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THE MERRIMON LECTURE

by

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AIDS: DISSONANCE BETWEEN SCIENCE AND POLICY

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THE MERRIMON LECTURESHIP IN MEDICINE

This Lectureship, which was established by the late Dr. Louise Merrimon Perry "in respect and honor of the Great Traditions of the Science and Practice of Medicine," was inaugurated in 1966. Dr. Perry's idea was that the lectures be open to all, but that they be concerned with "the Origins, Traditions and History of the Medical Profession and of that Ethical Philosophy which must dominate this Field of Human Endeavor." It was her intent that the Merrimon Lecturers be distinguished both for scientific or clinical skills and a notably humane attitude toward Medicine.

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SAMUEL O. THIER, M.D.

SAMUEL O. THIER was born in 1937 in Brooklyn, NY, the son of a general practitioner. His observations of his father—who loved what he did—and residence in several areas of the United States during his boyhood while his father was in the army, provided a broad range of experiences that have shaped his subsequent career.

Dr. Thier received his undergraduate education at Cornell University and his M.D. from the State University of New York at Syracuse in 1960. Following postgraduate training at Massachusetts General Hospital, including a year as Chief Resident in Medicine, he was appointed Chief of the Renal Unit and Assistant Professor of Medicine at Harvard. He then became Vice Chairman and Professor of Medicine at the University of Pennsylvania School of Medicine prior to appointment as Professor and Chairman of the Department of Internal Medicine at Yale. While at Yale Dr. Thier was also Chairman of the Executive Committee of the Faculty Practice Plan and a member of the Board of Trustees of the Yale-New Haven Hospital.

Dr. Thier has received numerous awards and honors including membership in honorary societies. He has been awarded honorary doctorate degrees from the State University of New York, Tufts University, The George Washington University, and Rush University and he has served as President of the American Federation of Clinical Research, Regent of the American College of Physicians, and Chairman of the American Board of Internal Medicine. Dr. Thier, who did research at the National Institutes of Health from 1962 to 1964, served from 1980 to 1984 on its Director's Advisory Committee. He has published numerous articles on renal physiology, and has had a particular interest in inherited disease of the kidney and kidney stones. He is also co-author of a text book of pathophysiology.

His activities in education, clinical care, administration and research have given Dr. Thier a comprehensive view of medicine. Although these broad responsibilities provided venues for the exercise of his talents, he felt that he was doing too little to effect appropriate change during a rather chaotic and difficult period in medical history. It was in this context that he agreed in 1985 to become president of the Institute of Medicine.

The Institute of Medicine of the National Academy of Sciences was established in 1970 as a private, nonprofit organization to provide the federal government and the public with authoritative and objective advice on health and health care policy. While it has influenced legislation and health care significantly, its relations with the National Academy of Sciences when Dr. Thier became president were strained, and financial difficulties threatened its future. In his three years of presidency, Dr. Thier has raised a substantial endowment to provide a strong financial base and has built new programs; relations with the National Academy of Sciences and the National Academy of Engineering have improved to the extent that the Institute of Medicine is now a full partner in the scientific advisory enterprise; the Institute has identified and communicated advice on a number of key health policy issues facing the nation; the Food and Nutrition Board and the Medical Follow-up Program have been transferred from the Commission of Life Sciences to the Institute. The Institute appears to have been re-energized by the force of his personality, commitment to excellence, and responsiveness to identified needs.

The School of Medicine is honored to have Sam Thier as its 1988 Merrimon Lecturer, exemplifying as he does the high ideals about medicine on which the Lectureship was established. These are clearly stated in the conclusion to a recent comment on the

principles of the practice of medicine: "Those that seek to preserve the status quo ought to examine what they are protecting and whether it is based upon the principles I have outlined or upon the fear of change. A reorganization, a rejoining, and a recommitment to the basic principles of advancing medical knowledge, transmitting it to the next generation, enforcing quality standards, and operating under a code of ethics that includes service to others, is essential. Also, a little idealism would not hurt as we face our continually developing system of medicine."

Dr. Thier joins two former Institute of Medicine presidents, Frederick C. Robbins and David A. Hamburg, as Merrimon Lecturers. We are proud to add his name to the list of distinguished predecessors.

AIDS: DISSONANCE BETWEEN SCIENCE AND POLICY

Introduction

AIDS is a topic that points up the difficulties caused by operating with a circumscribed and somewhat insulated set of ideas about how policy is formulated. We might assume that there are standards of proof and logical connections that dictate how policy is made. But that is not the case in AIDS. The reasons could have been predicted, but the health professions did not predict them well enough. Therefore, the situation is that what we know, recommend, and champion has not been translated into policy.

AIDS is an infectious disease. It is epidemic, lethal, can infect any member of the population, and it is most dangerous to sexually active adults and newborns. It is transmitted by only a few routes and infection can be avoided. Why don't we confront it effectively if we know the cause, the routes of transmission, and how to test for its presence? We are ignoring and repeating history. It is a fact that cultural, political, and economic institutions confronted with catastrophes have responded historically with practices that are traditional, even in unusual circumstances. That historical repetition of a failure to respond imaginatively is one of the things that has tripped us.

As in most previous epidemics of this sort there has been a disproportionate impact on the poor. This creates another problem: those who are responsible for health policy do not know how to communicate with those who are affected. The cultural, educational, and language barriers prevent these groups from talking to each other effectively.

Another serious repetition of historical fault is stigmatization, the marking of persons or groups for exclusion from society. The ideas and beliefs and judgments of the dominant group have suggested that another group is deserving of scorn or blame or even punishment.

Minorities have been blamed for plagues before. The killing of large segments of minority populations on numerous occasions during the Black Death surely had no discernible effect on the spread of the plague.

The health professions must resist stigmatization and speak out effectively. This may take time. Many of you may not remember but leprosy, epilepsy, and mental retardation — conditions that were not the victim's fault — were once stigmatizing.

In the way they present information, the media have abandoned their responsibility to serve as a major conveyor of the education by which we conceptualize the problem. Then, there are the politicians and lawyers. Supporting a stigmatized group is never a popular position, either for lawyers or politicians and it requires courage. I fear too little courage is being applied to the problem of AIDS.

The main concept you should keep in mind is that AIDS is a disease. As a disease it is a biologic process. As a biologic process it will require biologic solutions. The spread of the disease however, is a product of behavior in a social context. Social and behavioral solutions will, therefore, be required to reduce spread.

The biological problems of syphilis and gonorrhea illustrate the importance of my last statement. Although we have effective treatment, we have never eradicated syphilis or gonorrhea because we have not addressed the social and behavioral problems with the same rigor as the biological problems.

Let us now look at the medical information that we have about AIDS, and then at the apparatus for response in this country, and our response so far.

Pathogenesis and Clinical Disease

The first cases of AIDS were recognized in this country in 1981. We now know that there were people back in the 1970s who had HIV (Human Immunodeficiency Virus) infection. There may have been isolated entries of the disease in the 1960s, but not in sufficient volume to have established a foothold and basis for spread. We know that there are reports of antibodies to HIV in blood samples drawn in the 1950s in Africa. Thus the disease, or at least the virus, has been around for at least three decades. The disease has been present in the USA for at least a decade, and clinically evident for about eight years. It first appeared in this country among homosexuals and then subsequently was seen in populations for which blood contamination was a problem, i.e. hemophiliacs, transfusion recipients, and drug abusers.

It is hard to appreciate the short time frame of our experience with AIDS, because most diseases that we know about have been around for decades or centuries. AIDS was first recognized in 1981 and by 1984 two laboratories had identified the cause of the illness as a virus. By 1985 we were using monoclonal antibody technology to test for exposure to the virus. Parenthetically, even a decade earlier we would not have been able to capitalize on the investment in basic biological research that provided us with the resources to identify the cause of this disease nor begin to track it.

The disease is caused by HIV, a retrovirus. Retroviruses are RNA viruses characterized by the presence of reverse transcriptase. This enables translation of their genetic messages into DNA that can be inserted into the genome of the receptor (human) cell. Although rapid mutation is a characteristic of all retroviruses, HIV has a more complex genome than most other retroviruses and may mutate more rapidly.

The primary disease we see in this country is caused by HIV1. A second form of HIV virus, called HIV2 appears to be capable of producing an AIDS-like illness, but it is not yet a major factor in the United States.

HIV is transmitted by very few means. It is transmitted sexually — from male to male, male to female, and female to male. (There has been only one known episode of female to female transmission; it is almost certainly possible but not very common.) HIV also is transmitted through contaminated blood products. It was transmitted by transfusions and the use of contaminated antihemophilic factor concentrates in the early phases of the epidemic. The major blood route today is the sharing of contaminated needles by intravenous drug users. It is also transmitted from mother to child during pregnancy, at the time of delivery, and probably from mother to child via mother's milk. There is some evidence that it can be transmitted by lab accident involving pure culture of the virus.

Not a single person who did not have a sexual relationship with the infected individual converted antibody tests in families caring for patients with AIDS and having all levels of contact. This suggests very strongly that sharing utensils, sheets and bathrooms will not transmit the disease.

It is hard to convince some people that insect transmission does not occur, but a simple bit of epidemiology may help. In the areas of heavy HIV infection in Africa, AIDS occurs in neonates and young children and in sexually active adults. Unless mosquitoes can tell when humans are sexually active, and avoid all older children and sexually inactive adults, I think we have fairly strong evidence tht HIV is not a disease transmitted by insects.

But despite the evidence against casual contact and insect transmission, there is disbelief on the part of the public. It is crucial to learn why people fail to believe such overwhelming and important information.

Clinically, the viral infection impairs the immune system and leads to opportunistic infections and Kaposi's sarcoma. We are beginning to be more and more concerned about the dementia that occurs. Little is known about the rate of neurologic dysfunction with HIV infection before full-blown AIDS. It will become very important to know whether antiviral therapies will be effective in the central nervous system; if not, we might create a further catastrophe: individuals who are protected from progression of the disease generally but are destroyed by neurologic injury.

Infection with HIV means establishment of the infection within the genome of the host. Whether it remains latent, or whether it progresses, or whether it progresses after a latent period, there will be progression ultimately in the majority of people. We can anticipate that within seven or eight years, half of infected individuals will begin to develop evidence of suppression of immune function and ultimately will develop the full-blown set of complications we call AIDS. In terms of slowing progression to active disease or eradicating disease before there is injury, it is more important to consider HIV infection than AIDS, the clinical disease. It will become even more important when we talk about financing of care for patients with the infection.

Epidemiology

The pattern of the epidemic is a composite of several patterns. In this country the infection started out in the gay population and moved later to the drug addict population. That is still the main distribution in patients with AIDS, but new cases are shifting more toward the addict population. This produces what you would expect: the heterosexual partners of the addicts are more likely now to become infected. We know that the major route of heterosexual spread involves the partners of patients who are infected through drug use. The even more devastating complication of heterosexual spread is that it leads to the fastest growing set of new cases — children. The offspring of mothers who become infected either through their own use of drugs or because the father is an infected drug addict are adding up to tragic consequences in certain areas. In some areas of New York City two or three percent of newborn children are positive for antibodies to HIV. That does not mean they have the infection since the test may be picking up antibodies from the mother. However, it appears that 30 to 50 percent of those children will end up with the infection.

The disease itself, a state which is easily recognizable, is now past 80,000 reported cases and over 40,000 deaths in the United States. The projections, regardless of reassuring stories in the newspapers, are on the track CDC projected a couple of years ago. Those suggested that more than 200,000 people will die of AIDS in this country in the next few years. However, we are seeing only the final phases of the disease because we track only the AIDS patients. We do not know how many people are infected and asymptomatic. Various estimates are that 500,000 to two million people are infected. The estimate that most people agree on is about one million. The reassurances that we have been hearing about a slowing epidemic have no basis in fact.

The AIDS epidemic is not an epidemic in the classic sense. The classic epidemic rises exponentially, flattens out, and then tails off. However, AIDS is not one epidemic; it is many different epidemics with starting points in one place after another. Spreading then occurs from each of these points. If we think about the numbers, we should not accept the reassurances about heterosexual spread. It is simply a matter of time until the number of infected people becomes great enough that the statistical possibility of transmitting it heterosexually poses another expansion of the epidemic. There is nothing reassuring in the number of heterosexual people infected; they represent a constant percentage of an ever-increasing number of cases. This means that a critical mass can be reached in several areas, and permit spread as we have seen in other parts of the world where heterosexual transmission is obviously the major route.

Organization and Financing of Care

What we do about the care of AIDS patients? We provide supportive care. We provide AZT, which works by inhibiting the reverse transcriptase but is highly toxic. Those who can take it gain an apparent extension of life, but it is certainly no panacea

and it is not a cure. It is simply all that we have at the moment, along with therapy for secondary infections and support of patients. We have established a system that either ostracizes such patients or forces them into care in expensive hospital settings. We have not established enough of the out-of-hospital care programs which have been shown to be so successful in San Francisco and represent wise use of our resources and humane care for patients. Why not? In part because we have not addressed the financing of AIDS care.

In the early phases of the epidemic, when the gay community was most heavily hit, most patients were insured. Now, as the disease progresses more into the addict and poorer populations, less and less of the population has insurance. Two-thirds of the AIDS patients in New York state now rely on Medicaid for indigent care. In many states, where Medicaid coverage is not as good as it is in New York or California, AIDS patients may not qualify for Medicaid even though they have very few resources. People who were employed and insured could purchase a continuation of their insurance for 18 months, at up to 102 percent of their insurance premium, if they had the money. Many of them ran out of money after becoming unemployed and could not maintain that coverage. But they were disabled, so they would qualify under Medicare disability coverage but only after they had been disabled for 24 months. But even if they could afford 18 months of insurance after becoming disabled they still had six months in which they are uninsured, uninsurable, and disabled. Many of them died during that period.

That is the financing situation at present. It is a problem in any catastrophic illness and a particular problem in AIDS. It is a major problem that often forces patients in the direction of more intensive care by what it covers.

International AIDS

When the Institute of Medicine and the National Academy of Sciences released the report Confronting AIDS in 1986, we had a press conference that ran longer than usual. But there was not one question about the international aspects of AIDS. When we held a press conference on the 1988 updated study I purposely never mentioned the international problem, and there was still not one question about it. I then asked the press why they did not want to know and got no answer. Yet we are talking about a disease that is devastating parts of sub-Saharan Africa. It is wiping out the young adult, productive, managerial class. If you want to get crass, it is spreading in a fashion that makes investment in the industrial development of those countries a very bad investment. And we do not respond.

The investment of the United States in the international aspects of AIDS is, at best, modest. It is fragmented, with the result that we purchase a series of studies with subcritical amounts of money, giving us subcritical data, and allowing us to draw almost no conclusions about the epidemiology and spread of the disease. Yet

we lack the cooperation between the various participants in the international arena needed to come up with the focusing of their resources, even to get some answers.

That is the situation. What are the opportunities that we have for addressing it? Let us start with the research opportunities.

Confronting AIDS

We know a tremendous amount about the virus. We are recognizing that it has the ability to infect cells other than lymphocytes, and that those cells (e.g., macrophages) may offer the virus more protection than lymphocytes, and this protection may account for some of the viral latency.

We know a lot about the viral life cycle. We know its structure, how it attaches, how it gets into cells, how it is converted to DNA, how it is inserted into the host genome, how it reproduces, and so on. That should provide a series of opportunities for designing a treatment. There are also a whole series of supported activities in basic immunology and immunology related to AIDS which are ongoing and promising.

We are doing fairly well in treating the complications of AIDS. We have been testing drugs such as aerosolized pentamidine that reduces superinfection with *pneumocystis carinii* pneumonia, and we are now targeting the unusual mycobacterial infections of AIDS.

The epidemiology is a real problem. We have not been able, for political and social reasons, to apply reasonable sampling techniques that would allow us to know prevalence and incidence of HIV infection — not of AIDS the disease, but of the infection itself. So we are extrapolating from a whole series of partial observations, then seeing how close we come to what is actually happening. That cannot be the best way to operate; we need much better epidemiology.

We cannot effectively treat the virus once it is established, but we do know how it is transmitted. We know that behavioral modification would be useful, because the virus is transmitted by behaviors that we ought to know something about, such as sexuality. What in fact do we know about sexuality? We know what Kinsey told us about a selected Midwestern population in the 1940s and 1950s and we are extrapolating that to New York and San Francisco in the 1980s. This is an inadequate basis for our understanding and ability to project where the disease is going. It is also an inadequate basis for modifying high-risk behavior.

We must try to change people's behavior. Education is the only route we have. It is very hard to tell what works in education. We have considerable experience with other sexually transmitted diseases about what does not work. The military tried altering

sexual behavior through education by fear, demonstrating for instance the fearful events that follow infection with syphilis. They terrified everybody, but they never really followed up with good information about what to do to avoid those terrifying events. Failing to provide viable options to the behavior to be changed greatly reduces the chances of changing the behavior.

What are the strategies for prevention or cure? Reflexly, we say we'll vaccinate because it is a virus. That sounds good, except for a few small details. First of all, the virus is spread not only by attaching to a cell, but almost certainly by cell-cell fusion, and there are periods of time during which the virus may not be available to antibodies. Much more disturbing is that individuals who have AIDS have antibodies. But the presence of antibodies does not stop them from getting and dying of the full disease. So there is reason to believe that our regular strategies for approaching vaccine development may not be terribly effective. We are using animal models to develop vaccines. However, the pressures and hysteria surrounding AIDS have made us bypass the usually required animal model proof of efficacy. We have gone instead straight to humans in testing vaccines — with little evidence I know of that they will be successful. People seem to be reassured by our saying that we are testing in humans. We, as professionals who understand that this is not very sound, ought not to allow people to be so easily reassured. As far as we can tell, there is virtually no likelihood of having a vaccine ready for general use in the next five to ten years.

Drugs, I think, are a better possibility than vaccines. We do know the various stages of the virus' life cycle, and my guess is that we will develop combinations of drugs — as in cancer chemotherapy — hitting two or three sites in the viral life cycle at the same time to see if subtoxic levels of drugs can control viral replication. I think that that at least has some potential in the next several years.

If those are not going to be the ways in which we are going to be able to get at the disease now, what are we left with? We are left with classic public health. We once thought we had got ahead of infectious diseases with our machinery for epidemiology, and for public health education, and surveillance, and so on. The states that were the bastions of public health have let their departments go to seed. The public believes it has this kind of protective net sitting out here, but the net has giant holes in it in literally every state in this Union. There is no state now that has the type of public health apparatus that New York or Michigan had 30 years ago. That is going to be a problem in addressing AIDS.

We need to be able to track the epidemic. How do we track it? By testing. We can test for the antigen, HIV itself, but that is too expensive and not really better than testing for antibodies to HIV. As Robin Weiss and I wrote recently in an editorial in *The New England Journal of Medicine,* we seem to have become completely muddled on this issue. My sense is that testing policy has some very simple guidelines. The first question we ask is, "Why do we test?" Do we want to do the test for a purpose? The second question is "Do we have a good test?" If we do not have a good test, all

the good reasons are no help. If we have a good test, but not a good reason that is no help, either. If we have good reasons and a good test, then we proceed.

What are the good reasons? Protecting the blood supply, protecting semen, protecting tissues that are donated are valid reasons. Another valid reason, in most circumstances, is to identify people so that we can treat them, to slow the disease or eradicate it. However, we cannot treat HIV infection very effectively at this point. With the addition of more effective drugs, I hope to change my mind on whether we should test for that purpose. We can test so that the persons who know they have the disease will change their behavior. Unfortunately, we have absolutely no evidence that the behavior of people who are told that they are HIV positive is changed in any way. If we want to do testing and really work at changing behavior, we cannot do it without coupling it to counseling. There has not been a willingness to do that broadly yet, because it increases the expense dramatically. But without counseling I would have no idea what we are doing. Another reason would be to test for the purpose of changing the behavior of others. If you knew that when your patient came into the hospital and was positive for HIV that you would behave differently, then that would be a valid reason for testing. However, the CDC recommendations are that one operate with universal precautions assuming that anybody could be infected. If that is the policy of the institution then there is no basis for testing for that reason.

We could test so that we could intervene on behalf of others. This comes down to mandatory testing. We saw this in the premarital testing in Illinois. But what are we going to do after testing? Prohibit marriage? Prohibit pregnancy? What is the purpose? What is to be done with the information obtained by the mandated test?

We could measure the prevalence and incidence of the infection and that would be an extremely important and useful thing to do. It becomes important that we can be sure that we obtain a reasonable sample for this purpose. The problem is, how do we do that? What are people afraid of? Obviously people are afraid of a stigma. We cannot simply bring people in and test them because we have decided they should be tested. However, there are waiting lists of people wanting to be tested where confidential testing is offered. Positive test rates as high as 15 and 30 have been thereby found in some areas. People know when they have engaged in high-risk behavior. They will come forward if it is voluntary, available, and confidential. Belief in the confidentiality of the information is essential at this stage. What we need to do now is to develop mechanisms in which confidentiality and anti-discrimination are assured. Then we can go after some broader aggressive voluntary testing systems. My guess is that we will probably do reasonably well if we do it that way. But if we revert to a punitive strategy, I think we will drive people out of the system. This was demonstrated very effectively in Illinois, where the number of weddings dropped dramatically. People either went across the state line to get married or did not get married at all.

We need a testing policy. We need a response to drug addiction. Drug addicts may not come forward for testing readily, but might come forward for treatment. Drug

addiction is unquestionably the most rapidly growing route of spread of HIV infection. It is the route that will be the doorway to the heterosexual population and is already injuring a large number of children. There is a six-month waiting list for people trying to get into drug abuse treatment programs in New York, a six-month waiting list of those who have not given up on trying to get in. There are reasonable data now to indicate that people who enter therapy programs reduce their use of drugs and their likelihood of HIV infection. Anti-drug abuse treatment is a valuable though expensive activity, but we cannot rely on methadone programs because the major drug of abuse is cocaine. We need counseling and treatment programs for addicts if we are going to approach this disease, or most of what we are talking about is going to be after the fact, particularly in the poorer communities.

What about education? It has to be tailor-made. It should be targeted at the teenage population — at those experimenting with drugs, at those experimenting with homosexuality — and at certain segments of the adult population. There will not be a single way of doing it. Plenty of studies on behavior modification indicate that if you do not match the message to the culture, you only frighten people. You do not change behavior if you do not teach them not only what to be afraid of but also what do so that they can carry it out to avoid getting infected. If a behavior is changed and not reinforced, the new behavior will slip.

Mechanisms for Responding to AIDS

Those are some of the opportunities and problems we have. What is the apparatus we have for dealing with this? We have what I call a health care system that is really four or five systems in oscillating equilibrium, connected to each other only loosely and not connecting very rapidly in times of crisis. There is transmission of information and activity across these sectors but they can be totally isolated, one from the other.

We have public health — state, local, national. This is almost completely separated from health care delivery, and may be separated from biological research. We have health care delivery, public and private, with no coordinated system for the care of patients with AIDS. This is disconnected from public health. We have biological research, with very little feedback and communication to the practice and public health sectors. We have financing, which operates at a still further distance from the other sectors, and we have regulation. To show how disconnected regulation is, the government of the United States is now investing about $600 million to $700 million in research on AIDS, but because of an uncoordinated congressional committee system the government is not providing adequate resources to the Food and Drug Administration to evaluate the products of that research.

Nonetheless, certain things have happened that are impressive. The Centers for Disease Control picked up on AIDS when there were about 16 or 17 reported cases and began tracking the new epidemic. The recognition that this was something new

and worth paying attention to was picked up very quickly. The NIH and the CDC both began working on the causative agent and within three years we had information on the HIV virus as a cause of the disease. The CDC designed means of reporting and projecting, and the projections of the epidemic have been pretty good up to now. However, we are sitting on a large reservoir of HIV infection, the dimensions of which we do not know, and I fear those projections may get less good with time.

The FDA approved AZT faster than any other drug — two months. They also approved the tests for HIV antibodies in record time. But they did it by shifting resources out of other areas in the FDA, and there will be back up in those other areas. The press for vaccines and drugs has not proceeded very effectively, although there are at least attempts to set up testing networks. The problem is coordination. We have a disease that cuts across the departments of Health and Human Services, Defense, State, Justice, and Education, to mention but a few federal concerns, and we have the unseemly actions of a couple of years ago. The Justice Department was pursuing a course in exact opposition to the advice of Health and Human Service. We see in the development of vaccines a circumstance in which the NIH is pursuing one course, industry is pursuing one independent course, and the FDA is pursuing another independent course. The same is seen with drugs and it is made worse by the fact that the patients, who are desperate and dying, no longer trust the system to be responsive. They can see the fragmentation and conclude that if people were really interested in developing and getting drugs to them as rapidly as possible they would not be operating as they are. So the patients in New York and San Francisco get their own drugs, black market drugs. A clinical trial cannot be done if your patient is taking your drug and three others also. And the fact is that we do not have enough promising candidate drugs. It is not that the NIH are holding back; it is not that FDA is delaying; it is that we need to develop better conceptual frameworks and better targetting of drugs to go after AIDS. But we are now seeing pressure to shift into a very poor evaluation system — for drugs we know not to be effective. Hence we risk being distracted from developing the drugs and vaccines that we need.

Another unseemly lack of Federal coordination had to do with the DHHS trying to come up with an antibody testing policy in the face of active criticism by the Department of Education, which is neglecting its own role in AIDS education. This is almost a farce in the application of the best of modern science to the most fearful epidemic that we have confronted in our lifetime. This is unacceptable performance.

Recommendations

What do I think should be done? The same thing I have been thinking for the last three years. We need a coordinating mechanism in the form of a public/private body that reports to the President, the Congress, and the public. Its members should be the equivalent of Caesar's wife, people who are not there for their political positions. The President's Commission came out with a well-structured, reasonable report in

the short time they had. But if we put another commission in place, it cannot be for another one-year study. We do not need a commission to tell us we need a commission. We need a group to coordinate the activities of this country and stay with it for the duration of the problem or until we can begin to have realistic hope for a solution. That means that commission must be in place for years. It will continue to focus on the entire spectrum of activities against AIDS from basic biology through pathophysiology through clinical medicine through health services research through financing, and through international health. If it misses any piece of that, we will not have a properly coordinated program.

Such a commission will find great variations in the quality of effort against AIDS. In biology it has a pretty good show through the NIH. In health services research it does not have adequate activity going; this needs to be done much more effectively. In epidemiology a sound testing policy is needed that would give people protection from discrimination and could then be the basis for an expanded voluntary testing system. We can do mandatory testing when it is appropriate, for instance to protect the blood supply and tissue donation. When appropriate we can do it, if we have a treatment of the disease. We have to know when we are doing testing that we have something to offer. We might allow people to override some of the Medicare time boundaries that are totally unrealistic.

We need to recognize that the NIH is the source of basic research, and that the pharmaceutical industry is quite capable of developing and testing drugs if they have something to develop and test. The NIH should not fund drug testing at the expense of funding more basic research. Industry should fund drug testing, and the FDA should regulate it. The FDA needs the personnel and space to do that. And patients must be involved in the process so that credibility is built into it. We need all of this so that we can have a system that makes sense.

We need better organization and financing of care for AIDS patients. Effective models of care exist and should be replicated. The Institute of Medicine has recommended federal grants to states with heavy burdens of AIDS. Those grants should be expended according to guidelines focused on documented effective therapy and sites of care. Such grants would be a stop gap measure to provide time for AIDS to be integrated into a broader strategy for the care of patients with catastrophic illness.

When all of that has been done, we come back to the place where we are right now. We need education. We need to educate people in a manner sufficiently effective to change behavior. That is an extremely difficult challenge. We are talking about changing sexual behavior, knowing the history of the difficulty of so doing. However, it must be done. We need to experiment with it and evaluate it. Most of all, we need what we have been missing for the last several years, i.e. national leadership. I am not being facetious. I am saying that when we have a system in which there is a vacuum in credibility and leadership, we have a system into which any fantasy can flood. That is why we end up with mosquitoes, why we end up with books such as

that by Masters and Johnson, why we end up with a documentable cyclic response from the media.

As far as we can tell from picking up the papers, there is no AIDS epidemic going on in this country, although the number of people appearing with the disease and dying of it continues to increase at a very steep and frightening pace. Perhaps when the epidemic hits 100,000 cases the media will wake up to this devastation and then there will be a flurry of terrifying information. This could petrify the population back into paralysis and so alarm the media that they will then reassure the public again. Cycle after cycle...

Without a group able to vet for scientific and public health accuracy the information coming at the public, the public does not know what to believe. We find, as Blendon and Donelan describe in their recent article in *The New England Journal of Medicine* that the public is becoming more punitive and more biased against patients with AIDS the more it knows. Most of the people in this country have never seen a patient with AIDS, that will not be true in another two or three years. My concern is that if we do not step in now we will have a major social issue, in terms of what we will do to sectors of our population, that will rival the health issues of AIDS. In historical perspective, populations as educated to their times as we are to ours have been capable of fierce iniquities. This suggests that there is nothing that we would be incapable of doing.

I think we can only head off chaos by approaching AIDS as the kind of combined biological and social problem that it is. We cannot expect biology or social science to solve the entire problem alone. We need to bring both approaches together and expect both to be addressed appropriately at the highest level of our government. Until we do this, we shall have dissonance between science and policy which will continue to cost us lives.

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