FOIA Number: 2018-0755-F

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Subgroup/Office of Origin: National AIDS Policy Office

Series/Staff Member: Patsy Fleming

Subseries: National AIDS Strategy

OA/ID Number: 10182

FolderID:

Folder Title:
Patsy Fleming Speeches - July 1996

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Remarks By

Patricia S. Fleming

National AIDS Policy Director

to

Eleventh International Conference on AIDS

Trinational Luncheon

July 9, 1996

GOOD AFTERNOON:

It is certainly a pleasure and an honor to join you today for this historic event.

Secretaries Shalala and de la Fuente and Minister Dingwall have eloquently described the importance of this trinational declaration and the impact it will have on the people of the United States, Mexico, and Canada.

The theme of this luncheon is "Creating and Enhancing Health Care and Social Services for HIV Affected Families." Those of us who are in this room today know the tremendous impact that HIV has on a family. The emotional, physical, and spiritual strain of a disease like AIDS can often tear a family

apart. It can tear a community apart. And it can tear a nation apart.

Each of us in this room has seen the very real consequences that AIDS has on a family. We have seen the children orphaned by the death of not one but both parents. We have seen grandparents raising their grandchildren. And we have even seen children left on their own, having watched their parents and their grandparents killed by AIDS.

So we have seen the tragedy of this disease first-hand.

But we have also seen how AIDS can bring us together. And that is exactly what AIDS has done for the nations represented here today. It has brought us together in a spirit of unity and purpose. It has forged new agreements and built

new bridges between our nations and our people. And it has caused us to explore new ways to deliver services to our people.

Today's meeting and the work that will follow it are important steps in our global response to HIV and AIDS. Each of the nations represented have helped to advance that response. Our joint efforts in research, prevention, and care have created models for other nations to follow. But clearly much more needs to be done.

We are all rightfully optimistic about the promise of the new therapies that have been approved in recent months. If they are as effective as they now appear, we could truly be living through a turning point in this pandemic.

But new drugs, no matter how effective, no matter how speedily approved, mean nothing to a woman living in a developing country where the price of aspirin is prohibitive and the thought of protease inhibitors is but a dream.

And new therapies are meaningless unless we make sure that our health care professionals are up to date with the new developments in science.

It is our task, as leaders of government, and as leaders of affected communities, to resolve these difficult but important issues. Now, more than ever, we will need to pull together. We will need more innovation and more cooperation. And, we will need greater resources.

All of this requires an alliance of the heart and of the mind. It requires an alliance that crosses all our borders. And it requires an alliance of governments and the people we serve.

We have succeeded in building those alliances. The presence of so many of you in this room today are evidence of that. So we have a solid base on which to build.

The work ahead won't be easy. But our mothers taught us that nothing worth its while is easy.

Thank you.

Remarks By

Patricia S. Fleming

National AIDS Policy Director

to

Eleventh International Conference on AIDS

STDs Workshop

July 9, 1996

GOOD AFTERNOON:

Thank you for that kind introduction. It is an honor to join you today to discuss a subject that is near and dear to my heart.

It is sometimes difficult to believe that the pandemic of HIV and AIDS has been with us for 15 years. In that time, more than a million women, men, and children have lost their lives and millions more are living every day with this deadly virus in their bodies.

This epidemic has torn at the fabric of our society and at the structures of our communities and our families. It has created untold misery for the millions of people who love and care for those who are infected.

But AIDS has also brought us together, forging new partnerships and new movements. It has strengthened our resolve to fight for the rights and the needs of those who are affected. And it has unified our nations against a common enemy.

Those alliances have helped us to share information and lessons. One important lesson has been the need to focus our attention and our efforts on the prevention and treatment of sexually transmitted diseases.

We know from the work being done all around the world that infection with STDs make people -- especially women -- much more susceptible to HIV infection. We know, too, that by controlling STDs we can achieve a significant reduction in the number of people who become infected with HIV.

But we also know that women are much more susceptible to STDs; they are more difficult to diagnose; and they are more difficult to treat. Finally, we know that complications from STDs, like pelvic inflammatory disease, can cause serious health problems in women.

Take a look, for example, at chlamydia, which has reached epidemic proportions in the United States. Approximately one in ten adolescent females in the U.S. between the ages of 15 and 19 are believed to be infected with chlamydia. The same holds true for approximately 1 in 20 women between the ages of 20 and 24.

These kind of numbers make it clear that we have a large task before us. We need better diagnostic tests. We need

more basic research on the pathogenesis of STDs. And we need more methods of prevention.

There are a number of methods available to us to control STDs, but it is also clear that those methods are not as effective as we would like them to be.

That is why I am such a passionate proponent of research and development of topical microbicides.

Currently, women have very few prevention methods available to them that they can control themselves. The advent of the female condom was certainly a welcome development. But, so far at least, the female condom has not been widely accepted by women in my country and in most countries around the world. That is not to say that we should

not continue to work to improve that product and promote its use.

But other methods are needed and a microbicide is at the top of the list. A safe and effective topical microbicide can prevent HIV infection as well as a long list of other sexually transmitted diseases.

A microbicide is likely to be easy to apply and can be applied without the knowledge of a woman's sexual partner. It can be tasteless, odorless, and virtually undetectable. And, perhaps best of all, it can be inexpensive. Combined, these factors build a strong case for the rapid development of a microbicide as a powerful tool to fight sexually transmitted diseases.

Just yesterday, Donna Shalala, Secretary of Health and Human Services, announced a four-year $100 million initiative to develop a safe and effective topical microbicide by the year 2000.

This will require unprecedented cooperation among nations and between government and the private sector -- especially the pharmaceutical industry. And it will be a challenge for all of us to keep the pressure on and make sure that this initiative is successful.

We have a unique opportunity to change the lives and the future of millions of men, women, and children around the world.

Marshall McLuhan, the great Canadian philosopher, may have been the first to talk about our global village.

Well, today, our global village is threatened by sexually transmitted diseases including HIV and AIDS.

It is our job as scientists, as public health professionals, as activists, as citizens of this planet to take back our future.

It may well take a village to raise a child, but it also takes the commitment and the passion of millions of individuals to preserve a village.

I know that we are up to that task. We all know that we must be.

Thank you.

Remarks By

Patricia S. Fleming

National AIDS Policy Director

to

Eleventh International Conference on AIDS

Symposium on Treatments in Developing Countries

July 9, 1996

I Greetings and Acknowledgements: Jairo Pedraza and GNP+, Peter Piot, UNAIDS; Elizabeth Reid, UNDP; Dorothy Blake, WHO.

II Time of Great Hope

A. This is the most promising time in the 15 years of this pandemic.

1. Our knowledge of HIV is much greater.

2. AZT as an intervention to reduce perinatal transmission is beginning to show results -- 10% reduction in the number of HIV+ babies born in the U.S.

- But access to this lifesaving treatment by women in developing countries is yet to be accomplished

3. Protease inhibitors are approved and on the market

- But again, they are not available in developing countries.

4. UNAIDS reports certain countries (Thailand) showing a decline in HIV seroprevalence among specific populations, and other countries (India and Nepal) are reporting declines in rates of sexually transmitted diseases as a result of early STD treatment, increased condom use and needle exchange programs.

- But STD treatments, condoms or clean needles are not accessible in many countries

B. Important work ahead:

1. More research on protease inhibitors: Long-term effects; dosages; combinations; resistance.

2. More prevention research on what works and why: Condom promotion and distribution; behavior change and communication campaigns; treatment of STDS and tuberculosis.

C. Epidemic is Growing

1. 20 million women, men, and children are infected now

   - 4 million infected in the past year alone

- By the year 2000, the world total will be 30-40 million people infected.
- 6000 new infections every day
- Subsaharan Africa remains the region with the highest HIV prevalence. However, we are starting to see alarming statistics from the South-East Asian countries, and it is predicted that these numbers will soon surpass those in Africa.

3. Women and youth continue to be heavily affected
   - WHO estimates that almost half of all newly infected adults are women with a disporportionate number young women and girls. The UNDP reports that 70 percent of all

HIV infection in women worldwide is in young girls and women aged 15 to 25.

- Approximately 1 out of every 2 infections occurs in women worldwide

- Close to five million children will have been orphaned in this decade alone with estimates that the numbers will increase to 15 million worldwide by the year 2000.

D. U.S. International Commitment

1. Full commitment to UNAIDS -- largest contributor

- The US feels a sense of urgency and committment to work with you on this important issue
- The US fully supports this initiative

2. Paris AIDS Summit Declaration

- The US was one of the signatory countries and supports the GIPA initiative, the greater involvement of people living with AIDS in all AIDS programs

3. Fighting for international assistance budget

- Despite pressures from Congress, President Clinton has maintained his support for international HIV/AIDS programs that are reflected in the FY97 budget.

E. Access and Costs

1. Virtual absence of treatments in many developing countries (80 + % of cases are in Africa, Asia, and Latin America)

- We need to increase efforts to ensure that existing treatments currently available in developed countries such as treatment for STDS, anti-HIV treatments, alternative therapies and treatments for HIV-related illnesses, are made available to PWAs living in developing countries.

2. In many countries, people can't even afford aspirin. For them, protease inhibitors are unrealistic.

- Low cost essential drugs, including those for STDs and tuberculosis, are in short supply in many countries - problems that are now exacerbated by the additional burden of illness imposed by HIV/AIDS. Although we are concerned about the problem of providing AZT and protease inhibitors, we

should also not neglect to provide aspirin and bactrim to prevent PCP pneumonia.

F. What Can We Do?

1. We must maintain and, if possible, increase our international assistance.

- Because of the current economic and political climate in all of our countries, both developing and developed, we simply must do more with less.

2. We must continue to work to develop preventive measures -- including microbicides and vaccines-- that are effective and affordable .

- In addition to efficacy and affordability, we must also find a way to make these preventive measures

accessible, for it does no good to know that these treatments exist, if they are not available to those in developing countries.

3. We must train health care professionals in primary care, prevention and to diagnose and treat AIDS related illnesses.

- Hospital staff and medical workers need training to understand the problems of HIV infected patients, and eliminate discrimination and other negative attitudes they might display while caring for their patients

4. We must step up our efforts in STD prevention (43% reduction in HIV infection)

- We should increase efforts to treat STDS, increase access to drugs and information and education campaigns

5. We must work with the pharmaceutical industry to find ways to lower costs for antiviral treatments and prophalaxis for opportunistic infections.
   - Get pricing agreements

6. Work with Sponsors of clinical trials to get them located in developing countries
   - All people living with HIV/AIDS should have free voluntary and informed access to therapeutical and vaccine trials respecting ethical principles.

7. Work with NGOs and others to train people to be treatment advocates.

- Training and technical support for NGOs and others such as community health workers in developing countries to be treatment advocates so people will know what treatment is needed, what treatment is available and how to advocate for what they need.

8. Purchasing of generic drugs instead of proprietary drugs that are more expensive

9. Asking funders like the World Bank to increase their support for medications

10. Setting up buyers' clubs

Finally, During its most recent meeting in Geneva this past June, the PCB asked UNAIDS to enhance its activities in this

area of increasing access to antiretroviral drugs, drugs for associated conditions, and care.

We are pleased to be here today to share in this very critical discussion with you.

Thank you.

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Remarks By
Patricia S. Fleming
National AIDS Policy Director
to
Eleventh International Conference on AIDS
Microbicide Workshop

July 9, 1996

GOOD AFTERNOON:

Thank you for that kind introduction. It is an honor to join you today to discuss a subject that is near and dear to my heart.

The fight to protect women against HIV is not a new one. It is one that all of us in this room have been waging for more than a decade.

We have made some progress, but as one of my favorite political buttons would say:

"We haven't come <u>that</u> far and <u>don't</u> call me Baby."

In the United States we have launched a major natural history study of women and HIV. We have included more women and more children in AIDS-related clinical trials. And we have expanded our research efforts into female-controlled barriers, including the female condom.

In February, Vice President Gore met with the leaders of 11 pharmaceutical companies and leading AIDS researchers from the National Institutes of Health to discuss ways to accelerate our progress in the development of AIDS vaccines, therapeutics, and microbicides.

And tomorrow, Secretary Shalala will discuss some further actions we plan to take in this area.

This panel discussion could not be timed any better.

All of us know the promise of microbicides. And all of us know how difficult it is to overcome the institutional resistance to this field. After all, microbicides aren't glitzy. They certainly won't win any Nobel prizes. They are relatively low-tech in an era in which high-tech means high priority. And, let's face it, they are female oriented in a world that remains male-controlled.

Does that mean the fight is over? Does that mean the battle is hopeless? Of course not! It just means we have to fight that much harder. One of my favorite quotes came from the former governor of Texas, Ann Richards, who noted that Ginger Rogers had

to do everything that Fred Astaire did and she had to do it backwards and in heels.

So, as women we know what it means to fight hard for something we believe in. Microbicides are something we all believe in very much.

Microbicides can give women the power to control not only their sexuality but their vulnerability. They can allow women to protect themselves by themselves. And they can accomplish those important goals without placing women at risk for abuse or condemnation.

The need for a microbicide is obvious and it is immediate. Of the 20 million women, men, and children already believed to be infected worldwide, more than half are women. Worldwide, more than 80 percent of HIV infections are acquired heterosexually and we know that women are more vulnerable to infection than are men.

Most current barrier methods are male-controlled and require mutual consent. And we know that for many women, asserting their right to demand a condom can often result in violence. And the only female-controlled barrier method -- the female condom -- is neither widely accepted nor widely used.

As a result, far too many women are at risk because they won't or they can't gain control over that risk.

This is not to say that topical microbicides benefit only women.

First, it is likely that some of the products we develop in this field will be useful for men, too.

Second, by reducing the number of women who become infected with HIV, we will also reduce the number of babies -- male and female -- who are born infected.

We have made some important inroads to microbicide development. But clearly we have more work to do.

I look forward to the discussion we will have today. Some of the world's experts in this area are with us today and I'm sure that we all will benefit greatly from what they have to say.

Thank you.

Remarks By

Patricia S. Fleming

National AIDSPolicy Director

The White House

Washington, D.C.

TO

Eleventh International Conference on AIDS

Chair, Distinguished Lecturer Series

July 11, 1996

Jonathan Mann once again challenged us provocatively. Dr. Mann discussed his perception that solidarity is over and we are moving apart--rich and poor, North and South, men and women, gay and straight, infected and uninfected. But the global pandemic of AIDS has not caused this societal separation, but has illuminated the chasm between rich and poor, the vulnerability of gays, drug users, and the subjection of women that has existed long before AIDS.

With regard to AIDS, some of these societal preconditions, or cofactors to infection, are homophobia, sexism, racism and poverty--found in developed and developing countries alike.

As an African-American woman, mother of a gay son, it is clear to be that these societal negatives are issues of human rights. In the case of homophobia, societal condemnation can lead to a devaluation of the gay or lesbian individual which is internalized. The resulting loss or prevention of self-esteem can lead that person to take behavioral risks that someone with a healthy self-concept would try to avoid. I have heard young gay man say - we feel HIV infection is inevitable for us , so why paractice safe sex?

It is essential to promote self-worth and self esteem among young gays and lesbians people of color in majority--white societies and the most vulnerable among us--especially women everywhere--in order to prevent HIV infection and promote public health in general. And poverty is also a cofactor of AIDS--in both developed and developing countries. So many are poor to begin with; almost all then die poorr.

Mary Atkinson's presentation on compassionate access to experimental therapies and Jonny Galvao's speech on community responses to the HIV/AIDS epidemic point toward the unprecented role that AIDS advocates and activists have played in this epidemic. The community of persons living with HIV and AIDS and non-governmental especially in developed countries such as the U.S. have changed drug research and regulation policies. They could be the change agents in developing countries as well.

The hot topic at this conference has been the smazing results achieved with protease inhibitors. But nearly as much discussion has been dedicated to the issue of access to these promising therapies and other treatments for HIV and oppurtunistic infections.

In the U.S., the President has made clear that he will continue to fight for that access by maintaining the Medicaid program which covers 50% of people with AIDS and by continuing to fund the Ryan White CARE Act which pays for drugs for another 15% of the PWAs in the U.S. But for the developing world, we must also take action. Access to even the cheapest drugs is limited ot nonexistent in some countries. We could begin with drugs to treat STDs, TB, pneumonia, and fungal infections and with painkillers.

But it is not enough to improve access to these drugs. The hope that AZT as an introvention in perinatal transmission and the new antiretroviral drugs bring must be extended to all who need them. The sun is not yet shining, yet, as Yolanda Simon said, there are glimmers of

light. As life saving therapies are developed, it is not acceptable for them to be available only to a small percentage of the people around this world infected with HIV.

We must develop stronger, more effective partnerships between the pharmaceutical industry, governments, NGOs, international financial institutions, international organizations such as UNAIDS, and the community of persons. We must identify mechanisms that can simultaneously respect intellectual property rights andimprove access in developing countries. WE must held networks of NGOs and PWAs to become treatment advocates in their own communities usingthe models developed in the U.S.

We should not let the magnitude of the problem of access to drugs daunt us. Every small step we take is progress.

Tuesday night I attended a symposium on this issue where nearly 300 PWAs, NGO representatives, government officials, representatives of two or three, and others met to begin planning strategies to address this problem. It was a remarkable experience and the recommendations they produced were excellent. It was an example of the spirit of collaboration, cooperation, and partnership I have witnessed at this conference whose theme is One World One Hope. I want to emphasize as both Maggie Atkinson and Jonny Galvao's presentations did that no voice rings louder or clearer than the voice of someone living with HIV or AIDS. No public official or drug company executive can for very long ignore these voices. So I say to the affected community: Keep your voices loud and clear. As Peter Piot said, now is the time for audacity.

Thank you all for coming to hear this group of distinguished lecturers.