HIV/AIDS Drug Donations and Price Reductions in Sub-Saharan Africa

PROCEEDINGS

Edited by Margery Boichel Thompson

INTRODUCTORY REMARKS

Dr. Elaine Wolfson, Founder and President, Global Alliance for Women's Health

This roundtable on HIV drug donations and price reductions in Sub-Saharan Africa is a public-private discussion on drug registration, diversion, and other challenges. It is co-sponsored by the Permanent Missions to the United Nations of Angola, Benin, Burkina Faso, the Kingdom of Lesotho, the Republic of Mali, the Republic of Mauritius, Niger, and the United Republic of Tanzania, all of whose representatives are seated around the table. Our colleagues in the private sector are also here to talk, including Dr. Jeffrey Sturchio and Susan Crowley from Merck & Co., Inc, Mark Speaker from Bristol-Myers Squibb, and Heather Lauver from Pfizer, Inc.. The room has filled up with people concerned about the issues of HIV/AIDS and the movement of drugs in country. I am pleased to see Dr. Desmond Johns of UNAIDS here and am really delighted at the turnout.

Many people have enabled us to present this program. Merck & Co., Inc has given us a partial grant. The Global Alliance for Women's Health (GAWH) and its advisory board members have been especially important, including Ambassador Emilia Castro de Barish, Alice Shiller, and Barbara Magner who are present today, as well as public-private advisory board members such as Christine Kapalata and Susan Crowley. They have enabled us to continue the Alliance's work of addressing women's lifelong health and to focus a campaign on creating and expediting access for women to the treatment of HIV/AIDS.

Some of you know that the Global Alliance for Women's Health will soon be nine years old. We have been working at the United Nations here and in Geneva and in many countries around the world. Our work has been largely advocacy and education, but we recently received a donation from Johnson & Johnson for

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a palliative drug for HIV/AIDS, Tibozole, which is en route right now to Burkina Faso and will be delivered to ambulatory care centers for the treatment of people with oral thrush. A representative from Johnson & Johnson, Dr. Gary Noble, is here at the Roundtable. We have also received a grant from the Accelerating Access Initiative to continue roundtable discussions with African government Ministers in Geneva and Ethiopia. In Geneva we plan to hold a roundtable with Health Ministers at the World Health Assembly; in Addis Ababa we will meet with Finance Ministers and Development Ministers attending the Economic Commission for Africa meetings. We feel very blessed that we will be able to move this issue into the governmental arenas and articulate concerns for women in HIV/AIDS.

But our concern here today is broader. We are concerned with people in Africa living with HIV/AIDS who are in need of treatment. We have addressed and narrowed our focus to look at some of the issues involved in getting drugs into countries. Frequently, when we hear that 29 million people in Africa are living with HIV/AIDS but only 50-60,000 people in Africa are receiving antiretrovirals, we wonder why people are unable to get drugs? Many, many issues are involved, some of them technical issues. We know that the drug companies have reduced their prices considerably in the past two to three years. We know that many drug companies are donating many drugs free of charge for palliative care and some antiretrovirals. We want to see where the roadblocks are. As we have discussed different issues with UN missions, it occurred to us that it might be useful if we could all sit around the table to exchange ideas. So, there will be no power point presentations, no slides, but just talk at this roundtable. We are all familiar with talk, but I hope this talk will be open and transparent. Participating presenters will have an opportunity to review an audiotape of their comments.

It gives me great pleasure to introduce our co-chair, His Excellency Ousmane Moutari, permanent representative of the Permanent Mission of Niger to the United Nations. Ambassador Moutari has worked in the diplomatic field since 1979, when he became Niger's ambassador to the Soviet Union. Nine years later, after a number of other important positions, including posts in Morocco and Saudi Arabia, he came to New York as Niger's ambassador to the United Nations. In Niger he served two years as diplomatic advisor to the Office of the President and permanent secretary at the Ministry of African Integration. He has been educated in public law and received a maitrise in international relations from the University of Cameroon Faculty of Law and Economics. He holds a professional degree from the International Institute of Public Administration in Paris and a Master of Public Administration degree from the Robert S. Wagner School of Public Service at New York University.

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KEYNOTE REMARKS

H. E. Ousmane Moutari, Permanent Representative, Permanent Mission of Niger to the United Nations

I would like, first of all to thank the Global Alliance for Women's Health and its president, Dr. Elaine M. Wolfson, for convening this meeting to address such an important issue and for affording me the opportunity to speak. I am privileged to join Dr. Wolfson in welcoming our guests and in thanking the representatives of Merck & Co., Pfizer Inc., Bristol-Myers Squibb, and Johnson and Johnson who are here with us today. Their presence is most highly appreciated, as it translates the full commitment of those pharmaceutical companies to contribute to the international partnership against AIDS in Africa.

According to the December 2002 AIDS Epidemic Update, released by WHO in collaboration with UNAIDS, 42 million people live with HIV/AIDS worldwide. Sub-Saharan Africa, with nearly 30 million living with HIV/AIDS, has the highest number of HIV-positive individuals in the world. It is estimated that more than 4 million of those infected have a sufficiently advanced stage of the disease to warrant antiretroviral (ARV) treatment, but only about 50.000 are actually receiving it.

Nothing can more vividly illustrate the emergency situation created by the HIV/AIDS epidemic in Africa than the extraordinary proliferation of AIDS orphans. Their numbers have reached 11 million. By 2010, 20 million African children will have lost one or both parents to AIDS.

In industrialized countries, antiretroviral drugs (ARVs) have greatly improved the prognosis for people living with HIV/AIDS. However, 95 percent of people with HIV/AIDS live in developing countries, most in sub-Saharan Africa, where access to these medicines remains unacceptably limited. As new resources become available to provide HIV/AIDS treatment and care both at bilateral and multilateral levels, major opportunities now exist to greatly expand coverage. But challenges remain in implementing national treatment programs.

We are grateful to those pharmaceutical companies that are responding to international calls to the private sector to engage in partnerships with African governments for expanding the global response to HIV/AIDS. Our roundtable today is part of those efforts undertaken to explore practical and specific ways of

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working more closely with the private sector to accelerate access to HIV/AIDS–related care and treatment in Sub-Saharan Africa.

This public/private cooperation should be based on principles that reflect a common vision of how the HIV/AIDS epidemic can more effectively be tackled in developing countries. Among those principles are the following:

- Unequivocal and ongoing political commitment by national governments.
- Strengthened national capacity.
- Engagement of all sectors of society at the national level and of the global community.
- Efficient, reliable, and secure distribution systems for medical supplies.
- Significant additional funding from national and international sources for long-term success.
- And continued investment in research and development by the pharmaceutical industry.

For those among the pharmaceutical companies who have been pioneering initiatives to increase the standard of care for HIV/AIDS patients in different parts of the world, please feel free to share with us your experience of the best practices worth replicating in Africa. We know, of course, that even with the cost of medicine removed as a barrier to access, it requires collaborative efforts from NGOs, government health institutions, private foundations, and competent international organizations to fight HIV/AIDS in the poorest regions of the world.

We will be very glad to hear today from our private partners what they see as obstacles confronting them in carrying out their commitment to accelerate access to HIV care, support, and treatment and how our respective governments may help. Speaking on behalf of my country, the Republic of Niger, which is among the fifteen countries of the Economic Community of West African States (ECOWAS) that signed a formal statement of intent in July 2002 on the occasion of the XIV International AIDS Conference in Barcelona, I can assure you that we will do whatever is necessary to ensure that medical supplies and other consumables procured by public and private sectors or by NGOs are made available to people who need them at the appropriate contact points within our national health system.

To this end, we are ready to work closely on the operational level with all the stakeholders, including public and private donors, the United Nations system, and non governmental organizations, to avoid diversion, to increase accountability and transparency in HIV/AIDS distribution, and to address national barriers likely to hinder access to treatment.

Dr. Elaine Wolfson, Global Alliance for Women's Health

Thank you very much, Mr. Ambassador. It gives me great pleasure to turn the floor over to the other co-chair of today's program, Christine Kapalata, Minister Counsellor of the Permanent Mission of the United Republic of Tanzania to the United Nations. Many of you in the audience who work on women's issues and children's issues know Christine very well from her work on the Third Committee. I am also pleased to remind us all that she was a chairperson of the Ad Hoc Committee of the Whole for the 23rd Special Session of the United Nations General Assembly (UNGASS) entitled, "Women 2000 — Gender Equality, Development, and Peace for the 21st Century". We are delighted that she has been such an active member of the group that has cosponsored this meeting and that she has agreed to serve as its co-chair. She will be followed by Dr. Jeffrey L. Sturchio of Merck & Co., Inc.

IS HIV/AIDS AN EMERGENCY REQUIRING URGENT ACTION?

Christine Kapalata, Minister Counsellor, Permanent Mission of the United Republic of Tanzania to the United Nations

Let me begin by expressing a special appreciation to the President of the Global Alliance for Women's Health, Dr. Elaine Wolfson, for her initiative in holding this roundtable discussion today. I also wish to recognize and acknowledge the presence and participation of the representatives of pharmaceutical companies. My government is very pleased to be part of this initiative, which is also cosponsored by some other African permanent missions here in New York. I will try to address the issue of HIV/AIDS from the gender perspective and in the process discuss the question of whether HIV/AIDS constitutes an emergency that requires urgent action.

I would say that the question whether HIV/AIDS is an emergency requiring urgent action was answered in the Declaration of Commitment on HIV/AIDS that resulted from the special session of the General Assembly held in June in 2001. In the first article of that declaration, Heads of State and Government declare that they had assembled, and here I quote, "as a matter of urgency to review the problem of HIV/AIDS in all its aspects". They went on to express their deep concern in article 2 that HIV/AIDS, "through its devastating scale and impact constitutes a global emergency and one of the most formidable challenges

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to human life and dignity." That was almost two years ago. At that time the number of people who had been affected by HIV/AIDS was put at 36 million, of whom 70 percent lived in Sub-Saharan Africa. By the end of 2002, the number of people affected with HIV/AIDS had risen to 42 million, as we have just heard from Ambassador Moutari. According to UNAIDS, by the end of that year, women for the first time comprised 50 percent of the 42 million people living with HIV/AIDS worldwide. In Sub-Saharan Africa the percentage was even higher; it was put at 58 percent.

I quote these figures because I want to show that for women and girls the emergency is real, the vulnerabilities are many, and urgent action is indeed required. Why am I saying this? I would just ask you to consider the plight of women and girls. In almost all the countries of Sub-Saharan Africa, women and girls are biologically, culturally, socially, and economically more vulnerable than men. It is women who bear the burden of care. They are the ones who have to deal with the risk, the pain, and at times the condemnation of mother-to-child transmission. In most cases, they do not have the power to negotiate sexual safety. More often than not they find themselves at the tail end of the treatment queue. They suffer stigmatization, which in some cases makes them victims of violence. If this does not require urgent action, I do not know what does.

I would argue that for women, the HIV/AIDS pandemic is a crisis of emergency proportions. That the number of women who are infected is on the rise worldwide should be a call to action for governments. It is important that governments understand the impact of HIV/AIDS on women and its consequences for society. In many countries in Sub-Saharan Africa women contribute to over 50 percent of food production and in many areas are the linchpin of subsistence farming activities. To neglect 50 percent of any nation's workforce in such a critical area of production would spell doom for that nation's economy. Let us not forget that, in many families, women are the glue that hold the family together. According to UNAIDS, a study in Zambia reveals that 65 percent of households in which the mother has died have invariably been dissolved.

I could go on giving examples, but let me just conclude by quoting Dr. Gro Harlem Brundtland, Director General of the World Health Organization: "To suffer from a disease with no treatment or cure is tragic; to know that treatment exists but is too expensive brings the ultimate despair." I thought this quote quite appropriate concerning women. A great many women face that ultimate despair everyday. There is world agreement today that HIV/AIDS is a gender-based disease and is fueled by gender inequality.

I am pleased to note the presence here today of representatives of both government and the pharmaceutical industry. As we go through this discussion we can pose useful questions: Should we reassess the way we do business and resolve to put women on the same level as men in terms of treatment and follow-up care, even empowerment? Should we not make sure that women's physiological and social needs are taken more seriously than they are today? Should we not change our perspectives on HIV/AIDS in terms of gender. If so, we must ask how.

Dr. Jeffrey L. Sturchio, Vice President, External Affairs, Merck & Co., Inc.

Let me first add my thanks to the Global Alliance for Women's Health and to the UN Missions that have cosponsored this event. It is always important to have an opportunity to compare notes, to share our thoughts on these issues. We certainly welcome the chance to take part.

Let me address the question for this section of the discussion: Is HIV/AIDS an emergency requiring urgent action? I think that both Ambassador Moutari and Ms. Kapalata have told us with eloquence many of the reasons why the answer to that question is definitely yes. AIDS, it's been observed many times, is not just a health crisis; it is also an economic crisis and a social crisis. We have just heard, for instance, many of the ways in which AIDS has a disproportionate impact on women and girls in Africa and other parts of the world, thus underscoring the significance of looking at AIDS as a social crisis. It is also a security crisis. My country, the United States, for one, has indicated that dealing effectively with the HIV/AIDS crisis is an important part of U.S. national security strategy. So I think that urgent action is definitely required.

As Ms. Kapalata said, the UN General Assembly in its Declaration of Commitment in 2001 made it quite clear that this was the opinion of all the nations involved. But what should we do about it? That is the question that continues to vex us all. Infection rates continue to rise, and literally millions of people are dying every year. Such statistics—which I won't repeat—have almost lost their ability to shock us. We need to find ways to reinvigorate our efforts to deal with HIV/AIDS. Though the statistics may no longer shock us, the everyday human toll of this disease continues to grow.

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An example that I think has some useful implications for how to deal with HIV/AIDS is the experience that Merck & Co., Inc., has had with many partners in dealing with river blindness (onchocerciasis), another disease that affected millions of people and still holds millions at risk in Africa and other parts of the developing world. In 1987, Merck & Co., Inc began to donate a drug called Mectizan (ivermectin) for the treatment of river blindness. Now, fifteen years later, more than 30 million people are being treated annually for this disease. Of course, the differences in treatment regimens are quite significant—HIV/AIDS treatment is a complex regimen taken every day for a chronic condition, while one dose of Mectizan once a year is enough to keep river blindness under control and to prevent further infection. Still, the other lessons of this example are quite important for understanding what might be done as we move forward with HIV/AIDS.

The first theme, which we will hear more of this afternoon, is that success was only possible through public-private partnership. Merck & Co., Inc's donation of Mectizan was in many ways the least of it, because success required cooperation with dozens of Health Ministries at the national level, with intergovernmental organizations like the WHO and the World Bank, and with dozens of NGOs in the business of actually delivering care to people in some of the poorest areas in the countries most directly affected.

The lessons learned from this public-private partnership are instructive. First, it is important to focus resources on feasible targets of clear public health significance. So while AIDS seems like a terrible crisis and it is hard to know where to start, one thing we learned from the example of Mectizan is that, by focusing on something feasible and starting somewhere, you can make progress. This applies as well to HIV/AIDS, which is such a complex issue that it is beyond the ability of any single country or any single organization to deal with effectively. So partnerships and coordination and commitment from stakeholders who have unique resources and expertise to bring to bear will remain important in dealing effectively with HIV/AIDS.

Second, the Mectizan example demonstrated the essential role of distribution mechanisms and health-care infrastructure in ensuring that the medicines got to the people who needed them. We have found that cost is not the only barrier to care and treatment, although it is clearly a factor (and our company and others have tried to make our HIV medicines as inexpensive as possible in developing countries, particularly in Africa). Without an adequate infrastructure, medicines were not reaching the people who needed them the most, and without integrating the intervention, in this case for river blindness, into the country's health care system, it was not possible to make much progress. In short, today

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more than 61,000 communities are directly involved in the distribution of Mectizan as a treatment for river blindness.

This case shows that even when medicines are free, it is impossible to make progress on these broader access questions without addressing the questions of health infrastructure and distribution mechanisms. By setting up partnerships that involve the communities most directly affected, progress is possible. This is an important lesson for dealing with HIV/AIDS. Because of the scale of the HIV epidemic, public-private partnerships will be absolutely critical, so that all actors—the governments involved, civil society, the private sector, and other stakeholders—can help.

We should also keep in mind that each partner should contribute where that organization or individual has unique resources or expertise to bring to bear on the problem. In the case of pharmaceutical companies like Merck & Co., Inc and my colleagues represented here today, the first thing that we can do is what we do best—discover new medicines and vaccines. We have therefore put a lot of effort into finding medicines. We have two antiretrovirals available now (Crixivan and Stocrin), others in development, and are working very hard to help find an HIV vaccine. We can also help train physicians and other health care workers so that they are aware of the most up-to-date methods of patient management. Companies can also help by focusing on what is happening in the workplace. As employers we can help provide care and treatment to patients who work in the private sector, and that will help take pressure off government programs.

With the new resources now becoming available through the Global Fund to Fight AIDS, TB and Malaria, the World Bank's Multi-country AIDS Program (MAP) and through bilateral programs like the U.S. President's Emergency Plan for AIDS Relief, there is hope that we will be able to pull all of these pieces of a very complex puzzle together and find ways to really scale up the response to HIV/AIDS in countries facing this epidemic most directly. Finally, I would just say that I agree very strongly with the set of criteria that Ambassador Moutari mentioned for what needs to be done to address HIV/AIDS most effectively, beginning with political will and commitment.

THE REQUIREMENTS OF DRUG REGISTRATION AND THEIR IMPACT ON HIV/AIDS: WHAT CAN BE DONE AT THE GOVERNMENT LEVEL?

Heather Lauver, Senior Manager, International Philanthropy, Pfizer Inc.

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I will address how we are going about making both drug donations and discounted drugs available to patient populations in an effective way. The world is calling for better medicines, provided more quickly and disseminated to those most in need. Other research-based pharmaceutical companies around the table here are diligently addressing the issue, many by either donating medicines that are free to the populations or by providing discounted prices. While there is no nepenthe, R&D pharmaceutical companies are providing one part of the solution to the existing global health problems through these product offerings. I say one part, because it takes many other partners to improve public health on various levels outside the clinical. Some of the operational issues in offering medicines across borders include the following:

1. Revising the packaging across multiple countries is difficult when you have disparate information and language needs. When providing a product to one country, a company can fairly easily meet that country's language needs. However, once a product is requested across countries with multiple language and labelling requirements, it is nearly impossible to meet all the regulatory and language needs of the entire globe in one package. Some of those regulatory issues are quite complex and can require up to two years to address.

2. Other regulatory hurdles include excessive bureaucracy in product registration. In Pfizer, Inc.'s case, we are donating, so the product must be registered as a unique, donated medicine. Registration occurs by submitting a thick dossier for each product. Providing the dossier to a country's ministry authorities begins the process of review. The dossier contains all of the product's clinical research, prescribing experience, safety and efficacy, manufacturing information, and molecular structure. Each time you bring a product into a country legitimately, you need to register that dossier or obtain a waiver for medical necessity or emergency. Each country has a slightly different process, and some face staffing shortages. Getting through the bureaucracies of different countries can be problematic in providing timely assistance to populations with health crises. Each sector needs to look at this problem and provide a hand and a voice in speeding up our ability to respond to pandemics.

3. Taxation of donated medicines in particular can be an obstacle that further delays support. After going through all the trouble of re-labeling a product,

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obtaining registration, and paying for shipping to destination, to get to the doors and be taxed on that donated product is a real tragedy. Such policies are not conducive to partnerships. Usually, the recipient is responsible for paying charges at the port of entry. If the product is presented to the government, sometimes the Ministry of Health will pay the fee to the Ministry of Finance, but these two agencies are frequently out of communication with each other. We need to explore collectively how countries can meet IMF and other revenue-generating needs without further slowing down medicines that are offered free or at cost and address a public health emergency. The Global Fund might address some of these issues, which apply to all providers of drugs, not just the private sector. We are all in this together.

4. Product diversion harms the donor and continues a cycle in which the less fortunate suffer the brunt of the health crises. Diverted product usually ends up back in developed countries, where the pricing power is much higher. Pfizer, Inc. expends significant resources making sure that product gets to the targeted patient, who is unable to afford medicines at any price. Additionally, we package our donated product differently from commercial product, which helps identify diverted product.

I will focus my time here on the registration issues. I hope government representatives will gain some ideas that they can take back to their ministry officials. For those in the drug supply business, I hope we can discern where we can further unify and simplify. The regulatory issues of registration include these:

1. Overall registration processes for humanitarian initiatives, which differ by country, take far too long and lack transparency. In one country, it took us 16 months to register a product for donation. It should not take 16 months to donate a product to a country that purports to need emergency assistance or has a hyper-endemic disease situation. In such situations, the government should be responsible for expediting shipments once they reach the port. If there are issues that pharmaceutical companies can help countries address, for example understaffing or training, such partnerships can be useful. Pfizer, Inc. is building

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a training facility in Uganda to address some of these issues and provides money to support clinical training around the use of our donated Diflucan® (fluconazole). In many countries, though, this dialogue doesn't happen. It requires political will and staff dedicated to aligning partnerships within the government. The private sector and NGOs can knock on the door only so many times before the knuckles start to bleed. Somebody has to be willing to open the door.

2. The request for unusual or extraordinary studies significantly slows or prevents humanitarian initiatives. For example, one country asked for a completely new study that would have involved a million-dollar investment and a new clinical trial. For a product that has well-established safety and efficacy for the particular indication, the additional costs are unwarranted and most companies that are already providing medicines at cost or for free will not agree to such further research. Public monies or charitable funds should be pooled to assist a regional or global body to fund studies that have no commercial application. Pfizer, Inc. spends a good deal of time negotiating on this issue despite the fact that we maintain the highest safety and quality standards through the FDA and our facilities meet Good Manufacturing Practices. New clinical trials for well-established products should be avoided if at all possible. The WHO or other multilateral agency might have a role to play in establishing suitability of products for targeted diseases.

3. On a related topic, we are often requested to register disease indications in developed countries that rarely treat those diseases. The current country-specific registration process and the resulting regulations for resubmitting a dossier in an OECD country complicates regulatory control. For example, Pfizer, Inc. donates Zithromax to countries that have problems with trachoma, a bacterial disease. Trachoma is rarely seen in the United States beyond maybe a handful of cases. Pfizer, Inc. would not pursue U.S. registration of trachoma as an indication for Zithromax. Why not? To reopen a dossier in the United States, for example, allows the FDA to review all existing clinical data, some obtained over fifteen years previously, and request that an earlier study be redone to incorporate new policies, such as obtaining larger sample sizes or altering reporting structures. A process that may seem simple can jeopardize the entire use of a drug while new and expensive studies are conducted, which helps neither patients nor society. I am not an expert on regulatory constraints within the FDA, but I flag this issue for further study. The regional or global approach to humanitarian initiatives is one option that might be explored. We need a rulebook that is clear to everyone.

4. Donated products for long-term programs will often have, as I mentioned, one or two languages on the package. But once you get to three or four or five languages, you cannot physically put so many languages on the package. It just

won't fit any more. We need a global understanding of what four languages may satisfy WHO guidelines for importation of products and a general acceptance from the countries that genuinely want to participate in global product donations or accelerated medicine access initiatives. Recipients will have to accept one of those four languages and make sure that their professionals are trained in at least one of them.

This is just the tip of the issue and of the task at hand in providing access to medicines. I invite your questions.

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QUESTIONS AND ANSWERS

Angela Ndinga, International Peace Academy

I am interested in the issue of converging guidelines to streamline donations. What are the underlying concerns that African governments might have? It seems to me that African governments may be concerned about medical ethics, warranted or not, and I wonder if a dialogue is going on between pharmaceutical companies interested in making these donations, international NGOs that can help with distribution, and African governments, perhaps with the African Union.

Heather Lauver, Pfizer, Inc.

There is a bit of a catch-22 in the ethical question you raise. I think the more often companies do clinical trials in developing countries, the more risk they take on in terms of coming across complications of diseases of poverty. There may be confounders or comorbidities involved. Patients who are very sick to begin with may be ill from other causes, or the medicine interacts with some other medication they took, often undisclosed to the researcher. Yet the coincidental problem becomes related to that particular clinical study. Too, informed consent is more complicated in areas where literacy is low and knowledge of health issues more limited. It is very risky for companies to operate in this environment, however necessary. So, unfortunately, if we are to take on further clinical trials that really satisfy the clinical needs, there needs to be some public mechanism for agreeing to assume this risk, or for the public to directly fund and conduct studies to remove risk from the company that discovered or developed the

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molecule or product and is not compensated for the humanitarian initiative. That said, it is important to continue studies in Africa and elsewhere. Providing global rules of engagement and achieving a public/societal acceptance of risk are two critical aspects of increasing access to medicines in less developed countries that have not been addressed.

Rev. Evatt Mugarura, Director, Balm in Gilead, representing Africa HIV/AIDS Initiative

What is the problem we are trying to address? Where is the problem? Until we get to that root cause of what is happening now, we keep talking, talking while the people are dying. We talk of public-private partnerships, but how practical are they in a country that is very poor and cannot even think of buying the drugs even when they have been subsidized. We are presenting a picture that is very good to people here, but we are not tackling the problem head on . . . I represent Africa and I speak because I have lost a lot of people. When I hear people talk, talk, talk, my mind asks, what are we doing for the people that are dying even now as we talk. So I think we need to change the way we are doing business. We need to look at life in a different way, because when we talk of economic and security issues, what are we talking about? I would like to know more clearly, especially from the pharmaceutical companies who are doing business in a relation with the poor countries, the poor communities, and the poor mother who is dying because she cannot afford the cost of this drug. I really am looking for an immediate solution.

Heather Lauver, Pfizer, Inc.

It is truly sad that many people cannot afford medicines at any price. This is a real societal dilemma. However, they say that planning, talking things through, saves a lot of wasted effort in the end, so this discussion is not wasted. To your second point, business is not evil, in fact private research and development supply the world with over 90 percent of the best medicines available globally. Take away the private sector and you have no drugs to fight over, period. The generics on the market came from private drug discovery. That's how the patent system benefits society in the long run. Do a little research on how those products came to be made publicly available. You will be surprised. Nonprofit drug development over the industrialized era has been a miserable failure. Russia tried it, Europe is now trying it. These efforts are commendable, but the bottom line is that private industry is able to direct resources back into the required mechanism of research and effectively bring products to market

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because it receives a profit and agrees to carry the risk of research failures. Further, we are here today, donating and providing products at cost or below because our medicines are of value and we want to do our part. How many generic companies are donating their products to those who cannot afford medicines at any price? Pfizer, Inc. alone gives over $500 million in cash and product each year. To put that in perspective, that is what the Global Fund raised for one year of operations. I think the pharmaceutical company is coming to the table voluntarily with very helpful and substantial resources, but we cannot address the problem alone, nor should we. This is a public health issue, a people issue. It comes down to helping people. How can all of us around this room take part in effectively addressing the problem. I think you are right. There are many countries that will not be able to afford drugs at any price, when a typical African lives on less than a dollar a day. There is no immediate answer, no quick solution that you seek.

Dr. Elaine Wolfson, Global Alliance for Women's Heath

Before the next question I want to say that one of the issues Heather Lauver was talking about was donation of a product that was free of charge but that the governments would not accept because it did not meet certain of their requirements that were different from U.S. requirements. In an emergency context, can governments consider variances to some of their policies? Would it be desirable to gather the donations and not to tax some?

Dr. Desmond Johns, UNAIDS

I have other comments that I will make further on in the program, but will direct this specifically at the regulatory issues raised by Heather Lauver. Certainly we understand that these could constitute an obstacle to access, and necessarily so. But mechanisms and resolutions such as regional registration are currently in evolution. For example I know within the Southern Africa region we have common registration mechanisms underway so that a single submission gets you registered in fourteen countries. Often it is the perceived market that determines where you would register or not register a product. So in part some of the blame has to rest with the pharmaceuticals in this respect. At the second level, the

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problem is more symptomatic of the limited regulatory capacity in many countries. The referencing to trials or registrations either in the European Union or in North America serves to convey a measure of comfort for countries that have such limited regulatory capacity, assuring policy makers that it is good enough to be used in Africa, Asia, and elsewhere. So these regulations are not necessarily there as an obstacle but to satisfy the same sort of needs to protect one's people that exist elsewhere. So referencing is not entirely bad, and maybe we need to see how we can work around those.

Joyce Braak

I would like to know, first, if anything specific has been done by the industries to bring together Health Ministers and policy makers for a conversation to increase their confidence. And, has anything been looked at about the language problem? This I see as a major obstacle that we have let slip. You mentioned four languages. Have you met with the Education Ministers? Is there is a way that training structures can be mobilized to provide training in the four languages or some minimum number of languages. I have worked in Africa and have found that languages change very quickly in a very short geographic distance and that this does become a major obstacle.

Heather Lauver, Pfizer, Inc.

Let me first address the registration issue, how we approach the ministries and other officials. I don't think we as a pharmaceutical industry have been able to bring Ministries together—it would be difficult for the industry to convene such a meeting. Individually, Pfizer, Inc. intends to meet with the U.S. Department of Health and Human Services, because many of the registration issues also start within the United States, many pertaining to our import and export law. Once we get some general discussion going, we hope to gain momentum within our key government institutions to provide that forum and drive it.

In terms of providing effective training and materials, most health care professionals will be trained in, or at least able to read, one of the four languages we will include in the packaging, English being the most commonly read. We do conduct training sessions in the key language of the country for those who will be treating the targeted patients or training others, so this provides an important aspect of focused communication. In terms of labeling, we really hope that English covers most countries, but we are in the process of adding French, Spanish, and Portuguese to the package inserts. That is about as much we can fit

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on the package. With Asian languages, there are so many different derivatives that it will become difficult for us to physically add more information. Further, differentiating the package inserts by region will require multiple inventory management processes, which is not feasible. Pfizer, Inc. provides all these resources because in our experience countries have very limited budgets for training and materials development (and it is the company that is regulated regarding package inserts, so a country could not change packaging on its own).

Mark Speaker, Vice President, International Government Affairs, Bristol-Myers Squibb

I just wanted to add that one opportunity may be the WHO-UNAIDS contact group on HIV, where a lot of the Health Ministries do come together with the private sector and where we actually could discuss how to streamline the regulatory process, at least from a language standpoint. There may be other possible places for such harmonization. It does remind me though, as Dr. Desmond Johns said, that infrastructure is a capacity problem in a lot of countries. Industry has information that could perhaps be shared to move that process along.

I did want to react to a comment about the prices of our products and how unaffordable they are, or at least that is the perception. Most, perhaps all, of the companies in the Accelerating Access Initiative (there are six of us) in Sub-Saharan Africa have said that each is offering products at a nonprofit price or actually below cost. Yet the uptake is rather limited within Africa. While the increases are dramatic since we started the Accelerating Access Initiative, probably quadrupled or more, the raw numbers are still mighty small. There are other problems, some of which we will address as we go forward, but the infrastructure is probably the biggest problem—that is, a country's ability to distribute donated or extremely low-priced product. But I would not like the group to leave with the impression that we have done nothing dramatic. Speaking for my company; the price we now offer for our products is in many cases below the cost by generics for the generic versions of our product.

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SOVEREIGNTY AND ACCOUNTABILITY FOR GOVERNMENTS: WHAT ARE THE PARAMETERS, AND WHAT ARE THE IMPLICATIONS FOR HIV/AIDS DRUG DISTRIBUTION?

François Oubida, First Counsellor, Permanent Mission of Burkina Faso to the United Nations

I would like to thank Dr. Wolfson for this initiative, above all for the good news you brought to our attention earlier regarding the donation of a pharmaceutical intervention to Burkina Faso. My intervention will focus mainly on the experience of Burkina Faso and draw lessons learned. I could have taken any other country, but my own country's is the only real experience I feel confident talking about. Additionally, in 2001, UNDP released a human development report on Burkina Faso focused on the epidemiological situation of HIV/AIDS.

1 – The Background

In Burkina Faso, the first cases of HIV/AIDS infection appeared in 1986, ten cases according to the UNDP report. Today, the rate of infected people is at 6.5 percent. Notwithstanding that the infection rate has decreased from 7.17 percent, it is still among the highest of West Africa. Due to the lack of screening capacity, these numbers may be different from the real state of HIV/AIDS in the country. The government has taken this matter as a high priority to tackle the situation and reinforce the good result achieved.

Since 1986, short- and medium-term plans have been established. These plans were reinforced first in 1991 by the project for marketing social condoms (known as 'Promaco' and founded by Germany) and again in 1995 by the project on population and the fight against AIDS (PPLS.)

Since 2000, Burkina Faso's HIV/AIDS activities are spread among all social sectors through a strategic planning process established by the government, which launched a strategic plan for the term 2001–2005.

1.1 At the national level:

— The National Council to Fight against AIDS and Sexually Transmitted Infections (CNLS/IST), headed by H.E. Mr. Blaise Compaoré, President of

Burkina Faso. As a political body, its core role is to supervise all activities on HIV/AIDS, make decisions, and take any required action.

— The Permanent Secretariat, directed to coordinate either local or external business.

— Decentralized bodies at the following levels:

- Ministerial department
- Private companies
- Provinces
- Departments
- Villages
- Municipalities
- Sectors

— Allocation of resources: 12.5 billion FCA will be allocated to the five-year program (2001–2005).

Aside from these structures, many NGOs and civil society organizations are deeply involved in the process. As a result of this network, it has been possible to release in 1999 a document of national consensus for treatment of HIV/AIDS infected persons.

1.2 At the external level:

Burkina Faso has ratified all related conventions on HIV/AIDS. Above all, the government has developed strong bilateral and multilateral partnerships. Countries like Germany, Italy, Denmark, and Japan, to name only a few, support the strategic plan. UNAIDS, UNDP, World Bank, also contribute positively. Thanks to these joint efforts, ARVs have been available to infected persons.

2– Lessons Learned

To quote Mr. Peter Piot in his declaration before the joint meeting of the 2nd and 3rd Committees of the General Assembly held on 25 October 2002: “Leadership, partnership, and resources” are vital in the fight against HIV/AIDS. How does it work?

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The government should lead the process. The political will must be strong and deployed. The major actors must be coordinated. For the fight to succeed, some laws have to be passed to protect the rights of infected persons and to set up required conditions.

To quote the Declaration of Commitment on HIV/AIDS of the UN General Assembly Special Session of 21–27 June 2001 regarding the need for strong leadership at all levels of society for an effective response to the epidemic: "Leadership by governments in combating HIV/AIDS is essential and their efforts should be complemented by the full and active participation of civil society, the business community, and the private sector."

The government should work to bring together external and internal partners with public leaders. Any strategy should take them on board to ensure success. Resources are critical to any success against HIV/AIDS, and many governments have launched special funds to facilitate the activities. In many cases, ARVs are made available thanks to these funds. It's important to underline that partnership and resources would be impossible to build without government leadership. Such leadership brings hope for infected people and paves the way for successful activities.

In the case of Burkina Faso, the leadership shown by the government has solved many problems related to HIV/AIDS drug distribution. There is better control of resources made available by the partners. The government has appointed a ministerial committee to handle drugs donated to an individual, a community, or the government. The Permanent Secretariat assists all partners to clear drug control processes. From the clearance stage to the infected person, groups that discourage diversion of drugs handle the matter. Furthermore, actions have to be evaluated by the president with the members of the National Council. Even though this policy is still ongoing, it has improved drugs distribution control, as shown, on the UNDP web site, in the first report on the policy.

SHOULD GOVERNMENTS INFLUENCE THE PRICING OF HIV/AIDS DRUGS ONCE THEY ARE IN COUNTRY?

François Oubida , Permanent Mission of Burkina Faso to the United Nations

There is no need for me to recall that poverty is one of the root causes of the HIV/AIDS pandemic. More than 70 percent of Burkina Faso's people can't afford manufactured medicine. Usually, the government has a strong policy regarding

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drug importation and distribution with the aim of disbanding trafficking. Some diseases like malaria and tuberculosis are pandemic and could not be eradicated without a strong drug control policy.

To control quality and disband trafficking the government must register any medicine. The main manufacturers of ARVs are fully aware of that and have already cleared this process. But once the drug is in country, there is no further direct action from the government on the prices.

Nevertheless, the government has developed generic production as an indirect way to combat the diseases effectively. Generics are cheaper and likely to be handled anywhere across the country. They are affordable by most of the people. Generics also influence prices because distributors of generics must also maintain quality standards and affordable prices. At this stage it may not be easy to have generic drugs for HIV/AIDS. On the other hand, the government is able to influence pricing through negotiation with pharmaceutical companies and also through funding.

In 2001, the government ratified the Bangui Convention as revised on 2 March 1997. The revised Bangui Convention aims to promote transfer of technology and to fight against poverty while taking care of the interests of the member states' people. The convention opens the opportunity to take required action.

Have the price controls achieved any results? In Burkina Faso, before 2000, the costs of ARV drugs ranged from around $35 (VIDEX 100mg) to $221 (Stocrin 200mg). The negotiations held with the pharmaceutical companies—many of them here, namely GlaxoSmithKline, Bristol-Myers Squibb, Merck & Co. Inc., and F. Hoffman-LaRoche Ltd.—were conducive to lowering the prices. In its last report, the National Council stated that from less than a hundred, the number of infected persons using ARVs has now risen to around a thousand in only one year. But, much remains to be done. ARVs are still affordable for only a few people and are not a choice for many.

To overcome the current trend in HIV/AIDS, the goal is to work towards zero cost of ARVs. There is no solution to that. But through partnership, national budgets, and external funding, this goal could be achieved. We are convinced that in developing countries where poverty persists and drug availability remains limited, for a better control of HIV/AIDS only zero cost would be an incentive for voluntary screening.
It is not only that the pharmaceutical companies have a responsibility to do everything that must be done. The government has to do something more; our country has to make something available in the budget and to participate. It is why we are talking about leadership in that way.

Mark Speaker, Bristol-Myers Squibb

It is important to look at what makes products cost what they do, even once they leave our hands. Sometimes customs or import duties add to the cost significantly. In addition, various people touch the product before it gets to the actual patient, the distributors or the so-called middlemen.

At our company we have worked out arrangements with some of our distributors in Africa, where we are absorbing certain distribution costs. Anything that governments can also do to help reduce costs, discourage big markups, or eliminate customs duties enables admittedly overtaxed health systems to increase access to these low-priced products.

Dr. Jeffrey Sturchio, Merck & Co., Inc

I agree with Mark Speaker's comments about how to take a look at what happens downstream in the supply chain after the products leave companies like ours to go to patients. But I want to come back to the general point that Mr. Oubida just made, in quoting Peter Piot, about the need for leadership, partnership, and resources for an effective response to the HIV epidemic.

In our discussions here, we have heard about problems but also about many solutions. These three factors—leadership, partnership, and resources—are critical to finding solutions. We need to find ways to sit down with all stakeholders together to address problems that come up, like the problems in distribution, like the problems in registration. We have heard, for instance, about the Southern African Development Community (SADC) looking at a regional registration, which may be very helpful. ECOWAS is also talking about a regional response to some of these issues. Our companies would certainly welcome the opportunity to participate in discussions in these areas and to help find solutions to technical problems. At the same time it is important to keep in mind—and this is also a point that our colleague from Burkina Faso made—that companies cannot do this by themselves, governments cannot do it by themselves. Everybody has to participate in finding the long-term solutions, and that is where government leadership is absolutely critical.

Together with the government of Botswana—which has one of the highest HIV/AIDS prevalence rates in the world—and the Bill & Melinda Gates Foundation, Merck & Co., Inc is involved in an effort to completely transform Botswana's response to the epidemic and to do this in a comprehensive way,

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from prevention and education all the way through to antiretroviral treatment. The government and other stakeholders are making progress by supplementing government leadership with working through wide-ranging partnerships. These involve civil society, the private sector, and other development partners. They also try to find solutions in which everybody can bring different expertise and resources to the problem so that, in the end, those solutions will really make a difference.

Finally, to return to the point raised earlier about the level of donations being made by pharmaceutical companies, obviously other companies also make donations to help with issues in Africa. But donations are not enough and can never be enough, by definition, because the problems are so massive and the challenges we face in global health are so complicated that it is only by finding ways to bring to bear all of the resources and expertise of all the stakeholders that we are going to find long-term solutions. So yes, donations have a role to play. Our company is certainly doing what we can to help. But I think that the challenge facing everyone in this room—and certainly the countries that you represent and everyone in the UN system—is how to find ways to bring leadership together with effective partnerships and adequate resources to implement long-term solutions to the challenge of HIV/AIDS.

DRUG DIVERSION: WHAT ARE THE ISSUES, AND HOW DO WE ADDRESS THEM?

Heather Lauver, Pfizer, Inc.

Product is projected to meet the needs of the targeted populations, so any diversion removes that product from the hands of those who desperately need it and can least afford it. In drug diversion, the product does not get to its intended population, either due to lack of infrastructure or corruption or other issues. It often "falls off the truck," as they say, and gets diverted to the informal market, often at a price much higher than originally intended.

Such diversion particularly affects those in remote areas, who are last in the distribution chain and therefore bear the shortfall the most—given that several losses may occur before the end of the distribution chain is reached. These same people tend to bear the greatest burden of diseases because of lower income, fewer accessible resources, and less ability to advocate and be politically heard. Hospitals or clinics in remote regions often do not receive shipments or receive

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less than what was ordered. Sadly, this is so common that they often do not bother to complain about it.

In some countries, diversion can be up to 40 percent of the shipment. Assistance from governments through actively monitoring and prosecuting product diversion is going to help improve overall public health in the countries most affected. In sum, infrastructure issues need to be addressed to create a working system that can respond to a population's health care needs. The drug is an important but small part of the whole picture.

GOVERNMENT-PHARMACEUTICALS RELATIONS: THE CRUCIAL NEED FOR OPEN COMMUNICATION AND TRANSPARENCY TO ACCELERATE ACCESS TO TREATMENT

Lefu Manyokole, First Secretary, Permanent Mission of the Kingdom of Lesotho to the United Nations

I will align myself with those who thanked the UN and in particular the Global Alliance and the pharmaceutical companies for being here. I want to start by aligning myself with the Reverend Mugarura. I think you can take his message in good faith when he said he is mostly concerned about the tangible things we can do to address the problem.

My assigned question of government and pharmaceutical company relations has been well covered by Dr. Sturchio, and UNAIDS director Dr. Johns has also addressed it. I just want to add that it is important for this partnership to exist. Both government and the pharmaceutical companies have a responsibility, but if things go wrong, who has to be blamed and who has to take the responsibility for what goes wrong? Who has to take responsibility for paying for those drugs and making sure the drugs are distributed?

Dr. Sturchio was talking about things like distribution problems and coordination, and how much government commitment to infrastructure in the health sector exists. Things like that are of concern, but even if we might be positive about that partnership the problem persists. The Reverend too raised the very important point that some of our governments or countries are so poor that they cannot afford many basic things for people, and that is a disaster.

My country says that 1 percent of the population is infected. What do you do? What are the priorities? These questions require people who can come up with ideas to concretize solutions, but the solutions have to come from both directions. Governments have responsibilities to their people, because the people have

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voted those governments into power to make sure that they keep the people safe and alive and provide services to them. I think a solution exists, but one must consider that some responsibilities differ. Governments have the very, very important responsibility to look after their people's safety.

Questioner from the audience

On the diversion issue, I should like to ask the pharmaceutical companies for an example of where you worked with government to limit or eliminate the problem. Just give us a brief note on practice that we may follow. On the issues relating to training, I would like to hear a company's experience on how to have our people trained, and what is the contribution of pharmaceutical companies.

Mark Speaker, Bristol-Myers Squibb

One thing we have done on diversion has been to change our packaging and the look of the capsules or pills. We have actually changed the marking numbers on the capsules. So, that is one way for us to at least identify a product intended for sub-Saharan Africa and hope that it stays there. I think what governments can do is help us make sure it stays there. It was widely reported in the press that Glaxo had a major diversion of product. The product intended for Africa ended up in Western Europe, and that certainly enriched the pockets of some middlemen in Europe. More importantly, drug diversion means that poor persons in Africa never get the product. So, I think collaborative work is one way to address it.

On training, a number of us are doing a lot of things, but let me just mention that we have a program, "Secure the Future," in nine different countries in Africa. One thing we developed in it is a nursing curriculum to teach nurses how to take care of patients with HIV/AIDS. The curriculum is available in multiple languages throughout much of Africa.

Jeffrey Sturchio, Merck & Co., Inc

To add to what Mark Speaker said, Merck & Co., Inc has also taken steps to change the packaging for Crixivan in Africa to make it clear that if it shows up in another market it was actually intended for developing country markets. Also, on training, we do similar programs, as noted above.

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One last comment in response to our colleague from Lesotho: I think he is absolutely right that governments have responsibility to protect the people. What we have found works best is to sit down with governments and other stakeholders to identify clear programs in which we can share a common goal, and then work together to make sure it happens. Then, once that goal is achieved, we can work together on something else. But the best way forward is clearly to find a common goal to which we can contribute some expertise or resources and then work with others to achieve that goal. I confess I am optimistic. It may be a long journey, but if you start on that road, you eventually get there. That is the spirit that we want to suggest.

HOW CAN EDUCATION AND CIVIL SOCIETY HAVE AN IMPACT?

Issa Konfourou, Third Counsellor, Permanent Mission of Mali to the United Nations

First of all I would like to express my government's appreciation to Dr. Wolfson for organizing this meeting. I am pleased to report that the Government of Mali is honored to be cosponsor of this roundtable to consider the HIV/AIDS scourge. There is no doubt of the common determination of the international community to fight this pandemic. In most of the countries, media, non-governmental organizations, militants, physicians, and economists mobilize public opinion and persons infected by HIV/AIDS. The best example of this common engagement is the Declaration of Commitment of the June 2001 Special Session of the United Nations General Assembly on HIV/AIDS.

However, we must keep in mind the fact that while we are talking, adopting resolutions and declarations, people are suffering and dying of HIV/AIDS. In Africa particularly, 29 million people are living with HIV/AIDS. This means that HIV/AIDS is now a matter of peace and security, public health, development, and even a human rights issue.

Taking into account this sad picture, we must ask ourselves what concrete steps should be taken to give hope to those people in need, to enable them to fully participate in the common effort of building their societies and to put an end to the spreading of the disease. In this regard, I would like to focus on the two following points, which in my view, can help to tackle this issue.

First, it is well known that to fight a sickness, we need to know how to prevent and treat it. Thus, efforts should increase on education, to inform and sensitize

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people on this danger. In Mali for example, all the partners including the government, civil society, media, non-governmental organizations, physicians, economists, and others are mobilized to provide the public with information on HIV/AIDS. This campaign of information and sensitization is also helpful in reducing the stigmatization and discrimination of infected persons. In addition, I believe that customs officers and medical personnel should get involved in this effort, since they are in position to do the tests and provide care; they may give the best advice and treatment. To this end, Mali has recently trained many imams, other religious leaders, and media personnel to get them more involved in the fight against the disease. This training also concerned the country's customs officers and physicians in the care of infected persons. All these efforts have maintained Mali's seroprevalence rate at 1.7 percent.

Secondly, I would like to underline the need to strengthen public-private partnership for provision of HIV/AIDS drugs—pharmaceutical companies, governments, people living with the disease, NGOs, civil society, medical staff. The developing countries in the South have not enough resources to buy drugs from pharmaceutical companies in the North. It is also essential to increase political engagement, resources, and institutional measures to concretize this partnership. In this regard the World Fund on HIV/AIDS has a particular role to play.

* * * * *

QUESTIONS AND COMMENTS

Martha Henries of Liberia

I have a question for the pharmaceutical companies. Because of the civil war and periodic unrest that has been going on for the past almost 13 years in Liberia, my government tends to pay more attention to purchasing arms than to looking after its citizens. I am here today to ask on behalf of myself and other women interested in getting help, especially those who are raped and now have HIV/AIDS, do we have to go through our government or can we approach you one on one?

Question from the audience, female

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I want to emphasize the prevention program. I note that even the pharmaceutical companies are involved in training, but what do you do in the prevention sector? Because I think we also have to stop the disease from progressing and put as much as emphasis on preventing as on curing.

Lamin Faati, Permanent Mission of the Gambia to the United Nations

Mr. Sturchio dealt with the question of providing drugs on a donation basis to some of our governments. I think what may be lacking is confidence-building between the pharmaceutical companies and the scientific and medical communities in our countries. As you will realize, these are new drugs and they are meant to treat a disease that is somewhat elusive. So increasingly I think even the medical and scientific communities in developing countries tend to see this donation as, if I may say, Trojan horse donations. For that reason I think you need to raise the level of awareness and confidence within these communities, probably with the involvement of WHO, so that they can more readily accept these drugs, better understand them, and be able to serve as a bridge between the pharmaceutical companies and the consuming public.

Jeffrey Sturchio, Merck & Co., Inc

Let me respond first to the question about prevention. I think that most would now agree that a balance between prevention and treatment is really the way to go. That was one conclusion that came out of UNGASS, as you will all recall; certainly our company and, I am sure, the other companies here agree with that. Just to give one example, in the project in Botswana where we are working with the government and the Bill & Melinda Gates Foundation, one component of that project right now is to introduce a social marketing program together with Population Services International so that condoms will be made more widely available. We know from much work that has been done in many countries that availability of condoms alone is not enough to change behaviors. There will also be a strong educational program so that people will have more information about the disease and about the importance of prevention. Also, as we are finding out from the example of Botswana, the availability of treatment is now giving people hope that they really can do something about this disease, and that in itself is encouraging people to go for testing and counseling. It is also having an impact on changing behaviors. This really offers a long-term solution in prevention as well as treatment for HIV.

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Mark Speaker, Bristol-Myers Squibb

In addition, we fund programs that help communities prepare for treatments as they become available in some places. We don't want simply to deliver product and then walk away. We need sustainable programs where people understand how to use medicine and what a person who is HIV-positive needs.

Heather Lauver, Pfizer, Inc.

We are working with several NGOs to provide social support for those infected. Through the Pfizer, Inc. Foundation, we make grants to NGOs providing health information on AIDS. If you have Internet access, you can probably search www.google.com for an organization called AXIOS International. It handles many of the drug donation programs. Its web site provides background information about eligibility for those programs. Currently, each program has its own application, but Axios and its client companies are working toward one all-purpose application to reduce the paperwork burden. AXIOS will walk you through all those different applications. I believe some ARVs are offered; for, example, you can review Pfizer, Inc.'s Diflucan Partnership Program there. Additionally, look into the Accelerating Access Initiative, the collective effort of five or six drug companies that are reducing their prices on specific drugs needed in developing countries.

Further, see if you can align yourself with organizations that are receiving product through a state system. Many of the charitable organizations work with the state systems, so I would encourage doing that. We are working in several countries facing political strife: Sudan, Zimbabwe, Rwanda, to name a few. This is to say that Liberia is not out of the question, but the applicant will need to provide assurance that it can distribute product safely to targeted patients—no small task. Too, participation eligibility varies by company, so look into this carefully. I understand the pain of the situation for women and I encourage women to continue to come forward, as you have, to join together and support each other and be strong—expect product and ask for product that is available through these programs.

Dr. Elaine Wolfson, Global Alliance for Women's Health

Remember that 29 million people already have HIV/AIDS, and we have to determine whether they are going to be treated or if we can help them get treated.

Sylvan Barnett, Rotary International

I address this comment to the governments and to other NGOs here. On the subject of social mobilization, we were talking just now about education. Public education is terribly important. The next president of Rotary will be from Northern Nigeria, and we are intensely interested in the whole African continent, particularly on this subject. We just finished immunizing 165 million children in India, led by Dr. Gro Harlem Brundtland of WHO.

What does it mean? How do you get to this position where you can cover 165 million children? We have immunized children against polio in every one of your governments. What I am saying is that it takes social mobilization from the grassroots up and from the governments and the media down. I urge you to come to us and come to the Rotary clubs in your countries, because we will work with you.

Dr. Desmond Johns, UNAIDS

I realize you are running out of time. Just a few comments: In an ideal world, donated drugs or differentially priced drugs will be available in large quantities such that people needing them can receive them in a sustainable manner. Once in the hands of the recipient governments, they will reach the people they are actually intended to reach. That is the ideal world. The reality is somewhere else.

We have a plan that is a declaration of commitment. We know what works. We need to scale up. Therefore the challenge is to move from demonstration and pilot projects to programs with real coverage. That is the only way we are going to have an impact on this epidemic. The challenge is to get out there and get the job done.

SUMMATION

H.E. Ousmane Moutari , Permanent Mission of Niger to the United Nations

First, we agree that HIV/AIDS is really a major problem and the situation is an emergency situation. This is not only because of the health and social and

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economic impact of HIV/AIDS, but also because of the peace and security aspects. We heard from our friend Christine Kapalata that this is even more so when it comes to the impact on women, and I agree with that.

Another point where we can agree is that the complex registration requirements are a hindrance to drug donation. Government and pharmaceuticals need to work together on this issue, because we know that even if we were to remove the price issue and the lack of financial resources, many obstacles remain that hinder easy access to the drugs.

We heard from Burkina Faso about their good experience on a legislative and institutional framework to fight HIV/AIDS. The lesson he draws is that leadership, partnership, research, and resources are crucial for an efficient response to the problems with HIV/AIDS.

Drug diversion is a very important issue and a very serious one. What we need to tackle this problem, again, are close partnerships between government and private companies. Government accountability is also vital and is again a matter of governments working hand in hand with private enterprise so that we can solve this problem.

In conclusion, the availability of treatment now encourages people to instruct the sick about voluntary testing. That also requires people to change their behavior, as we see in the case of Botswana.

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