ARTICLES

HIV LAW & POLICY: KEYNOTE ADDRESS

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We really find ourselves at an extraordinary time in this country, and in the world, with the convergence of multiple forces that are really unrelated. At the end of the twentieth century, we are about to embark on a variety of different arenas, all of which seem to be coming together to put us in a position where there are many opportunities in the area of HIV and AIDS, as well as many areas of concern: areas that have been neglected and areas that have been either poorly defined or not defined.

First of all, I think we have to acknowledge that the epidemic is continuing to expand, increasing in populations that, although present at the beginning of the epidemic, are now increasing in their rates of seroconversion: women in particular, minority women specifically, adolescent gay men, all integrated and related to the injection drug using population in our society. The inequities of infrastructure, I think, have been highlighted and are amplified in looking at these different trends within the epidemic. The data will show, over the next couple of weeks, a "plateauing out," an actual decrease in the number of people on an annual basis that seroconvert. This is a calculation and not a measurement, but all indicators seem to show that we are actually impacting on the number of new seroconversions in the United States. The estimates of 50,000 seroconversions each year remained flat and in 1996 and 1996 and actually may be showing some decline.

The number of AIDS-reported deaths will also begin to drop; we saw an inkling of this last year, where we saw it reflected in the number of seroconversions occurring in the pediatric cases, but we are going to see it reported soon in the number of adult cases. This drop in the death rates and in seroconversions I think is not attributable to the advances that we have had in the availability of protease inhibitors, but really has been due to the structural and infrastructure supports that we have been focused on over the last four years in the Clinton Administration that have increased dramatically our ability to identify individuals who are HIV-positive, to enter them into continuums of care, and more importantly, to retain them in those systems of care. Our ability to do that for spe-

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cific populations, to identify, enter, and retain, is really the key to our ability to deliver both prevention messages, as well as to enter individuals in continuums that ultimately lead to a drop either in their infective behavior or in their infectivity. The infrastructure commitments that have occurred in 1993, 1994, and 1995 have been substantial, focused predominantly in epicenters throughout the United States and in each of the states, mainly through the conduit of Medicaid and Medicare and to a significant degree in the area of the Ryan White CARE Act. The ability to identify points of access for difficult-to-reach populations and to put resources and dollars into delivery systems that are partially or not quite complete has really made the difference in these seroconversion trends. The last aspect of that is the treatment advances, which I will talk about in a second.

I think the second major force that has identified itself at this period in our time is the evolution from federal to state authorities and power structures. There is no question that the movement and authority for decisionmaking around issues of eligibility and coverage, around formulary development, as well as around infrastructure, scope and support, is now falling to state levels and state decision processes. The states hopefully will become more responsive to local needs as defined by the expansion of the epidemic on a local level, but also the diversity of infrastructure capabilities that you see as we move from one municipality to another. The downside to this movement from federal to state is a lack of uniformity. The diversity that we see within the Medicaid and Medicare systems is extraordinary in terms of eligibility and coverage, as well as in our ability to integrate our resources with delivery systems that meaningfully deliver services to individuals in need. I think that this evolution from federal to state needs to be recognized, and individuals in the legal profession and with leadership roles within your communities need to act as watchdogs as this transition occurs. We need to acknowledge that with the resource shift there also comes a shift in responsibility to be responsive to the totality of your community and not just to portions of it.

The third area that has engaged in a huge dialogue of reform is the welfare area, and Medicare and Medicaid in particular. The differences that we see across states with fifty to sixty percent of the adult population who are HIV-infected benefiting from Medicare and Medicaid services, and over ninety percent of the children benefiting from it, makes this really the cornerstone of our effort. Any attack or any reduction in those resource funding lines will have a profound impact in our ability to identify and retain individuals in delivery systems. This movement toward the state level, and manifested in local orchestration, is happening, and in many areas has already happened and will continue to happen over the next two-year period. Experiments looking at Medicaid labors and caring for the specific needs of HIV-infected communities have head starts. Some of the successes that we have seen have also been marked with some failures. I think that our ability to learn from the failures and to reproduce the successes also needs to be addressed with a higher level of communication going on between Medicaid-related bureaucracies within each of the state systems.

The fourth area that has been hitting the health care community is the advent of managed care systems. I trained at a time when we did not talk cost-effectiveness; we looked at differential diagnosis and treatment without any real

regard or training in thinking through cost considerations. As I went on to the faculty at the University of California, San Francisco, the shift in the medical school's emphasis to highlighting a cost-effective analysis reached an intense level, but paled as we realized that we really did not have enough data in most areas of medicine to do a true cost-effective analysis. There is no question that that does not matter in the managed care arena as much as we would like. People in private sector insurance companies have moved ahead quickly in making decisions around the scope and quality of care that are impacting our patients every day. Not only are these considerations limiting the range and arena of what is or is not available to individuals, but they also have limited the choices that individuals have in the locations or places in which they do receive care for what is a rapidly progressive illness in terms of a relatively short timeframe that requires ever-increasing resources to care for it.

This formula of a chronic disease with increasing needs over time is a formula that generally is not embraced in the managed care world, and considerations around discrimination, patient selection, exclusions, and the inability of individuals to have real recourse in or out of a job setting are going to be predominating issues for the legal profession in the next few years. I think that the managed care arena will begin a dialogue internally, out of necessity or perhaps pushed by the legal system in terms of holding people accountable for these decisions, and will probably swing back to a more reasonable position, where the trained professionals in the medical field are again brought back into a dialogue around what is and is not appropriate. But until that occurs, the individuals who are going to get hurt from this incomplete dialogue until will be the chronic disease patients, and HIV is a perfect example of that. I think that we have an obligation as a society to foster this dialogue and to complete it as soon as possible.

The last area are the advances that have occurred in medical treatment. There is no doubt that the advent of anti-retroviral treatment in the form of the protease inhibitors is making an impact on our ability to arrest progression of the disease and improve the quality and decrease the morbidity in an individual's progression. There is also no doubt that the advent of the protease inhibitors is not a uniform answer to the spread of the virus within an individual, but is definitely part of the solution. Individuals from the original studies that now are a eighteen months out have shown originally that in about eighty-five percent of individuals on three-drug therapy, using nucleocyte, AZT treatments, and the protease inhibitor indinavir, showed a response in eliminating the virus from their circulating blood that was quite dramatic. Individuals with 100,000 copies of virus per milliliter of blood going were down to undetectable amounts. That still left fifteen percent of the individuals from the earliest studies who did not respond to this therapy. I want to underline this point: three-drug therapy is not an answer for everybody. It was never presented as an answer for everybody and we need to remember that. We also need to remember that for the eighty-five percent who do respond, they will not respond unless they have access to the medication.

These are complicated cocktails. The combinations require a sophisticated understanding of how the drugs work but also how to respond to initiation of the therapy in an individual to get them through that initiation period into a pe-

riod of maintenance, and then to effectively monitor them with viral-load testing and CD4 testing over time to keep them there. The options that are available to clinicians now in the area of anti-retroviral therapy have made a huge difference in our ability to address the progression of HIV in individuals. There is hope that this drop in viral load being observed with the combination therapy will also reflect a drop in infectivity. There is indirect evidence that the drop in infectivity is real; there is also some evidence that it is not an absolute relationship, and that some individuals with low viral loads still will remain infected. But the overall trend of infectivity is clearly dropping with the advent of three-drug therapy.

The drugs are expensive; people have heard that the cost considerations are huge: $7000, $8000, to $12,000 per month are the estimates as you move across the country. Individuals who are in this constellation of therapy also need to be in a delivery system that is responsive to their needs twenty-four hours a day, seven days a week. Our hope is that people who have started the drugs do respond and will decrease their utilization of emergency rooms and hospitalizations, but that is yet to be determined. It is our responsibility to be ready for the needs of this population in the protease era or without.

The final area that I wanted to bring in as one of the divergent forces that are converging here is the continued realization of inequities within our society. We are once again, with the advent of HIV, put in a position where we are reminded that we are not in a world where there are equal playing fields within our populations. Individuals who are able to access delivery systems will require not only that the delivery system be available, but that it be embracing or nurturing or conducive to the cultural, ethnic, and gender-diversity that our society is so richly blessed with, and that that be reflected in our ability to take care of individuals in times of crisis. Insensitivity to those needs is a profound barrier to care. It has been shown over and over again, and with HIV I believe it is highlighted once again.

The virus has always amplified the issues that are predominant in our society. One of the remarkable things about the AIDS epidemic is that it has turned spotlights on those areas of our society that have always been there but once again are brought to light. The diversity in our population is not reflected in the diversity in resources and is not reflected in the diversity of options. Indeed many aspects of our AIDS epidemic in the United States, especially the injection drug using population, are quite flatly disenfranchised from our society, are participating in a felonious act, and are hesitant to interface with institutions such as medical delivery systems that are not sensitive to the specific needs and peculiar needs of an individual who is concerned around revealing himself or herself to institutions. It is time for us to turn our systems toward these populations, and acknowledge their needs, define them better, and develop systems that embrace them in a continuum of services that once again enters them in a delivery system, retains them in a delivery system, and follows them over time.

The inequities at all these levels, the individual liberties within minority populations, the sexual preference differences, and the discrimination that is manifest with individuals whose HIV status that is revealed both in their private lives and in the workplace, are all barriers that present themselves to the individual and their decision to engage themselves in a system that will hopefully

improve their life quality and, from a public health perspective, decrease their ability to infect others. Your efforts in the school and in the efforts with your AIDS Legal Assistance Project are just the types of efforts that need to be focused and developed in areas that are convenient and available to the populations that we are concerned with. We need to ask ourselves if we are honestly engaged in the work that will result in maximizing our ability to identify and retain. The leadership role that you will play, that this meeting will begin a dialogue in, to better define the key issues and to take these issues and take the next step with them into a discussion around the policy concerns, is crucial. The HIV epidemic is at a potential turning point but that potential will not be realized if we cannot orchestrate systems of care that continue to be realistic and responsive to real people, in real time, and in real places.

I look forward to the deliberations that you are about to embark upon, the areas that your panelists have defined: the social constructs of HIV, the impact on Medicaid reform for HIV, the partner notification issues and the ramifications they have for both the individual and the society they are in, access to breaking clinical trials, and access to informed, effective legal services that can address the discrimination that is evident throughout the legal system. All of these are key policy issues that will continue to present themselves, each with a different slant depending on the population you focus on. I look forward to the deliberations, and I look forward to the development with you of strategies that effectively address them, and I once again thank you for the opportunity to talk with you. Thank you very much.