association,* written by a physician:

In 1985, I was the primary physician for a young man whose life was ruined by the inappropriate disclosure of a positive human immunodeficiency virus (HIV)-antibody test. A physician ordered the test without consent and notified the local health department of the positive result. The health department notified the individual's employer and he was promptly fired. These events became common knowledge at his workplace and in his rural Midwestern town and he was shunned. His landlord asked him to move. Ten days after testing, the life he had known for the past ten years was permanently ruined and he left town. With the loss of his job came loss of health insurance and insurability; he has been unable to obtain health or life insurance since then. (JAMA, Jan. 8, 1988—Vol 259, No. 2)

This defines the outer limits of risk in careless or inaccurate HIV testing—loss of job; uninsurability; shunning; adverse psychological consequences, including suicide attempts and major depressive illness; and a false sense of security with a negative result.

II. The Legal Dimensions.

The law is a mechanism for handling and allocating risks—of economic and personal loss, injury, future harm to self and others—and for facilitating individual and social goals, in an attempt to accommodate, or at least provide a forum for settling, often clashing interests. It is also a source of norms for social conduct, backed by the ability of courts and legislatures to articulate these norms through judicial opinions and through legislation.

A. Public health efforts. State legislatures are pumping out the legislation, and Congress is considering hundreds of bills. The goal of all of these efforts is to better understand the epidemic, to modify risky behavior, and to provide treatment for those afflicted.

The public health functions of a legal response can be grouped into six categories.

1. Planning Strategies. Task forces are established and guidelines published to recommend strategies and precautions for slowing the spread of AIDS. The State of Delaware has created such a Task Force, which is to be commended for its careful work on proposals for legislation to deal with

problems of informed consent and confidentiality.

2. Informing Choice. Public health officials can be authorized or required to provide the general public or specific groups with services: education, counseling, and social support. The private counterpart is in the hands of physicians and therapists: they must understand with precision what is known about the risks of contagion of AIDS, its mechanisms and epidemiology, and tell patients where they stand and what options they have. We don't want to repeat the mistakes we made in the past in handling diseases such as syphilis.

See, e.g., Brandt, "AIDS: From Social History to Social Policy," 14 *Law, Medicine & Health Care* 231 (1987)

Accurate information is needed, transmitted not only in the privacy of the medical suite, but also through the mass media in explicit terms, not in the euphemisms of "bodily fluids" mysteriously transmitted through unspeakable orifices.

Accurate information is needed, transmitted not only in the privacy of the medical suite, but also through the mass media in explicit terms, not in the euphemisms of "bodily fluids" mysteriously transmitted through unspeakable orifices.

3. Regulating to Control. Legislatures have considered mandating compulsion against individuals via such regulatory functions as case finding (screening, reporting, and contact tracing), segregation of prisoners, exclusion of infected individuals from school or certain professions, isolation of persons with AIDS, imposition of criminal penalties for intentional sexual transmissions; or regulation of meeting places such as bathhouses. Some or all of these legislative choices may be unconstitutional; many pose significant dangers to civil liberties and individual autonomy.

The public health perspective blends epidemiology and medicine with education and state action. Public health looks at the role of the state in fostering health by prevention, education, and isolation. But the traditional public health tools do not fit well with this new disease. See Parmet, "AIDS and Quarantine: The Revival of An Archaic Doctrine," 14 *Hofstra L. Rev.* 53 (1985); Curran, Clark, and Gostin, "AIDS: Legal and Policy Implications of the Application of Traditional Disease Control Measures," 14 *Law, Medicine & Health Care* 27 (1987).

Public health broadly defined also includes a range of government regulation through administrative agencies that have a direct impact on AIDS research, testing, funding and treatment. Consider Food and Drug Administration policies on drug research and human experimentation; National Institutes of Health policies on research; Occupational Health and Safety Administration regulation of workplace safety; Federal Trade Commission advertising policy, as it becomes clear that marketing of condoms and safety information generally could be effectively done through radio and television. The government is already heavily involved, but its involvement has too often been largely fragmented and uncoordinated.

4. Regulating to Protect. Courts and state legislatures have a major role to play in safeguarding the rights of those who test positive, those with ARC, and with AIDS. These individuals must be protected by ensuring their privacy and the confidentiality of health care information and prohibiting discrimination in employment, housing, and insurance. AIDS presents the law with a strong tension: between individual rights and a State desire to protect the uninfected public. Given the inevitable error rates as testing volume increases beyond the best laboratories, and the nature of the AIDS virus (in the words of infectious disease experts, a "wimpy" virus), the burden of proving the need for onerous and personally dangerous regulation lies with its proponents.

AIDS presents the law with a strong tension: between individual rights and a State desire to protect the uninfected public.

5. Facilitating Treatment. The law can facilitate treatment in a variety of ways.

a. Remove disincentives to prevention and treatment. How does the law provide incentives for research on vaccines, and how is the law counterproductive? Manufacturers are worried about their tort exposure if a vaccine is

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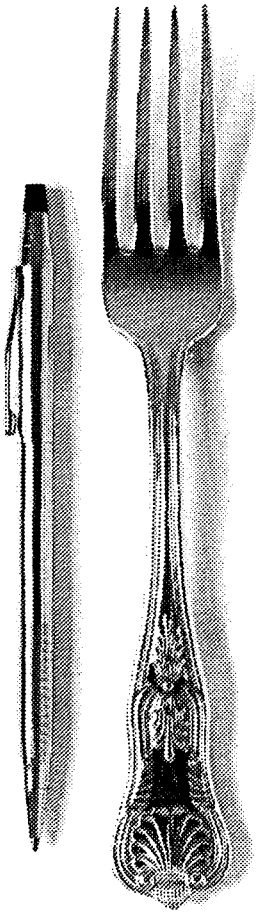

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Legislative Response
(continued)

developed that has pernicious side-effects. See Mariner and Gallo, "Getting to Market: The Scientific and Legal Climate for Developing an AIDS Vaccine," 15 *Law, Medicine & Health Care* 17 (1987) (discussing problems with buffering vaccine manufacturers against liability for side effects of vaccines).

b. Develop mechanisms and new institutional forms for funding and locating treatment. How is treatment for those with AIDS funded? What federal and state policies should be adopted to pay for this new catastrophic illness? What modes of institutional treatment should be available? Should we design and fund a new hospice program with heavy subsidies and incentives to provide humane and economical cost for the dying? See Bulkin and Lukashok, "Rx for Dying: The Case for Hospice," 318 *N. Eng. J. Med.* 376 (1988); Report of the Commission.

The financing perspective forces us to consider both governmental and private mechanisms for insuring the AIDS patient, from the point of view of state risk pools, private insurance, and national handling of AIDS treatment through existing and expanded programs such as Medicare and Medicaid. We handle our life insurance through private insurance, and our health insurance through a complex mixture of federal programs like Medicare and private insurance like Blue Cross and other third party insurers. AIDS poses an actuarial nightmare for the insurance industry, and they are struggling to avoid insuring a person who is likely to fall into a high risk category for exposure to the disease. But should they be allowed to avoid insuring this risk pool? Isn't the value of insurance precisely its spreading of social risks over a large pool of insureds?

See Clifford and Iuculano, "AIDS and Insurance: The Rationale for AIDS-Related Testing," 100 *Harv. L. Rev.* 1806 (1987) (arguing for proposition that insurers must be allowed to use AIDS-related testing to determine insurability, in order to avoid distorting the fair and equitable functioning of the insurance pricing system); contra, Schatz, "The AIDS Insurance Crisis: Underwriting or Overreaching?", 100 *Harv. L. Rev.* 1872 (1987) (financial concerns of the insurance industry insufficient to outweigh the social, medical, and moral costs of sexual orientation discrimination or HIV antibody testing.)

6. *Facilitating Death.* Lawyers spend substantial portions of their time in private practice preparing clients and their families for death, by drafting wills, trusts and estate plans. New tools have been added to cope with medical decisionmaking and incompetent patients: living wills, durable powers of attorney. AIDS patients at the end of their disease trajectory have need of these legal instruments as well as the more traditional ones. Until we have managed either to prevent the disease or to offer a cure, the magic bullet will have to be replaced by the half best legal document.

B. Civil tort actions to deter individual misconduct or professional

Legislative Response
(continued)

negligence. The threat of a tort suit frightens and angers medical professionals, and simply frightens laymen. AIDS promises a new spectrum of tort actions for grievous injury to others: the doctor who fails to recognize the symptoms and properly advise a patient, thereby turning him loose to infect others unknowingly; the individual who gives AIDS to his or her lover knowing that his disease is well developed; the testing laboratory that sloppily conducts a test and produces a deceptive false negative rate. What must the extent of informed disclosure be? To what extent must that doctor shoulder the obligations of warning a third party about a patient's level of antibodies? His ARC status? His AIDS status? Tort law provides some hints as to the directions the courts may take in this area.

The problem with a tort suit is that it is at best an indirect and limited method of deterring people from engaging in negligent or intentional risky conduct. And it is also primarily a compensation mechanism. With AIDS, we need to develop more efficient means of transferring resources to the afflicted for their care than the tort mechanism can systematically provide. Nonetheless, the threat of a tort suit for a variety of AIDS-related acts of negligence and intentional misconduct is desirable to insure a minimal level of cautious behavior.

C. **Criminal actions to punish.** Several criminal actions have been brought against individuals for knowingly or recklessly transmitting or intending to transmit the AIDS virus. Should we criminalize AIDS, so that mere refusal to be tested is criminal? So that intentional or reckless exposure of another to the virus is a crime? These are difficult questions that address the nature and power of the legal system, and its limits.

See Field, and Sullivan, "AIDs and the Criminal Law," 15 *Law, Medicine & Health Care* 46 (1987) (concluding that an AIDS-specific criminal statute is not a desirable means of fighting the spread of AIDS, because of fears of harassment of select groups and deterrence of their seeking medical advice for fear of being prosecuted). Contra, Robinson, "AIDS and the Criminal Law: Traditional Approaches and a New Statutory Proposal," 14 *Hofstra L. Rev.* 91 (1985) (proposing legislation criminalizing certain sexual behaviors as best way to modify individual behavior, in order to reduce the rate of spread of the AIDS virus infections.)

III. A Legal Case Study: Hospital Testing and Legal Hazards

A. **The World of Testing.** The desire of employers, insurers, health care providers and others to test individuals for AIDS is growing. In the *Journal of the American Medical Association,* Jan. 8, 1988, an article appeared entitled "Analysis of the Use of HIV Antibody Testing in a Minnesota Hospital." The authors studied the clinical use of HIV antibody serology at one 450-bed medical center. The results were surprising. The authors concluded:

1. "Only 10% of tests performed fulfilled the criteria for an appropriate test (where the test was indicated and consent and counseling were provided with documentation in the medical record.)"
2. "In 44% of the tests performed, the patient had no recognized factor for acquiring HIV infection."
3. "In an additional 44% of tests performed, the test was medically indicated but patient consent and counseling were not documented in the medical record."
4. Errors were common. Eleven patients were tested, with no record of who ordered the test or why. With six patients, a positive ELISA result was interpreted by physicians as a positive test, in spite of a negative Western Blot. In five patients, asymptomatic seropositive HIV patients were diagnosed as having AIDS. In one case, a patient specimen was mislabeled.

Other studies have confirmed the extent to which physicians and health care professionals generally are poorly informed about the meaning of a positive HIV serotest. See for example Searle, "Knowledge, Attitudes, and Behavior of Health Professionals in Relation to AIDS," *The Lancet* (January 3, 1987) at 26 (surveying English doctors). It is to be hoped that in the year that has passed much of this ignorance has vanished.

B. The Nature of the Risk. Some health care professionals are clearly at increased occupational risk compared to other professions, because of the risk of exposure to patient blood products. The risk may be overstated, however. A recent study of dental professionals, a group assumed to be at high risk, suggests that the risks may not be as high as thought. Klein, et al, "Low Occupational Risk of Human Immunodeficiency Virus Infection Among Dental Professionals," 318 *N. Eng. J. Med.* 86 (Jan. 14, 1988).

Dental professionals are often exposed repeatedly to persons who are HIV positive for months or years before the patients know they are positive. Accidental parenteral inoculations and splashes and aerosolizations of blood and saliva are common. In the author's words, dental professionals are "...a 'sentinel' population that is likely to indicate the maximal anticipated rate of occupational risk for health care workers in general." The study conclusions were as follows:

"This study demonstrates that despite infrequent compliance with recommended infection-control precautions, frequent occupational exposure to persons at increased risk for HIV infection, and frequent accidental parenteral inoculations with sharp instruments, dental professionals currently are at low occupational risk for HIV infection".

The authors noted that risky patients cannot be detected reliably, and that infected persons may not feel or appear ill. They may not want to inform the dentist or may not consider themselves at high risk. Testing takes time, requires confirmatory testing, and may yield false negatives. "Therefore, routine practices to prevent occupational infections should be formulated with the idea that all patients have the potential to transmit infection. ...Strict adherence to recommended infection-control guidelines for dental professionals should help to minimize the risk of occupationally acquired HIV infection."

The same recommendation should apply to hospital personnel. In Searle's words:

"...in view of the fragile nature of the virus outside the body, the large volume of evidence indicating an extremely low risk of transmission in the hospital, the certainty of not being able to identify which patients are in high-risk groups, and the danger of forcing homosexuals to seek help elsewhere, it seems most appropriate to adopt hepatitis-B-level precautions in all situations involving possible contact with body fluids that may contain virus."

The conclusion of the Task Force on AIDS of the University of California, San Francisco, strongly reinforces this position:

"HIV is not readily transmitted to health care workers, even after accidental parenteral exposure to infected blood. Existing guidelines for reducing exposure to blood and other body fluids will protect workers who care for patients infected with this pathogen."

Why should a lawyer suggest such an approach to what is arguably a medical problem? Because it is not a medical problem but rather a complex medical-legal-public health problem. The legal ramifications of various legislature choices support the position that screening should be very limited in the absence of patient consent.

I believe therefore that the following principle should guide legislation in this area. *No HIV test should be ordered until physicians understand the appropriate use of and potential adverse consequences of the HIV-antibody test, have provided complete counseling to their patients, and have obtained the patient's written informed consent to the test.*

This principle strikes a balance between valuable uses of such test results and the downside risks.

C. The Legal Hazards of Overbroad Testing. Tort law in this area is based upon social norms that we as a society value: individual autonomy in decision-making about the body and the self, even if others find those decisions irrational; the right to full information before making difficult medical choices; the right to control information about oneself that can prove destructive if generally known. Tort law and constitutional law both subject individual and government behavior to the test of reasonableness: what is gained and what is lost by the suspect conduct? The burden of justification lies with the proponent of an invasive and potentially harmful approach. Testing blood samples of a suspected HIV-positive individual must therefore pass the test of "reasonableness" before a defendant in a tort case can avoid liability, and before government action can mandate such testing. The privacy interests of the individual are important and powerful interests that deserve substantial protection.

Blood testing is not considered a minimal intrusion in the constitutional arena. Courts have found significant an individual's interest in maintaining privacy in personal information contained in bodily fluids, *Railway Labor Executives Association v. Burnley,* 1988 WL 8808 (9th Cir. Cal. 1988); *Tucker v. Dickey,* 613 F. Supp 1124 (W.D. Wis. 1985) (urinalyses and body cavity searches equally degrading). In the criminal law setting, testing of the blood for drugs has been circumscribed under the Search and Seizure constraints of the Fourth Amendment. "Particularized suspicion" had been held to be essential before toxicological testing of railroad employees is permissible; and broad based testing without such particularized suspicion has been frequently disapproved.

In the private arena, where constitutional constraints do not apply, the reasonableness principle of tort law combines with a strong judicial bias toward protection of individual autonomy in medical decisionmaking. Given the pernicious consequences that might flow from blood testing of suspected HIV-positive individuals, the courts are likely to impose a stringent burden on the defendants where plaintiffs are in fact injured.

Suppose that a hospital has a policy of allowing testing wherever a health care worker—nurse or doctor—has come in contact with patient blood. Many health care providers would like such a right—to test without the patient's permission. If the Minnesota study previously cited is at all representative of hospital practice around the country, then some of the test results will be misread, and some testing errors will also occur.

Errors in testing can result in a large damage claim. If a patient who tests positive is mistakenly interpreted as HIV positive, even though a followup test is negative, or a seropositive HIV patient is misdiagnosed as having AIDS, or the test is simply wrong, the resulting mental distress of that patient may be compensable in a tort suit. Given the nature of AIDS, such distress is foreseeable to a physician. (See, e.g., Holland, J., Tross, S. "The Psychosocial and Neuropsychiatric Sequelae of the Acquired Immunodeficiency Syndrome and Related Disorders," Ann. Intern. Med. 1985; 103: 760-764).

A physician has been held liable for erroneously informing a patient that she had tuberculosis, resulting in tuberculosis phobia. (*Kraus v. Spielberg,* 37 Mis. 2d 29, 236 N.Y.S. 2d 143 (1962)). A false or erroneous test result may trigger "AIDS anxiety" with debilitating effects on a patient, rendering a health care worker liable.

Overbroad testing by health care workers to alleviate their own anxieties about exposure to AIDS will do little to calm them, while exposing them to tremendously increased potential for tort suits. Patients are put at risk unnecessarily, and so are medical staffs.

If an unconsented-to test result is erroneously read, or a result is wrong, and the patient is notified, a new cause of action is created for the distress caused by the inaccurate news. Overbroad testing of a large group of low-risk patients will increase the error rate and the chances of suit.

If the testing is bootleg, with the patient not notified, and the results are positive, then a diagnosis is missed that could have led to positive medical action at the early stages of seropositivity. The courts' reactions in such a situation have been quite consistent: compensation has been awarded for any mental distress and psychic injury suffered by the patient, and also for the "loss of a chance" of treatment. (*Chappel v. Master,* 255 So. 2d 546 (Fla. 1972) (failure to communicate to prospective adopting parents that child was affected with fatal hydrocephalus held actionable). As more effective palliative treatments develop for the early stages of AIDS with AZT or other drugs, or prophylactic treatments are tried once the patient is seropositive, failure to let a patient know will increase health care provider liability risks.

This will also be the situation where the test, without patient consent or against the patient's desires, is least likely to be disclosed to the patient, because of the health care worker's expectation of patient hostility.

If bootleg testing is in error, and the patient not told, and the results somehow revealed to others, the patient might suffer economic injury and personal harm. The health care provider is ultimately liable for revealing such information and causing these results.

There is an interesting twist to overbroad testing and the increase in the

risk of suit. If a patient is offered a test after counseling, and declines, then the health care worker does not have information about the presence of HIV or AIDS in that patient. The obligation stops there. If however the provider tests a patient's blood and the test is positive, then must that provider warn the patient? Of course, since the provider now has information that can lead to injury to others if they are not informed if he does not inform the patient and explain how to minimize harm to third parties through safe sex and sterile needles, then an infected third party has a suit against the provider. This *Tarasoff* obligation to warn third parties may extend even further the risks of unconsented to testing. All of this points to the importance of patient consent and adequate counseling and followups with patients, whenever possible.

Routine screening in the health care institution, in order to relieve staff anxiety, is a bad idea. Testing without patient consent is a bad idea. The best justification for screening, if any, applies to carefully circumscribed categories of patients that typically include transplantation patients and high risk prenatal patients. The purpose of such screening is to help in the management of the patient rather than to protect staff. Staff protection is best achieved by a general practice of using precautions in any situation where medical personnel might come into contact with patient body fluids.

Health care providers should test only with the consent of the patient. This avoids most of the liability hazards, follows the practice of several states, such as Illinois and Minnesota, and minimizes the destructive side effects that inadvertent or intentional breaches of confidentiality might have on a patient's life.

The recommendations of Searle and others are relevant here: "...those professionals who do not believe that informed consent is essential before HIV serotesting are risking many difficulties for their patients, and perhaps also medicolegal hazards for themselves."

III. The Constitutional Issues.

A. The constitutional questions raised by AIDS revolve around Due Process and Equal Protection scrutiny of state action to regulate individual behavior. Most academic discussion has looked at the extreme cases of quarantine of infected populations, prison populations, and drug testing in the workplace. The Supreme Court has not considered a case directly involving AIDS, although the *Arline* case comes close in its protection of the employment setting for someone with tuberculosis.

The traditional constitutional doctrine accords deference to state action in the area of public health regulation. The classic decision has been *Jacobson v. Massachusetts*, 197 U.S. 11 (1905), upholding a Cambridge ordinance requiring mass public vaccination to prevent the spread of an epidemic. The case is cited as an example of the high level of deference shown toward public health measures, with such measures treated as presumptively valid. Even this deferential view has been tempered by some constraints on state regulations. Courts will look beyond the stated purpose to question the true legislative purpose. Thus a provision motivated largely by homophobia would probably be struck down.

Jacobson recognizes that there must be a substantial relationship between the control measures and the underlying public health objectives. Later case law in the 1960s and 1970s expanded both Due Process and Equal Protection requirements so that any legislation affecting "suspect classes" would be subject to heightened scrutiny.

The test of the "least restrictive alternative" might be applied to regulatory measures to control AIDS. Certainly the measures adopted may not be unreasonably obtrusive or go "far beyond what was reasonably required for the safety of the public." (*Jacobson*, 197 U.S. 11, 28). For an extensive discussion of the constitutional dimensions of AIDS, see Curran, W.J., Gostin, L., and Clark, M. *Acquired Immunodeficiency Syndrome: Legal and Regulatory Policy* (Washington, D.C.: US Public Health Service, 1986).

B. Mandatory testing programs have not yet been fully explored by the Supreme Court, but the new 9th Circuit decision in *Railway Labor Executives Association v. Burnley*, 1988 WL 8808 (9th Cir. Cal. 1988) recently held that "particularized suspicion is essential to finding toxicological testing of railroad employees justified at its inception.... Broad based testing, without particularized suspicion...has been frequently disapproved." ■

Summary

We need a balanced legislative and judicial response to the problem of AIDS. The intense anxiety of prison officials, health care professionals, employers, and others is understandable, in the face of the risks. Such anxiety however can lead to extreme and unreasonable responses if not tempered by a balanced appraisal of the risks.

The legal system's touchstone for evaluating calls to action is the test of reasonableness. Might the proposed state action do more harm than good—to the individual affected; to that person's family, friends or lovers; to society? Does the action create unanticipated side effects? The advocates of intrusive state action need to justify their demands with reference to these principles. The burden of proof is on them.

We should protect patients from being tested against their wishes, since testing for HIV positivity is distinguished from other forms of testing by the potential social repercussions if the results leak out. We should aim to protect patients from disclosure by others of their HIV status, whether inadvertent or intentional.

We should also insure that resources are available to help health care providers counsel their patients and treat them. Those physicians, dentists, and allied health professions in the State of Delaware who are actively involved in caring for HIV positive patients are to be commended for their efforts. But they need more help. The State needs to expend more efforts in counseling the citizens of Delaware about the risks of HIV, and making available the information and the means for protection. Financial support for the treatment and sustenance of those with AIDS is needed. We as a society have an obligation to help, overcoming our own fears in order to extend our support to those who suffer.

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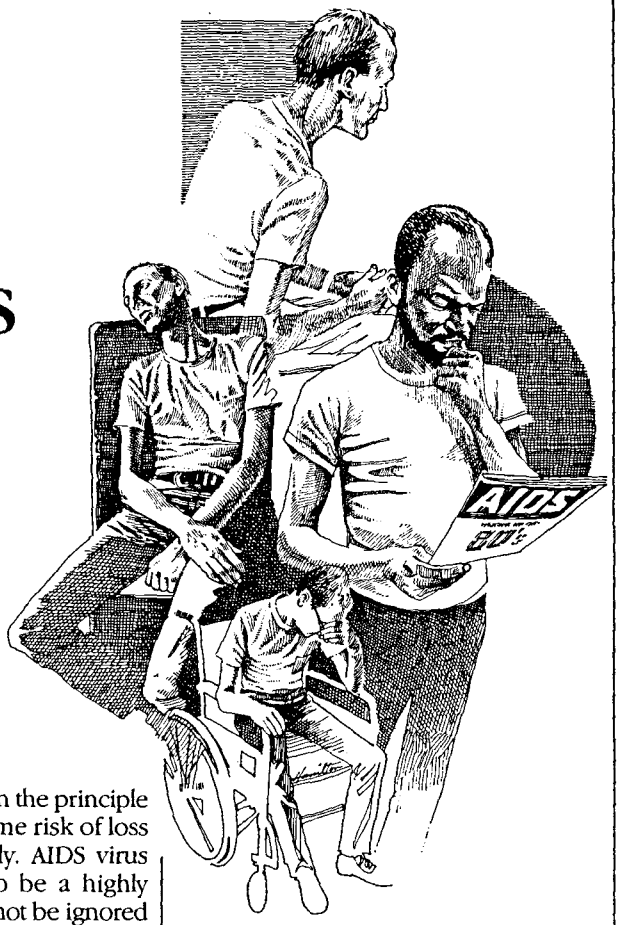

AIDS is potentially the most serious health threat our country has ever faced. It is now conservatively estimated that AIDS has afflicted 57,000 Americans and, according to *very* conservative estimates, may afflict as many as 270,000 people in the year 1991, causing an estimated 179,000 deaths.[1] Most of these deaths will occur among the predicted 1.5 million Americans already infected with the virus, many of whom show no signs of illness.[2] Great as the danger of this disease to life itself may be, it poses a corresponding threat to the country's financial well-being and the solvency of the health care system. Unfortunately, in some instances legislatures have enacted measures that mandate the abandonment of time-honored principles of underwriting, thereby endangering the financial stability of many insurance companies.

Estimates by the U.S. Public Health Service put the annual direct cost of health care for the estimated 171,000 AIDS patients in the year 1991 between 8 and 16 billion dollars,[3] assuming a cost per case of $46,000 to $92,000.[4] Other studies predict a considerably higher cost, and only a rare few (e.g. San Francisco) have shown a lower per case cost.

While these figures are high, they do not take into account the cost of outpatient care, counselling, and home health care. In addition, they do not reflect loss of income due to disability, and they do not measure in any way the impact on the life insurance business. Insurers expect to pay billions of dollars for AIDS-related claims over the next several years as they fulfill contractual obligations to policyholding AIDS victims.

Insurance is founded on the principle that insureds with the same risk of loss should be treated equally. AIDS virus infection, now known to be a highly significant risk factor, cannot be ignored by any actuarially sound insurance system. However, state legislatures moved by sympathy for persons with AIDS, are continuing to give serious consideration to a prohibition on the use of AIDS-related testing for insurance purposes: a ban that would seriously distort the equitable functioning of the insurance system in pricing its products.

Insurance underwriting is defined in general terms as the "process by which an insurer determines whether or not and on what basis it will accept an application for insurance."[5] The primary goal underlying this process is an accurate prediction of future mortality and morbidity costs. In carrying out this process, moreover, an insurer has the responsibility to treat all its insureds fairly by establishing premiums at a level consistent with the risk represented by each. It is basic to providing insurance for people of different ages, genders, jobs, and medical histories, that an insurer create classifications to recognize the many differences that exist among them. Those differences very often affect risk assessment. Such things as age, medical history and general physical condition, gender, occupation, the use of alcohol and tobacco are analyzed separately and in combination to determine their effects on a person's longevity.[6] Understanding the way in which these various characteristics influence mortality assists insurers in classifying insurance applicants into groups with comparable mortality risks and in establishing appropriate premium rates.

About 158 million Americans under the age of 65 are covered by some form of group health insurance, and an additional 9 million by individual health policies.[7] Unlike individual insurance underwriting, group underwriting involves an evaluation of the risk of a *group;* the most common example being a group of employees. This evaluation establishes the terms of an insurance contract acceptable to the insurer.[8] Unlike those writing individual policies, group insurers consider only the relevant characteristics of the group, operating on the premise that any large group will contain a few individuals who have medical conditions of such severity as would make them either substandard or uninsurable risks if they were to be subjected to individual underwriting standards.[9] It should be noted also that in certain instances,

group insurers do resort to individual underwriting methods (a) for small groups, (b) for those who enroll late in a plan or (c) in instances where would-be insureds apply for large supplemental amounts of life insurance beyond that given to them as part of their general eligibility under the plan.

Thus the issue of testing for the presence of the AIDS virus or the active presence of AIDS relates only to new coverage for which the insurer requires evidence of insurability of each person to be insured.

As mentioned above, an integral part of the insurance pricing system is the ability to inquire into characteristics of individual applicants in order to place them in groups with comparable mortality. This process thus makes distinctions between those in different classes or discriminates in the way in which these classes are established.

It is just this process of discrimination that is the cornerstone of insurance regulation. The Unfair Trade Practices Act developed by the National Association of Insurance Commissioners established statutory rules requiring the fair and equitable treatment of insureds in the underwriting process. By 1960 just about all the states and the District of Columbia had enacted some form of this Act. Its essential tenet, of course, is the distinction between fair and unfair discrimination. To discriminate in this sense is *not* pejorative, but in neutral dictionary sense, "to mark or perceive the distinguishing or peculiar features of...", or "to distinguish or differentiate". For example, under the Act it is deemed inequitable to charge a 60 year old male in poor health and a 20 year old female in good health the same premium for an individual life insurance policy. In such an instance an insurer must *differentiate* between these two persons to determine equitable premiums for each. It is thus appropriate that the rates in these instances should be adequate but not excessive and should discriminate fairly between the insureds so that each will pay according to the quality of his or her risk.[10]

In the same context, the Act prohibits an insurer from *"making or permitting any* unfair *discrimination between individuals of the same class and equal expectation of life in the rates charged for any contract of life insurance." (italics supplied)* There is a similar provision for health insurance. It is thus the contention of the insurance industry that persons who have been infected by the AIDS virus are not of the same risk and class as those who have not been.

"Fairness" has often been litigated. In a 1974 case,[12] a Pennsylvania state court upheld a ruling of the Insurance Commissioner, which had revoked approval of several health insurance policy forms on the theory that the low premium charge in the first month of coverage had no actuarial relationship to the actual risk and was therefore discriminatory. The principle is clear: under the Act an insurer must accord similar treatment in the underwriting process to those representing similar risks.

To ignore the levels of risk associated with AIDS infection and to treat a person who tests positive on an AIDS test the same as one not similarly infected would clearly constitute unfair discrimination against those not infected and would violate the states' Unfair Trade Practices Acts.

In 1986 the state of Washington became the first state to apply its Unfair Trade Practices Act to the underwriting of AIDS. The Insurance Department promulgated a rule[13] stressing the mandate of the Act that underwriting considerations for AIDS must be consistent with underwriting considerations for other diseases. This regulation underscores the real duty that insurers have to separate insureds with identifiable serious health risks from the pool of insureds without those risks. Failure to do so represents a forced subsidy from the healthy to those less healthy. To meet the fundamental fairness requirements of the Act aimed to address the concern for unfair discrimination, insurers must continue to use objective, accurate, and fair standards for evaluating the risk of AIDS. For the insuring process to remain fair to all applicants and insureds, insurers must be permitted to treat tests for infection by the AIDS virus in the same manner as they treat medical tests for other diseases. To ignore the levels of risk associated with AIDS infection and to treat a person who tests positive on an AIDS test the same as one not similarly infected would clearly constitute unfair discrimination against those not infected and would violate the states' Unfair Trade Practices Acts.

It is now generally accepted by medical authorities that the protocol of body fluid tests known as the "ELISA-ELISA-Western Blot" series is highly accurate for determining the presence of infection with the HIV virus.[14] In addition to findings by the National Institutes of Health, other evidence of the reliability comes from the epidemiologist for the state of Wisconsin who was directed by statute[15] in 1986 to determine whether any test or series of tests "was medically significant and sufficiently reliable" for detecting the presence of antibodies to HTLV-III. That epidemiologist concluded that the ELISA-ELISA-Western Blot series was "medically significant and sufficiently reliable" for detecting the presence of the HTLV-III antibody.[16]

It is the practice in the industry to administer this protocol rather than a single test to identify HIV infected applicants for insurance. Once an individual has been reliably identified as infected with the virus, it is conservatively estimated by the United States Center for Disease Control that an individual likelihood of contracting AIDS within five years can be estimated at 20 to 30 percent.[17] More recent studies estimate the risk as high as 50 percent within a span of ten years.[18] It is a stark reality that no one unequivocally diagnosed as suffering from AIDS has ever recovered, and most victims die within two to three years of the onset of disease.

The significance of these facts is difficult for the insurance industry to ignore. Using the most conservative estimate of the Centers for Disease Control of 20 percent—translates into numbers such as 200 persons out of each 1000 applicants who test positive as developing AIDS within five years and dying within seven. By contrast, mortality tables for life insurance estimate that a standard group of 1000 persons who are age 34, only 7.5 will die within seven years from all causes.[19] Thus, a person testing positive for AIDS is 26 times more likely to die within seven years than a person not infected, all other risk factors being equal. By further contrast, consider that a smoker is only twice as likely to die within seven years, a person with diabetes is four times more likely, and a person who has suffered a prior heart attack is five times more likely. The actuarial significance

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Flying Blind
(continued)

of these facts is overwhelming and cannot be ignored. Because such tests are reliable, accurate, and effective predictors of risk, they must be considered proper underwriting tools.

Until the recent controversy over AIDS, insurers have generally been given the right to inquire into and test for medical conditions shown to have an effect on mortality and morbidity. However, recently there has arisen a fundamental misunderstanding of insurance principles along with a desire to prevent discrimination against homosexuals, which in turn has lead to the passage of laws or regulations in jurisdictions granting those infected with AIDS a favored status in the underwriting process. These laws substantially impede our industry's ability to evaluate risk and undercut the industry's financial stability and compromise its ability to pay future claims.*

For example, in 1985 California enacted a law providing that "the results of a blood test to detect antibodies to the probable causative agent of Acquired Immune Deficiency Syndrome ... shall not be used in any instance for the determination of insurability or suitability for employment."[20] Likewise, in the same year Wisconsin enacted a similar but more restrictive law.[21] In 1986, the District of Columbia passed the most restrictive legislation of its kind in the country, prohibiting the use of *all* AIDS-related tests for a period of five years including tests for the AIDS antibody, tests to appraise the condition of the immune system, and tests to identify the existence of the AIDS virus itself.[22] The American Council of Life Insurance and the Health Insurance Association of America brought suit against the District, arguing that the Act violated both the 5th Amendment of the United States Constitution and the Home Rule Act of the District of Columbia.[23] Regrettably,

**Even insureds not fortunate enough to belong to a cosseted minority have some interest in the solvency of those to whom they pay premiums. Ed.*

the District Court declared the Act valid because the evidence presented by the ACLI and HIAA at trial was not similarly available to the City Council at the time the bill was under consideration.[24] The court otherwise appeared to agree with the plaintiffs that presently available evidence refuted the allegations made by the City Council that the test was unreliable, inaccurate, and of no predictive value.

This decision, while unfavorable to the industry, does seriously call into question whether similar legislation will pass constitutional scrutiny in light of the medical and scientific information supporting the credibility of the ELISA-ELISA-Western Blot series.

The major goal of legislative attempts to restrict insurers' rights to tests has been to prevent insurance companies from discriminating against homosexuals. The life and health insurance industry approve that principle: in fact they have endorsed guidelines adopted by the National Association of Insurance Commissioners in December of 1986 that set forth two general propositions:

1. No inquiry in an application for insurance coverage or an investigation conducted by an insurer or a support organization on its behalf in connection with an application for insurance shall be directed towards determining the applicant's sexual orientation, and

2. Sexual orientation may not be used in the underwriting process or in the determination of insurability.[25]

The insurance industry are in substantial agreement that sexual orientation of an applicant is not an appropriate underwriting tool and are equally strong in their agreement that current state of the art tools for predicting the AIDS risk are valid for that purpose and should be used accordingly in a responsible fashion.

In its support of these guidelines the industry refutes the contentions of certain groups that sexual orientation has a place in the underwriting process. Rather, we seek only to use the best medical knowledge available to evaluate the level of risk an applicant represents. The insurance industry are in substantial agreement that sexual orientation of an applicant is not an appropriate underwriting tool and are equally strong in their agreement that current state of the art tools for predicting the AIDS risk are valid for that purpose and should be used accordingly in a responsible fashion.

As I have stated previously, without the ability to properly assess risk insurance companies are left without the valuable tools needed to do a proper job in the conduct of the business of insurance. One of the real dangers that arises in such an environment is adverse selection. Adverse selection can be defined as the tendency of persons with poorer than average health to apply for or to renew insurance to a greater extent than persons with average or better health.[26] Such a process, of course, results in unfair and inequitable treatment of healthy people because it results in their subsidizing those at high risk. Practically speaking, insurance companies generally are not faced with the underwriting challenge of determining whether an applicant does or does not have full-scale AIDS. People are more likely to want to buy insurance at the outset of their infection when they already represent a very high level of risk, but present few symptoms. Thus the main underwriting challenge facing insurers is that of identifying people in earlier stages of the disease.

Strong evidence already exists of AIDS-related adverse selection against insurers. In 1985 the HIAA and ACLI initiated just such a survey of its member companies.[27] The results found claims for life insurance to be heavily concentrated in the first two years after issuance of policies. This pattern strongly suggests that these insureds knew or suspected that they had been infected by the AIDS virus before they purchased insurance. This adverse selection not only endangers the financial stability of insurance companies, but unfairly burdens the other policyholders who must support the increased claims through higher premiums.

Adverse selection can usually be combatted by mechanisms designed to protect insurers from such events. However, the uniqueness of AIDS significantly dilutes the effectiveness of these

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(continued)

mechanisms and renders insurers especially vulnerable to adverse selection.

Public health authorities have stated that the latency period between infection and overt AIDS averages four or more years in adults.[28] Individual life and health policies contain a clause that permits the coverage issued to be contested during the life of the insured for a period of two years from its date of issue.[29] Also, even assuming that an insured's misstatements about his or her health are discovered within this two year period, in most jurisdictions the insurer must show that the misrepresentations, omissions, or incorrect statements were fraudulent; or that they were material to the acceptance of the risk; or that the insurer, in good faith would not have issued the policy at the same premium rate or at all if the truth had been made known.[30] Also, insurers have the additional burden of knowing that actual fraud cannot be a basis for contest once the incontestability clause takes effect in some states.[31]

Because the fear of AIDS is very real for certain groups in our society, life insurance applicants who believe they have been infected with the virus may very well misrepresent their health history or present physical condition when applying for insurance.

Because the fear of AIDS is very real for certain groups in our society, life insurance applicants who believe they have been infected with the virus may very well misrepresent their health history or present physical condition when applying for insurance. These misrepresentations would normally be grounds for rescission of the policy. However, after the period of contestability has passed, benefits could not be denied on the ground that poor health or medical disability existed at the time the policy was issued.

Given the recency of the disease, state and federal courts are just now beginning to decide law suits arising from AIDS-related claims for insurance benefits. In a recent suit on a $100,000 life insurance policy the U.S. District Court in Alabama found for the beneficiary. The insured had not known he was suffering from AIDS when he applied for and received delivery of the policy. He had had lesions on his skin the same day the policy was issued. Almost a week after the policy was issued the insured was diagnosed as having Kaposi's sarcoma. The federal court required the insurer to pay the benefits under the policy, ruling that there was no material misrepresentation in the application even though the insured had not disclosed consulation with a doctor for skin lesions two weeks before he applied.[32]

The average latency period of four years for AIDS and legislative prohibitions against insurance-related testing, make it relatively simple for someone aware of his health status to misrepresent that knowledge to an insurer with some confidence that the incontestability period will lapse before the appearance of symptoms that would otherwise alert the insurer to the possibility of that misrepresentation.

As a proponent of AIDS-related blood testing to ensure the equitable treatment of all applicants for insurance in the underwriting process, I must address one inevitable and unfortunate consequence of effective underwriting—the denial of health insurance to some high risk applicants, particularly those with HTLV-III infection.

For those covered by group health insurance, various state laws operate to prevent interruption in coverage when an insured is no longer eligible for group insurance. The availability of continued coverage was also significantly bolstered by the 99th Congress in its enactment of COBRA.[33] This federal law now requires in most instances that employers of 20 or more employees provide a continuation of health coverage for up to 18 months following termination of employment. Given that most AIDS patients live no longer than two years following manifestation of the AIDS-related diseases, these continuation requirements effectively assure protection against the catastrophic costs of AIDS.

Even though a majority of Americans have group health coverage, some do not have such access and are medically uninsurable for individual coverage. Included in this group along with AIDS victims are those with developmental disabilities, chronic health conditions or other serious impairments. They are estimated to number around one million.

Many argue that the insurance industry should suspend its underwriting system and assume all future health care costs of AIDS patients. While those afflicted do need access to quality care, this approach shows a basic misunderstanding of the insurance process and does not make any provision for the receipt of premiums sufficient to cover expected claims. If insurers cannot collect premiums in amounts sufficient to handle the underlying risk, simple arithmetic would tell us all that there won't be enough money to pay the submitted claims and many insurers could be placed close to insolvency. Indeed if such a solution were adopted it would mean that insurance need only be purchased after the development of an illness, thus abandoning any method of risk assessment as presently practiced. Such a policy could have grave consequences for the U.S. health care system.

One solution alternately suggested is the establishment of state run risk pools

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for the uninsurable. Fifteen states already have established such pools by statute. A glaring problem exists however with their funding mechanism. With the exception of Illinois, losses are shared by health insurance providers and not through general state revenues. Since ERISA effectively prevents state assessments against employee welfare benefit plans that are not funded by insurance plans,[35] employers who administer such arrangements are shielded from the assessment visited by the pool on insurance companies, Blue Cross/Blue Shield, and HMOs.

Pools need to be established, we believe, with the assistance of the federal government, to ensure that the social responsibility of providing coverage to those not insurable because of health condition would be fairly apportioned. A bill introduced by Sen. Heinz and Rep. Kennelly in 1985 would have, if passed, imposed a tax on employers not voluntarily participating in state pools meeting certain minimum standards.[36] Legislation that imposes participation in pools only by health insurers shifts an unequal and unfair responsibility for the provision of health care expenses upon our industry, a responsibility that should be shared by all.

In concluding I wish to emphasize that in order to operate effectively in a voluntary market, insurance underwriting must be able to appraise the risk of an unknown and unanticipated occurrence and spread that risk over a large number of individuals as accurately as possible, because the whole price structure of insurance depends on the principle that those who present the same expected risk of loss pay the same premium.

... the whole price structure of insurance depends on the principle that those who present the same expected risk of loss pay the same premium.

Contrary to this principle, however, some jurisdictions have imposed legal constraints that place AIDS outside the normal medical and regulatory rules pertaining to underwriting for other diseases. It is no overstatement to say that the principal purpose and effect of these measures will be to elevate and single-out HIV carriers for a level of regulatory treatment and protection unavailable to any other group under the insurance laws and regulations of this country. Although it is legally permissible for an insurer to obtain medical information about an applicant who may contract any other disease, such as heart disease or cancer, some states grant AIDS carriers special treatment by completely exempting them from relevant tests.

Although the industry is fully cognizant of the concerns of AIDS victims, it must also consider its responsibility to those who have *not* been infected. If the projections of AIDS cases materialize, public policy makers will be faced with an increasingly pressing need to achieve a balance between competing concerns. This balance need not, and indeed should not, be achieved at the expense of an industry that will inevitably bear a substantial amount of the costs associated with the AIDS crisis. ■

[1]See U.S. Public Health Service, Public Health Service Plan for the Prevention and Control of AIDS and the AIDS Virus 5 (Coolfont Planning Conference June, 1986) (cited hereafter as Public Health Service Plan)

[2]See *Id.*

[3]Institute for Medicine, National Academy of Sciences, Confronting AIDS: Directions for Public Health, Health Care and Research 21 (1986) (hereinafter as Confronting AIDS)

[4]See Public Health Service Plan, at 15.

[5]Health Insurance Association of America, *A Course in Group Life and Health Insurance,* A p. 379 (1985) (hereinafter HIAA, 1985)

[6]See R. Mehr, E. Camaak & T. Rose, *Principles of Insurance* 657-59/8th ed. (1985)

[7]Health Insurance Association of America, *Source Book of Health Insurance Data: 1986 Update 6.*

[8]See HIAA, 1985 supra note 5, at 153.

[9]*Id.*

[10]Bailey, Hutchison & Narber, *The Regulatory Challenge to Life Insurance Classification,* 25 Drake L. Rev. 779, 782; accord Thompson v. IDS Life Ins. Co., 274 Or. 649, 654, 354 P.2d 510, 512 (1976).

[11]National Association of Insurance Commissioners, An Act Relating to Unfair Methods of Competition and Unfair Deceptive Acts and Practices in the Business of Insurance, 1972 Proc. NAIC I 493, 495.

[12]Physicians Mutual Insurance Co. v. Dinenberg, 327 A.2d 415 (1974).

[13]Wash. Admin. Code §284-90-010(2) (eff. 11/14/86).

[14]See J. Slaff & J. Brubaker, *The AIDS Epidemic 201* (1985) (citing Dr. Robert Gallo, National Institutes of Health researcher and co-discover of the HTLV-III virus).

[15]Wisc. Stat. Ann. §631.90(3) (a).

[16]J. Davis, Serologic Tests for the Presence of Antibody to Human T-Lymphotropic Virus Type III: Information Pursuant to the Purposes of Wisconsin Statute §631.90 Regarding Their use in Underwriting Individual Life, Accident and Health Insurance Policies 22 (Wisc. Dept. of Health and Social Services, 1986).

[17]Public Health Service Plan, Supra note 1, at 5.

[18]Confronting AIDS, Supra note 3, at 7.

[19]Society of Actuaries, Transactions: 1982 Reports of Mortality and Morbidity Experience 55 (1985).

[20]California Health & Safety Code §199.21 (f) (West Supp., 1986) (eff. 4/4/85).

[21]Wisc. Stat. Ann. §631.90 (West Supp. 1986) (eff. 11/23/85).

[22]D.C. Law 6-132, 33 D. C. Reg. 3615-24 (1986).

[23]American Council of Life Insurance v. District of Columbia, 645 F. Supp. 84 (D. D.C. 1986).

[24]*Id* at 87.

[25]Advisory Committee on AIDS, National Association of Insurance Commissioners, Medical/Life style questions and Underwriting Guidelines (1986), §I(A), (B).

[26]HIAA 1985, Supra note, pt. A at 347.

[27]American Council of Life Insurance & the Health Insurance Association of America, AIDS Survey of Member Companies 2 at I.

[28]Public Health Service Plan, Supra note 1 at 5.

[29]See, e.g., 18 *Del. C.* §2920.

[30]See, e.g., Hyman v. Life Ins. Co. of N. Amer., 481 F.2d 441 (5th Cir. 1973).

[31]43 Am. Jur. 2D Insurance §768 (1982).

[32](Kentucky Central Life Insurance Company v. Webster (N.V. Ala. 1986) 651 F.Supp. 935).

[33]Consolidated Omnibus Reconciliation Act of 1985, Pub. L. No. 99-272 §§10001-10003, as modified by Pub. L. 99-514 and Pub. L. 99-509.

[34]Con., Fla., Ill., Ind., Iowa, Minn., Mont., Neb., N.D., Tenn., Wisc.

[35]See specifically 29 U.S.C. §1144.

[36]H.R. 1770, S. 1372, 99th Congr. 1st Sess. (1985); see also 99th Congr., 2nd Sess. 14(1986) (Statement of Sen. Heinz).

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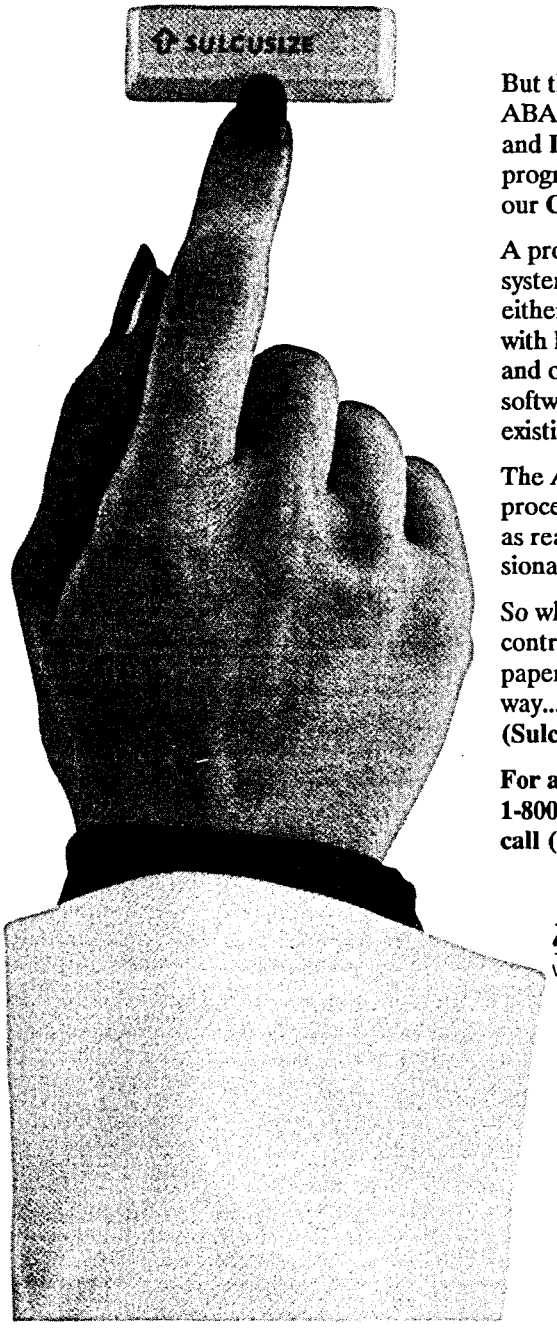

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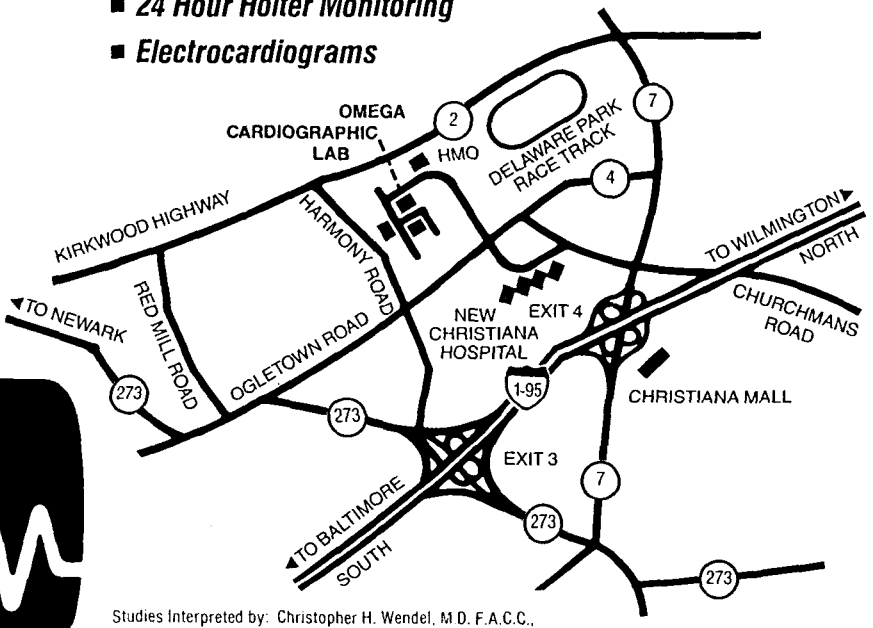

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The Department of Justice: Dealing with A Constellation of Problems

David J. Lyons

As a Deputy Attorney General I represent the Division of Public Health, and in that capacity I've had the opportunity to become acquainted with various issues surrounding AIDS. I do not pretend to any exalted expertise on AIDS. Instead, I see myself as a "conspicuous student of the disease" and its various ramifications. In that role I have come to be characterized in the Department of Justice as the "AIDS" Deputy. I'm a sort of clearinghouse, providing resource materials so that the other deputies can try to answer questions reasonably when they encounter problems with respect to AIDS.

I have a litany or a list of various topics, which I want to address briefly. I think it's important to put as many issues as possible on the table so that we can begin to acquaint ourselves with a very important area of the law, which is developing rapidly.

Biomedical Waste

Under Delaware law infectious wastes are indeed hazardous wastes, and subject to regulation [7 *Del. C.* §6302 (7)]. Until the advent of the AIDS crisis, there was little serious concern about regulating them. Then there were incidents in New Jersey where needles washed up on the beach. Some vials of blood were discovered by children behind a doctor's office in Dover, and people started to become concerned: perhaps we needed to take a look at how we managed and disposed of infectious waste. I've attempted to determine how far along the Division of Public Health and the Department of Natural Resources and Environmental Control have gone in formulating policies with respect to the disposal of such waste. At this point, the process has not evolved very far at all. Dr. David Verma of the Division of Public Health tells me they are currently attempting to determine what guidelines they should follow in formulating the Delaware response to disposal of infectious wastes. These guidelines would of course include 1.) how to segregate wastes, 2.) how to package them and 3.) how to dispose of them.

We're only at the threshold of this issue, but I recognize that the medical community will be faced with regulations that will add expense and employee time to the conduct of practice.

The Handicap Status of AIDS Victims

In September of 1987, the Attorney General announced the receipt from Dr. Lyman J. Olsen, Director, Division of Public Health, of a request for an opinion as to whether AIDS victims would be designated as handicapped under the Equal Accommodations Statute (6 *Del C.* Ch. 45) and the Equal Rights to Housing Statute (6 *Del C.* Ch. 46). In my capacity as the representative of the Division of Public Health, I was asked to initiate and to assist in drafting that opinion.

In doing so, I relied heavily on an opinion of the United States Supreme Court, *School Board of Nassau County Florida, et al. v. Arline,* 107 S. Ct. 1123 (1987), in which a teacher with tuberculosis, claimed that she had been discriminated against under the Rehabilitation Act of 1973 (29 U.S.C.A. §793 *et seq*). In reviewing the pertinent law, it became apparent that the federal and state definitions of the term "handicap" were identical, and that the federal regulations would provide assistance in trying to determine if AIDS, in fact, fell within the definition of the term "handicap" under federal law. We would take our cue from that determination in deciding whether under state law, the same held true. Indeed, we concluded that the federal law *does* include AIDS as a handicap, and we then concluded that under state law an AIDS victim would be accorded protection under the Equal Accommodation Act and the Equal Housing Act.

Having reached that conclusion, we also had to consider whether mere HIV positivity would also qualify as a handicap. We looked at *Arline, supra,* and noted that *Arline,* in talking about the Rehabilitation Act held that, notwithstanding an infected person's freedom from the physical effects of a disease, if he was *regarded* as diseased, he would indeed be suffering the effects of discrimination as a *result* of that disease and should be included within the protected class. We looked at the state law, and noting the similarity of the federal definition to the state law, concluded that those found to be HIV positive should also be accorded handicapped status under Delaware law.

Our opinion does not, however, disregard the circumstances where, for an unrelated lawful reason, a distinction may be properly made between HIV positive individuals or AIDS patients and the population at large. For instance, if someone applies for housing, and the landlord wants to know that a prospective tenant can afford to pay the rent. Similarly if the applicant has a criminal history, that is relevant to the landlord's deciding whether he should expose other tenants to one, who although HIV positive, has also demonstrated violent

(Continued on next page)

Department of Justice
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tendencies in the past and thus would represent a threat to other tenants. Likewise it might be reasonable for a physician to refer a patient for treatment elsewhere if that physician did not possess the expertise for treating AIDS patients.

Excluding Professionals?

The Equal Accommodation Act makes no express exclusion for professionals such as dentists, doctors, or lawyers so as to negate their coverage under the Act. It is conceivable that in Delaware a dentist, doctor, or lawyer could be the target of a complaint filed with the Human Relations Commission alleging denial of service merely because the complainant had been judged HIV positive. There is no Delaware case law that tells us whether the term public accommodation includes the practice of dentistry, medicine, or law.

In reviewing the various AIDS advance sheets I receive bi-weekly I noted that the New York City Human Relations Commission recently received a complaint filed on behalf of an AIDS victim alleging that a dentist had discriminated in declining to provide treatment to the sufferer and had referred him elsewhere because he had AIDS.(*AIDS Policy & Law,* March 9, 1988 at p. 4.)

The dentist defended, stating that his decision to refer the patient out had been an exercise of his professional judgment and that regulation of dentistry under state law was the exclusive province of the state education department. The dentist further argued that his office was not a place of public accommodation. Furthermore, if his office *was* a place of public accommodation, his referral was a reasonable accommodation for a person with AIDS. (The patient died five days after the alleged discrimination.)

The administrative law judge concluded that, although the issue of reasonable accommodation was relevant, it was a question of fact that he would have to decide upon hearing the evidence. He further concluded that under the New York City Code medical providers such as pharmacies were in fact places of public accommodation, and he found that the code was also intended to cover professional offices such as dentists'. According to the advance sheet, the defendant's counsel plans to seek a stay of the ruling to challenge the application of the term "a place of public accommodation" to a dentist's office. This case is probably one of the first in the country concerning treatment of AIDS patients. Other jurisdictions may reach different results. For example, unlike the New York law, the Philadelphia Public Accommodations Act contains an exception for professional services, although it is vague and subject to some construction. But let us posit a dentist or a lawyer with a big sign in front of his practice, actively soliciting public patronage generally, rather than by referral. It seems more than likely that such a professional would be found to be running a place of public accommodation. Surely the intent behind those laws was that such services along with other services generally, like access to a McDonald's when and if you please, should be available to everyone.

As of this writing The State Human Relations Commission has received only one AIDS housing complaint, and that an inconclusive one because the complainant died. In other jurisdictions these issues are developing more rapidly. We're going to have to watch this progress in determining a Delaware response. It's apparent to me that sooner or later there will be a large number of people in Delaware afflicted with AIDS,

David J. Lyons, Esquire, a member of the Delaware Bar, is a Deputy Attorney General in the employ of the Department of Justice, where he represents the Division of Public Health. He is a graduate of George Washington University and of the Widener University School of Law. Mr. Lyons's article is drawn from his remarks delivered at the Professional Conference on AIDS. His separate review of legislation was prepared subsequent to the conference.

and we're going to have to face these problems. Other jurisdictions are already doing so and we may find the developing precedents helpful.

Criminal Law Enforcement

This again is a somewhat controversial area. To begin with, there's a statute on the books relating to sexually-transmitted disease control (16 *Del. C.* §701 *et seq.*) of questionable constitutionality. It puts all enforcement authority in one administrative officer, who makes decisions with respect to quarantine, testing, and the treatment of those presumed to be infected with sexually-transmitted diseases. There is presently underway, however, a movement to revise the sexually-transmitted disease code (See HB 599, introduced June 2, 1988). We are taking a hard look at reporting requirements (e.g. How soon after a physician's or a laboratory's diagnosis of a sexually-transmitted disease must it be reported to the Division of Public Health?). We expect that new code provisions will inject a neutral third party to review the reasonableness of the public health officer's orders with respect to testing, treatment, and quarantine. Again, these provisions are in the preliminary stage, subject to review by the Office of the Attorney General, and will doubtless undergo changes.

What we propose is that the health officer, upon receiving reliable information, notify a presumably afflicted person that he or she is suspected of suffering from a sexually transmitted disease. That person should be given an opportunity to comply with the directives of the notice, which in the initial stages will probably be confined to testing and treatment.

The proposed legislation will direct the health officer first to seek voluntary compliance to prevent the infection of others before issuing an *order* of compliance to a recalcitrant. Absent voluntary compliance, an order could issue, requiring testing and restricting in a variety of ways, the activities of one who is allegedly infected with a sexually transmitted disease. If the health officer's order were ignored he or she could seek enforcement in court. Of course, the party affected would have an opportunity to contest the entry of such an order.

That statute will also authorize, *inter alia*, the health officer when confronted with an imminent threat to public health, to seek *ex parte* a court order to detain a suspected carrier for 72 hours for testing. It could be used, for example, in the case of a prostitute apparently infected with HIV who continues the practice of prostitution, raising a primary public health concern, and who cannot otherwise be removed from the street quickly without violating his or her rights. Such an order would, of course, be reviewable.

Such legislation *is* controversial. However, its need is very much apparent because in today's society people who are infected with HIV represent a risk to the public at large. If they refuse to alter their behavior, others can become infected. There is a 1985 Florida case [W. Dornette, *AIDS and The Law* 174 (1987)] in which a judge ordered a prostitute to remain in her home and to wear an electronic monitoring device so that the authorities could determine her whereabouts at all times. She had previously demonstrated no concern for the health of others. Infected with HIV, she continued to practice her profession, even though she had been prosecuted several times for prostitution. That's obviously the worst-case scenario.

(Continued on page 75)

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I suspect that our law will not be used very frequently, because most people will alter their behavior upon learning that they are dangerous to others.

Prisons

At this time, the prison system in the state of Delaware is not engaged in any type of mandatory testing, although there is statutory authority for it [11 *Del. C.* §6523(b)]. The decision not to test relates to imperfections inherent in the test, which is not yet so accurate as to allow the conclusion that, if the test is negative, the subject will not seroconvert within the next few days or months. In other words, there's a window phase of approximately of 6-12 weeks between exposure to the disease and the appearance of antibodies.

Secondly, it is thought that it would be expensive and difficult to segregate a group with already demonstrated antisocial tendencies and confine them with a death sentence. It will be very difficult to find people to guard them, and on a more serious note, corrections personnel question whether it's medically reasonable to place those who are just HIV-positive with people who are already sick with the disease.

At this time, although various states have initiated mandatory HIV testing of prisoners, only Colorado tests and segregates those who test positive.

That's not to say, however, that individuals are never segregated in Delaware. I have learned of a prisoner, who, informed that he was HIV-positive, declared that he had no intentions of altering his behavior towards other prisoners. The corrections personnel quite sensibly concluded that they should segregate him.

Finally, prison guards are not notified that a prisoner is HIV positive. However, the guards are told to take bodily fluids precautions when transporting inmates who have been determined to have infectious diseases.

Insurance Underwriting

Delaware has adopted national guidelines with respect to life and health submissions, permitting life and health insurers to test. They must, however, obtain written consent. Furthermore, that test has to be administered in accordance with Division of Public

(Continued on next page)

Just When You Thought It Was Safe to Get Tested

Many of the articles in this issue are drawn from the remarks of experts who spoke on April 16 at the Professional Conference. A great deal has happened in this fast breaking story since then. This magazine does not enjoy the stop press luxury of newspaper publication, but we can slip in a few pertinent references to what's come up in the past few months.

The early summer announcement by the Alfred I. duPont Institute of a blanket policy of rejecting any HIV positive patient demands comment. This action is calculated to worsen a situation that no one would have thought capable of worsening, a piece of Scarlet Letter—Off You Go to Molokai mentality that drives an epidemic underground to work its evil undetected.

Health care professionals can be proud of their colleagues at the Childrens Hospital of Philadelphia, who have challenged this misguided policy. Lawyers can be no less proud of the Attorney General's promise to challenge it in court. His swift and responsible decision is gratifying.

We are convinced that early, open, widespread testing without threat of stigmatic consequences is in everyone's interest: those who can be helped while their infection is still manageable, and who can be helped far better in the light of the fullest medical knowledge of their condition; the health care professional whose risk should be an informed one; the young and sexually active public who will unwittingly contract the virus from partners who will unwittingly bestow it; and, once again, the infected who, paradoxically, may need extra protection against the *healthy*, who are loaded with bacteria dangerous only to the immune deficient.

The Institute deserves some kind of medieval booby prize for hysterical inhumanity. They've given testing a bad name when it should have a very, very good one. The only good thing to come out of this sad and wretched business is the reinforcement it will give the conviction held by sensible men and women that the most stringent antidiscrimination measures on behalf of the infected have become imperative.

Health protocol. The results must remain confidential between the insurer and the insured to preserve so far as possible the quality of life for someone who tests HIV-positive.

Other regulatory guidelines specify that sexual orientation may not be used as an underwriting criterion or to determine insurability. Diagnostic questions can be used to establish the presence of AIDS or ARC. Questions related to the presence of a medical condition are proper if they're not used to detect sexual orientation. Furthermore, medical questions must relate to a finite period, and demographic information regarding the applicant may not be used to establish the applicant's sexual orientation. For the purposes of rating an applicant, an insurer may impose territorial rates, but only if such rates are based upon sound actuarial principles or reasonably expected experience. And no adverse underwriting decision may be made if an applicant has innocently in the past expressed AIDS concern to a medical provider. For example, if you had been in your doctor's office, had told him you had a cold for a month, and asked "Doc, do you think it's AIDS?" and he said "no", and if an insurer got a hold of that information, it would not be permitted to draw adverse conclusions.

I've spoken with insurance department personnel responsible for monitoring and administering the policy. I'm told that problems have arisen with respect to insurers who want to ask about AIDS but not about other life-threatening diseases or signs of disease. They've been told that this does not comply with the intent of the policy and is not permissible activity in underwriting insurance under Delaware law.

Furthermore, some insurance underwriters have asked the Insurance Department whether they could put a limitation on health care payments for AIDS patients. They have been informed that it would not be within the intent of the regulations to unfairly make AIDS a suspect classification just because it's AIDS as opposed to say, cancer, which can also lead to catastrophic medical costs.

Finally, insurers have asked whether they can, upon an applicant's seeking recertification or seeking to increase his benefits, test or ask questions related to AIDS. The answer is "Yes", provided the insurer also asks about other life-threatening diseases.

As you can see from the foregoing account AIDS is an across the board problem in the administration of justice. I get AIDS questions every day, and I'm only one of many attorneys in the Department of Justice. I'm trying to acquaint my fellow attorneys about their responsibilities with respect to AIDS and what they can expect to encounter in their practices. It's a difficult process that we're going to go through for the next few years, but it's one we're going to *have* to get through. We have no choice at this point. I hope that the decisions we make with respect to AIDS are reasonable and consistent with informed medical and scientific judgment rather than fear and discrimination, and I believe that with the effort we are making to become informed, our decisions will be fair and prudent. ■

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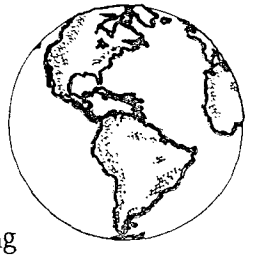

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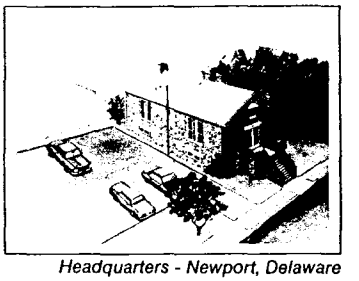

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The Legislative Posture

David J. Lyons

The informed consent and confidentiality legislation* regarding HIV related testing represents a compromise. This is not unusual as very little is done legislatively where some form of compromise is not required. AIDS legislation is no different. The AIDS crisis represents the major public health challenge of this century and reasonable minds have differed and will continue to differ on the multiplicity of complex issues that the crisis has engendered. With that in mind, I will highlight in a general way the major differences between the majority and minority view points of the AIDS Legislative Task Force with respect to informed consent and confidentiality of HIV testing.

A majority of the Task Force believed specific HIV testing informed consent guidelines had to be enacted to prevent unauthorized testing and potential misuse of the results leading to possible drastic emotional, social, and economic consequences for those tested. The minority believed that, although informed consent should be obtained before HIV testing and counseling initiated afterwards, the formality of the majority's legislative proposal would discourage physicians from requesting that a patient be tested and patients from agreeing to be tested. The legislature adopted the majority position, which specifically states the type of information that must be given for informed consent.

The minority recommended two additional exceptions to the majority's informed consent proposal: testing without consent in a pregnancy setting, when the knowledge of the mother's HIV status is considered necessary to protect the health of the mother's unborn or newborn child, and testing without consent where a health care provider's health has been threatened as a result of exposure to a patient's blood or bodily fluids in a manner known to transmit HIV.

With respect to pregnancy testing, the minority wanted to preserve a physician's right to order HIV testing of pregnant women in high risk groups even without informed consent in order to allow appropriate prenatal care. The majority believed that a women's right to direct her own medical care should not be disturbed, leaving the physician the right to refuse medical care on professional grounds. In other words, if the physician believes the test essential to ensure adequate medical care for mother and child, the physician can refer the mother elsewhere for treatment.

The minority strongly advocated a health care provider's right to unilaterally initiate testing after an accidental exposure to a patient's blood or bodily fluids in the interest of the emotional and physical well being of the provider. The majority believed little would be gained by this exception, arguing that imperfections in HIV antibody testing might leave the provider with a false sense of security if the test was negative and that the best way to ensure a provider's well being would be to have him undergo testing.

The legislature sustained the majority position on HIV testing of pregnant women leaving them with full autonomy. It should be noted, however, that the recently revised Sexually Transmitted Diseases Statute** would allow the State Board of Health to order HIV testing in a pregnancy setting. The Legislature accepted the minority position with respect to a health care provider's right to conduct HIV testing without informed consent in the case of accidental exposure to a patient's blood or blood products. However, the final definition of "in a manner known to transmit HIV" does not reference "bodily fluids" as proposed by the minority. Rather, the definition refers only to parenteral exposure to "blood or blood products", and allows the Division of Public Health to declare other possible modes of transmission.

Regarding confidentiality, the minority strongly agreed that one's HIV status, as well as all medical record information, should be protected from unauthorized disclosure. However, the minority urged that a health care provider be able to unilaterally access HIV test results when necessary to render appropriate care and treatment. The legislation as enacted adopted the majority position, leaving the patient full autonomy to decide whether a health care provider may have access to an HIV test record, absent an emergency in which the patient is incapable of giving consent. Once consent is obtained the legislation permits the dissemination of a patient's HIV status to a provider's agents or employees who have a medical need to know such information in order to provide health care.

The penalty section proposed by the majority stated that intentional or reckless violations would constitute a Class A misdemeanor. The minority objected to a criminal penalty for a violation of the Act, arguing that criminal sanctions against health care providers for violations were illogical, as it would be more appropriate to penalize those who intentionally discriminate against the HIV infected in various societal settings.

The legislature left intact civil penalty provisions, but adopted the minority's recommendation that criminal sanctions be deleted. The civil sanctions provide for liquidated damages and allow reasonable attorney's fees to successful litigants. ■

**HB 559, as amended by House Amendment Nos. 4 and 6.*

***HB 599, as amended by House Amendment Nos. 1 and 2.*

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Minority Report of the AIDS Advisory Task Force

The undersigned members of the AIDS Advisory Task Force strongly disagree with the specifics of and with the underlying assumptions implied by the Task Force's recommendations concerning informed consent and confidentiality.

The official charge given the AATF by the Division of Public Health, stated concisely in the September 1987 report of the Task Force, reads "issue recommendations as appropriate in the interest of:

a. Protecting the public health

b. Preventing the transmission of AIDS

c. Reducing unwarranted fears and misunderstandings about AIDS

d. Protecting legal and social rights of those afflicted with AIDS or otherwise infected with the AIDS virus."

Each of these four goals is worthy. They must be achieved in ways that do not sacrifice any one goal in the interests of achieving any other. Though we fully agree with the Task Force that discrimination against HIV positive individuals or against any subset of the population is odious and must be fought with legislation and education, we will not be associated with any recommendations that place anti-discrimination efforts above the interests of the public health.

The majority recommendations of the AATF are based on the assumption that protecting the legal and social rights of the HIV positive individual is a goal which must be sought at all costs. To place risk of criminal sanctions on physicians who diagnose this infection, rather than upon individuals who hysterically and intentionally discriminate against HIV positive persons, is to place this goal well above the goal of protecting the public health and the goal of preventing transmission of AIDS.

The rights of HIV positive individuals should be protected by legislation which specifies that discrimination on the basis of HIV positivity or diagnosis of ARC or AIDS, in the areas of employment, housing or education is illegal and punishable by criminal sanctions.

The burgeoning epidemic of HIV positivity, must be dealt with according to established principles of the disciplines of Public Health and Infectious Disease. To approach this disease as a purely sociological problem rather than as a serious medical problem is a tremendous mistake.

Our specific objections and recommendations with regard to this draft are the following:

Section 1. - 5.

We recommend, in the interest of consistency and completeness, that the CDC's definition of a health care worker be used here as well: "health care worker —nurses, physicians, dentists and other dental workers, optometrists, podiatrists, chiropractors, laboratory and blood bank technologists and technicians, phlebotomists, dialysis personnel, emergency health care providers (including paramedics, emergency medical technicians, law enforcement personnel, fire fighters), and others whose activities involve contact with patients, their blood or body fluids, or corpses."

Section 1 should also include the definition of the term "manner known to transmit HIV." "Parenteral exposure (for example injection through the skin) or exposure of a mucous membrane (for example, mouth, nose or eyes), to blood or blood products or body fluids. Also to include, prolonged cutaneous exposures to large amounts of blood or blood products or other exposures as may be determined by the Division of Public Health."

Section 2. C. Item 2.

Testing must be allowed for purposes of research and this testing should be anonymous. However, it is standard practice for the identity of research subjects to be retrievable by the researcher if the well being of the subject is in jeopardy. Specifically, the last phrase of Item #2 "and may not be retrieved by the researcher," should be deleted. As treatment becomes available to prolong life and improve the quality of life in HIV infection, researchers must be permitted to break the codes and to retrieve the identity of the HIV positive subject so that those subjects may avail themselves of such treatment.

Although it is unprecedented to require by law informed consent prior to diagnostic testing for any sexually transmitted disease or for any disease associated with immune deficiency, the fear of misuse of test results has occasioned wide public sentiment in favor of informed consent for HIV testing. Such informed consent as is recommended by the AATF is so cumbersome and convoluted that it will frighten many individuals into refusing to be tested.

A patient's consent should be obtained prior to HIV testing. The patient should know the test that is being done, the purpose of the test, the potential uses of the test results and the manner in which the test is being performed. Appropriate counseling should also be given. The much more involved "informed consent" recommended by the AATF will discourage the physician from requesting the patient to be tested, and will discourage patients from agreeing to be tested once asked. These two factors combined could lead to delay in timely diagnosis, treatment and institution of behavior that will decrease the risk of transmission of the disease. (Early diagnosis of the HIV infection may be particularly important for women in their child bearing years. Fifty percent of the babies born to HIV positive mothers will be infected, and the pregnancy itself can accelerate appearance of symptomatic immune deficiency in the mother.)

If informed consent should become state law, there are two exceptions that mut be added to those listed in Section C of the final draft. (Both of these exceptions were part of the original recommendations of the AATF. The deletion by more radical elements in the Task Force of exceptions for testing in the setting of pregnancy and of exposure of the health care worker to

(Continued on next page)

Minority Report
(continued)

potentially infectious material is irresponsible, and is a primary reason for the need for this minority report.)

HIV testing of a patient should be permitted when "the health of a health care worker has been threatened during the course of the health care workers duties, as a result of exposure to blood or body fluids of the patient in a manner known to transmit HIV. Most health care workers do not and should not have any choice about which patients receive their services. Although health care workers are seldom at high risk of being infected with HIV, the health care worker should have the right to demand HIV testing of any patient to whom they have had significant exposure of blood or body fluids.

We must be mindful also of the fact that there is nationwide, an enormous shortage of nursing and other health care personnel. The exclusion of this item from exceptions to need for informed consent would likely worsen our nursing crisis just at a period in time when the needs of babies born with HIV infection and of adults becoming symptomatic with ARC and AIDS and HIV encephalopathy could place a greater than ever burden upon the state's health care systems.

Exception must also be made "when knowledge of such test results is necessary to protect the health of the patient's unborn or newborn child." HIV antibody testing should be an important part of prenatal testing for women in high risk groups. (Since the definition of "high risk group" continues to broaden and now includes, among others, all sexually active individuals; and as more reliable HIV tests are developed, HIV testing may become a part of routine prenatal care of all pregnant women.)

Section 3. - Confidentiality.

We strongly agree that a patient's confidentiality is to be respected with regard to HIV status as well as to all contents of his medical record.

We would delete the description "legally effective" from the definition of release of test results in Item #2 under Section 3. A. Inclusion of these words would require the health care worker to make a judgement on the legality of the preparation of the release. This is a judgement that the health care worker is not qualified to make. Item #2 should read "any person authorized by the patient or the patient's legal guardian."

Exceptions #3 and #4 are very important. We would alter Item #4 only by deleting "emergency" as a definition of the appropriate care and treatment.

Section 4.

This entire section should be deleted.

It has never before been a policy in the United States to make a criminal offense of the performance of a diagnostic blood test for an infectious disease or for any other disease. Sufficient avenues for redress of grievance are presently available through the civil justice system.

More importantly, the purpose of this section being to protect HIV positive individuals from discrimination, the emphasis is entirely misplaced. Criminal sanctions should be taken against those employers, landlords or educators who are guilty of the discrimination, not against the health care workers who diagnose the infection and care for the patient. ■

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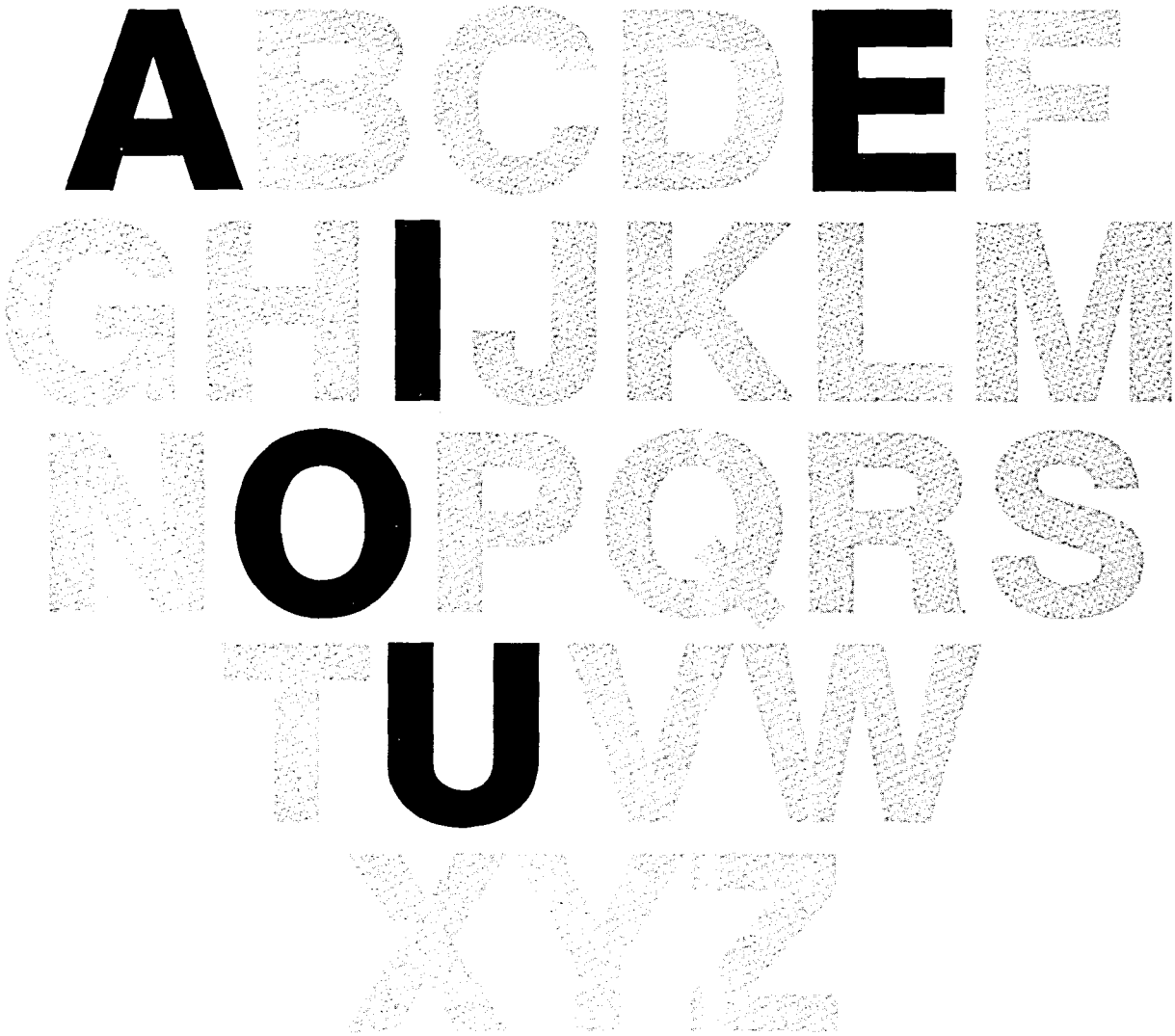

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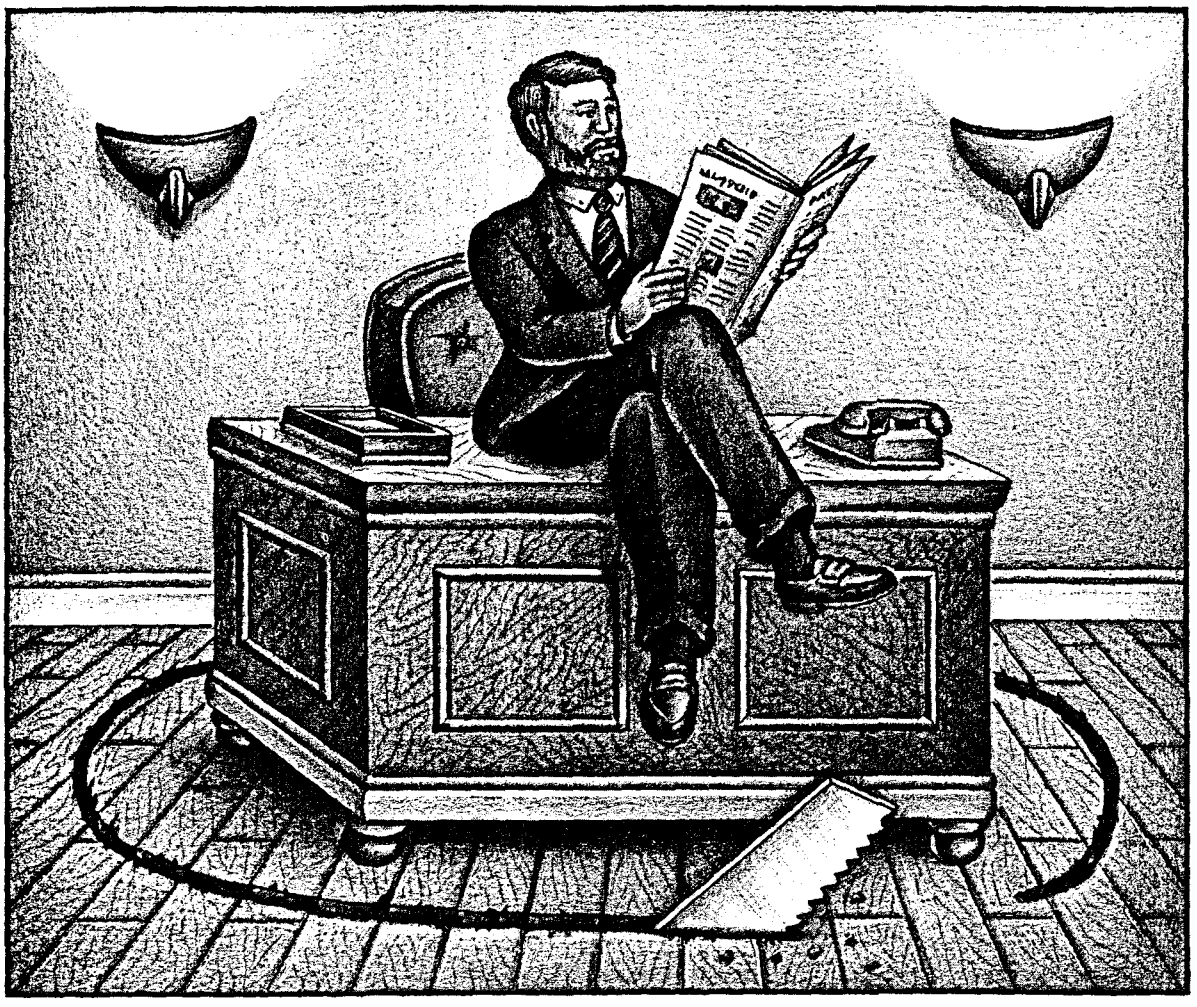

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