SCHOOL OF ADVANCED INTERNATIONAL STUDIES

GLOBALIZATION & DISEASE:

INSTITUTIONS, POLICIES AND THE THREAT OF BIOTERRORISM

NOVEMBER 6, 2001

WASHINGTON, DC

PROFESSOR BARRETT: (in progress) re-energized and ready for another session. The present session on "Globalization and Infectious Diseases" is going to be a blend of policies and institutions. As I said before, we've had to reshuffle, or shuffle some of the speakers, and the speakers for this session now are Dr. Klaus Leisinger and David Fidler, Professor David Fidler.

Professor Leisinger is the Executive Director of the Novartis Foundation for Sustainable Development, and a Professor at the University of Basel. He has experience, not only in academia, but also in the private sector, having been the former head of the East Africa office of Ciba Pharmaceuticals. And he's also advised a number of other organizations, including organizations under the United Nations' umbrella.

And David Fidler is a Professor of Law and the Ira C. Batman Faculty Fellow at Indiana University School of Law. He has written very extensively on both the international law, and I would say, the international relations of infectious diseases and public health more broadly. He has written a book with the title, International Law of Infectious Diseases, and it's a great book. I strongly recommend it to you. And he's also written recently another book, International Law and Public Health Analysis and Materials on Global Health Jurisprudence.

So I welcome both of these speakers. We're going to begin with Professor Leisinger, and then, Professor Fidler, and I'm going to ask if people have clarifying questions to ask of Professor Leisinger after he has finished speaking. But, otherwise, I think we should probably hold—let's experiment and try holding questions until the end, because there may be some discussion taking place between the speakers, as well as between the audience and the speakers. So, Professor Leisinger, please.

PROFESSOR KLAUS LEISINGER: Good afternoon, ladies and gentlemen, and I hope you didn't eat that much, so that you can still follow with full attention.

All of us here in this room belong to the lucky minority of less than 1 percent of the people in the world, who are unlikely to be personally affected by the fact that as I speak, many thousands of women, men and children are dying prematurely from diseases that could be prevented, managed or cured. And yet, in a way, we are all affected, because no sense of a person can be indifferent in the face of preventable misery and growing economic social and political disparities. In a world in which three billion people

have to survive on less than $2 a day, the question, what has gone wrong? Or more positive, what can each of us do better will have to answered by everybody who has a sense of responsibility.

As you expect me to present a meaningful message on a complex matter in less than 30 minutes, I will have to focus on certain things. And I will first focus on how Novartis is living up to its responsibility as a global good corporate citizen. You will hear it sounds like a commercial, but it is reality.

Novartis, through its Foundation for Sustainable Development, has for more than 20 years, been involved in development policy, and in assistance programs. And all together, we have saved thousands of lives, cured tens of thousands of patients, and helped millions of small farmers throughout the world. In the context of improving access to treatment, Novartis has shown leadership, and I want to give five examples for that.

First, Novartis has signed two Memorandums of Understanding with the World Health Organization. One, to provide free treatment for all leprosy patients in the world until this disease has been eliminated. And I don't know whether D.A. is still here. I would challenge him on the fact whether we are able, over the next 20 years, to eliminate the disease. And secondly, we have signed a Memorandum of Understanding to provide Coartem, which is an orally fixed combination anti-malaria product, and we do that at cost.

The second point, Novartis is committed to support research on diseases of poverty, and is currently evaluating locations for the establishment of a new research center that will focus exclusively on the discovery of Novartis drugs for the treatment of infectious and parasitic diseases that are endemic to developing countries. This research will be carried out on a pro bono basis, without the goal of generating any profit from these endemic areas. And this is a point where, in the course of this week, you will hear more. There will be an announcement in about two days that will give you more details on that.

Third point, Novartis will donate directly [unintelligible] short course treatment for tuberculosis as its contribution in response to the appeal of the United Nations Secretary General to tackle diseases of poverty, and I'm very grateful that it has been mentioned this morning that donations are such might be—will be the exception to the rule that we have to find solutions that create the win-win situation and are sustainable.

Fourth point, Novartis will provide prevention, diagnosis, treatment and counseling therapies for all of its employees and immediate family members for HIV, AIDS, tuberculosis and malaria in the developing world.

And the last point I want to mention here is Novartis is willing to become a partner in a pilot approach that the aims at improving the access of poor communities, in the Sub-Saharan African country, to comprehensive anti-malaria services that is prevention and treatment. And one of the aims is, not only to show that that if you really go after it, you can make a difference. Another goal is also how difficult it is to get multi-state called approach that's on the way. Today, too many people, too many actors in this

so-called civil society are reinventing the wheel, instead of cooperating with partners, who have the skills and the knowledge they, themselves, don't have.

All of this, of course, is far not enough to alleviate the immense poverty and disease threats in developing countries. For complex problems, and I assume you have learned that, at least though D.A.'s message on the eradication of smallpox, for complex problems there are no silver bullets. For publicly-related diseases, there is no "all" in place and cure. And certainly, no single actor will be able to provide all the solutions.

With the following remarks, I want to give a brief indication on important policy elements and possible directions in which results oriented stakeholder might want to go in search of better solutions. These are not prescriptions, but rather areas of concerns and proposals.

Point one, we should accept the societal division of labor and build upon it. The societies of the world are highly complex organizations that are based, to a large degree, on division of labor amongst individual members. To ensure that there is a maximum level of synergy, or at least a minimum amount of friction, the various players in the sea of our society passively expect that everyone, by and large, observes the rules. No one in society is responsible for everything. No one has sweeping rights, and no one is beholden for all of the duties of society.

Experience shows that a nation's economic and social success, and this is crucial for the public welfare of a society, is greatest if there is both a clear division of labor and responsibility between the different members of society, and a common understanding with regard to shared values, an overall goal of society, including a fair equilibrium of duties and rights.

National and multi-national corporations have specific and fairly clearly defined duties and responsibilities, and I will come back that. But, governments, and I want to start with that, also have fairly defined duties and responsibilities. First and foremost, they reached a necessity of a development policy that shuts its priority and poverty eradication, because this will result in the improvement of the state of health. There is a well known fundamental and relationship between the state of development and the state of health information and its citizens.

Fifty years ago, a publication of the World Health Organization said, men and women who are sick, because they were poor. They became poorer, because they were sick, and sicker because they were poorer. Poor health conditions are part of a social system of poverty. They are invalent [sp] in all aspects of it, be it the availability of food, education, housing, sanitation, hygiene, and primary health care services. Without sustainable social economic development, there will be no sustainable improvement in the state of health of poor nations.

The best of western thinking indicates that a human stand-up [sp], market friendly, good governments oriented approach is the most effective way to promote development, and reduce poverty in a particular country. This was the point when Laurie Garrett in the morning pointed to the table, and said, how come Costa Rica is up there? How come Sri Lanka is up there? And the development specialists

amongst you will know how come Caroli [sp] is so much more better off than the rest of India, then you know what I mean if I say good governments. Good governments, amongst other things, means put your priority, put your finance priority where your development priorities are.

And may I say here, already as long as ministers in Africa—ministers for ministers for health in Africa drives Mercedes Limousines, don't tell me there isn't money for vaccines. And they shouldn't make the mistake of saying, oh, it's all that the problem of the [unintelligible]. We should give more money. We have to very carefully look for what purposes this money is spent, and how cost effective. And if we don't do this, we commit a terrible mistake, because it was a bottomless affair if we don't insist on good government and a cost effective [unintelligible].

And let us not include that if, for example, Botswana, if there are countries that have good governments, if there are governments who have made up their minds on what's the right thing to do, that we support them with development aid. But, that's then conditionality, we must put conditionality on aid, then we can make sure that the money we spent is eventually creating the results we are hoping.

Sustained poverty reduction will lead to sustained reduction of infectious diseases, and after September 11, I want to add sustained poverty reduction. And we'll also try—have to dry out the swamp that breeds terrorism. Certainly, there are not only best practices for development policy, and may I also say, I worked five years in Sub-Saharan Africa. I know what I'm talking about, and our foundation is working since 25 years in Sub-Saharan, Africa, and if you do not have a counterpart who has the same definitions of the problem, and agrees on the same definition of the solutions, the flow of money isn't what we should measure.

There are best practices in health policy, because if you look at countries at all levels of income, have achieved great advantages in their state of health of populations, but some have done considerably better than others. Even after controlling for differences in income and education levels, country performances, assessed by the usual key indicators under-five mortality, adult mortality rate, life expectancy, and by the way, total fertility rates, they differ significantly over time and across countries. The explanatory shape of the articles lies in the policies, designed to improve health, but for those policies are within or outside the health sector.

As far as health policy outcomes are concerned, there are known cost effective best practices to learn from and to follow. And they are published by the WHO, and they are supported by the WHO, and that less than 15 countries in Sub-Saharan, Africa are following these best practices. Do we have a government issue, or don't we have one? Wherever known low cost strategies to prevent or treat infectious diseases have been implemented, dramatic progress has been achieved, and this is not clearly the best practice.

The health sector in developing countries react particularly sensitive to government issues, as it has a direct dealing on the performance of the health system, in which people's health and well being depends to a large degree. Whether or not public funds reach the needy, essential products and quality clinical services are available is, also, a matter of government.

I spent four years in Kenya, and the Jamii Kenyatta National Hospital in Kenya absorbed 80 percent of the recurrent costs of the country. And 10 to 15 kilometers outside of the city center of Nairobi, there are slums where children die of tetanus, because there is no vaccine. So, it's not money alone. It's the proper management of the money that is available.

The bad governments, and I want to say that I regret that Jeff Sachs is not here, because I would have loved to battle on that. Bad governments kill much more than most of the diseases do. Typical government issues in the health sectors that need to be addressed are committing politics to the highest attainable standard of public health. And there, you also can refer to the case studies that countries, in the same latitude with the same problems with the same infectious disease load, but differing health practices can result—can achieve very different results.

The pursuing of a broad poor approach to basic social and health services is the most important thing. And I just, two days ago, met somebody from the World Bank, who told me that even the, oh, we have rations for our sachets, the very image [unintelligible] to prevent dehydration, to diarrhea, even that does not reach 60 percent of the poor, and it's not a question of the money. It's a question of the logistics. It's a question of the political will.

The government should also make sure that there is a balance between the state, the NGO and the private sector responsibility in health care division, and it's a synergism. It's not an I overall. The state has to address the market failures, and I will come back to that. It also has to fight illegal practices and corruption, and it has to strive for responsiveness and fairness in financing, and by the way, it has to promote decentralizations for the health specialists amongst you. I do not know of many countries that a referral system functions. And if the referral system doesn't function, you have, at the teaching hospital in the capital, all of the diseases to treat that you can—that you should treat at the barefoot doctor's patients at the peripheral of the city.

As I said, so far, I haven't seen the minister for health going on a bicycle, but I have seen a lot of health stations being out of anti-malarials, being out of penicillin, and being out of a lot of other things.

Addressing extra maladies, regulating market failure and overcoming imperfect information, belong to the state's core functions. The general inadequacy or absence of health insurance of the health insurance market is both a state and a market failure. As the state promised a fully-funded health system, which collapsed, a private health insurance market could hardly develop. It is a market failure as commercial insurance policies do not respond to the specific insurance needs of the poor. And this exposes people, in particular, the poorest of the poor, to high financial and survival risk exactly when they can stand it the least. Micro insurance mechanisms, I would call it barefoot insurance mechanisms are amongst the initiatives that we acquire more public attention and support. My foundation, the Novartis Foundation for Sustainable Development is currently starting two pilot projects in Sub-Saharan Africa.

As some of the problems can be solved by the market, others are beyond the market's capacity. The role of the government, and do not misunderstand me, that the role of the government remains a crucial

one. This is why good government remains a crucial issue. And particular when Jeff Sachs mentioned the Upper Dential [sp], I know Nigeria very well. I just wanted to remind you that Nigeria, over the past 25 years, has an income of more than $400 billion in crude oil rewards. Now, where is this money? And if you talk about that forgiveness without conditionalities, we might ask that and realize the General of England that the coat does seal. Is this what you want to spend development money for?

Point two, you are here on frustrated sex [sic] frustrated as to effects, but it has to be mentioned. Point two, the business of business will remain business, also in an enlightened manner. The role and responsibility of the private sector is the satisfaction of material needs expressed in markets in profitable terms. And it is not from the benevolence of the butcher or the brewer or the baker that we expect our dinner, but from their regard to their own self interest, we should also not expect—we should also expect the same when it comes the availability of efficient drugs.

The key role of the pharmaceutical industry is to discover, develop, produce and market innovative products to prevent and cure diseases, to ease suffering and to enhance the quality of life of people. And intellectual property rights are the lifeline of a research-based pharmaceutical industry, and they are vital to sustain continued R&D into new treatments. And I have to be grateful that all of those people mentioned this in the morning, and by the way, when Jeff said the development discussion is so much more enlightened in Europe, the grass is always greener on the other side of the fence.

In view of the substantial investment of time and capital to bring a drug to market, as well as the high risk of failure in the research effort of the pharmaceutical industry are primarily focused on diseases with the potential of an adequate return on investment, and this is a problem. And this is one of the reasons I'm asking for the agreement of the Consultative Group for International Agricultural Research, we need a Consultative Group for International Health Research, because the private sector has much more to offer than money. Imagine that any—I don't know, Andrea [sp], correct me if I'm wrong—out of 10,000 drugs that make it through development, only one or two go to the market. And part of the reason is that there might not be drugs that should go to the market, but a Novartis or a Merck or Pfizer or anybody else, this focus is wrong. But, imagine there is somebody else, a nonprofit Consultative Group for Health that is able to take these components, who are not developed for the industrialized market, and develop them for our public diseases.

You know, the money that is inherent in the research results that are available and not used is much more than can be spent on a cash basis. In modern societies, most people expect successful companies to accept more than business obligations, and rightly so. There are profitable obligations beyond the narrowly defined role that results from a strict division of labor. Anyone who asserts the contrary is suggesting that those who have the ultimate responsibilities for their companies are severely lacking, either in intelligence, or at least in basic common sense.

It would be a terrible affair, and certainly not in the enlightenment of interest of the industry, or in the real world corporations, if big farmer would be portrayed as irresponsibly greedy and willing to let sick people die in masses, rather than make compromises on prices. Successful corporations have a triple bottom line. They are expected to deliver themselves in economic, social and ecological terms.

Point three, results oriented cooperation of different stakeholders will improve and accelerate solutions. Complex health problems, like any other complex problems, do not have simple solutions. Overcoming multi-faceted difficulties necessitates the synergistic cooperation of different social actors. Different actors in civil society have different concepts, different skills, different techniques, different experiences and different resources, and they are also driven by different motives. Although, there's a rational and natural division of labor and responsibility, synergies from corporations of different actors are feasible.

As a result of different backgrounds and experiences, different actors are likely to analyze the issues and appraise the problems differently. By the individual actors, be it government or NGO or the private sector, may be very effective and efficient in achieving their specific goals. No one can solve every issue of common concern, collaboration and, at least, coordination among the different actors can lead to synergies and to all—to different solutions, to better solutions.

And as I said, the precondition for successful cooperation is the common understanding of the structure of the problems involved, and the appropriateness of the measures that light solutions. And this is what I meant. If you listen to Europe, I recently was invited to write a speech for the German President, and I was not the only one who was there. There were people from the churches and people from Enchio [sp] as well. And I was very astonished, because they said it's all a problem of the globalization. It's all a problem of the international redistribution. If you wouldn't have to mark the map of corporations [sic], if you wouldn't have the monetary funds to pool, the world would be better off. I haven't heard that too often here, this why I mean the grass is greener on this side of the fence.

The precondition for a successful cooperation is a common understanding of the structure of the problem involved, and the appropriateness of the measures of light as solutions. And this, I can tell you, is sometimes difficult to achieve. I just want to mention one thing.

Two years ago, we announced that Novartis will give away for free all drugs that are necessary to cure leprosy until we eliminate the disease. Do you know who was unhappy about that? The Leprosy NGOs. All of a sudden, they didn't like that the multi-nationals, whom they accused for years are the greedy ones, are the irresponsible ones, because the prices are so high. Now, they give something away, and speak of elimination. And that would be taking away the [inaudible] of the Leprosy NGO. You must be joking?

And I can already tell you now in the last week of January, there will be an International Leprosy Conference in Brazil, and the International Leprosy Organizations will announce there that they withdraw from the global alliance for the elimination of leprosy. And I hope that those who are giving money to such NGOs, ask themselves the appropriate questions and draw the appropriate solutions.

I want to finish here by saying that the differences among the different actors are a source of thanks in partnerships, and they are a source of particular challenges. Bringing together organizations, diverse goals, values and perspectives means that there is plenty of ground for disputes and conflicts, but we should not put our ideological conflicts in the moth on the back of the poor people in the south. The

future is wide open, and solutions for many of today's problems are known, and it's much more a problem of a deficit of implementation than a deficit of knowledge. It depends on all of us to make things happen, and if all players in single society, politicians, entrepreneurs, researchers and people from NGO, assume their specific responsibilities as local and global citizens with the highest possible stand-ups, the they, if there is cooperation in a constructive manner, we can create the synergism that is necessary to find better solutions and to find the proper results.

And let me finish with something that I really feel, myself, very personally. Those who hold responsibility in our generation will eventually be measured by the extent to which they live up to the political, economic, social, technological, and not the responsibilities that face them.

We never had more knowledge than we have today. We never had more funds and resources than we have today. And it is up to us that those who have broad shoulders, we need to bear a greater burden, and it's equally clear that all those who can contribute, whatever that is, must contribute within their responsibilities. But then, let at home begin the subsidy or the principal. Let at home begin, in the countries what can support—can be supported from outside, and let us not substitute from outside what ought to be done by beyond responsibility in the countries.

It is my conviction, and I've been doing this job for over 20 years, that if we want it, it can be done. And I extend an invitation to all of those wishing in good will to help in the search to join us. Thank you.

PROFESSOR BARRETT: Since our conference is being live Web broadcast by the Kaiser Family Foundation, it's possible that Jeff Sachs is watching us. And he knows where to call up, so we can have that debate that I think would be illuminating. Maybe if I could just sort of make a brief comment before I turn it over to Professor Fidler.

You know, the idea is that money is the problem. There must be some sense to that, because I also heard, in D.A. Henderson's talk, when he tried to raise money for the Global Eradiation Program for Smallpox, how when they passed the hat around to governments, they got $75,000. And when I did some research, looking in the background on how they funded this program, it is absolutely extraordinary. If you looked at the list of the funding organizations, it turned out that roughly high up on the list, I can't remember where exactly on the hierarchy. But, roughly high up was a Japanese trade union in the shipping industry, and it really seemed to me rather extraordinary how little money was put into this by the international community, probably because of, perhaps earlier failures, particularly I think the malaria program that plagued smallpox. Because--so to some extent it seems to be that it may be a kind of problem here that people don't give money, even where it might could do some good, probably because they see it not doing good in so many other places.

And just a comment to tie in that last bit. When Laurie Garrett put that chart up showing the relationship between, I think it was life expectancy at birth and income per head, there is a very strong correlation between life expectancy at birth and income per head. There is very little correlation between health expenditure and life expectancy. And it really does make a difference how you spend the money. They actually—the most amazing example on that was not—I think not so much Costa Rica. Costa Rica is

an amazing example for a lot of things. Sri Lanka is really very extraordinary, because that country is much, much poorer than Costa Rica, and yet, its life expectancy is very high in the region, and that is very well known. They spend the money on public health.

And so, there certainly is a lot to be said about how you spend the money. And ultimately, you have to ask the question, why is it that some countries are doing this and others are not? Which I think is partly the point that you were trying to make.

If I could hold questions now maybe to clarifying questions. I know I should have—maybe I should have held my own comments, but it's the prerogative of the Chairman. But if there are clarifying questions, but otherwise, what I'd like to do is hold the bigger questions until we have a broader debate. But are there any clarifying questions?

OK, let's turn now to Professor David Fidler, and we have a very high-tech solution to our problem of how to the PowerPoint to work. There is a pamphlet that's leaning on top the lens, and, John, if you could possibly reach over and lift that up.

PROFESSOR FIDLER: Can everybody see that? Is that—no. Do we need some light adjustment here? Let there not be light. Is that better? OK. I want to thank Scott and the organizers of this conference for inviting me to participate in what I think is a very important topic, and I'm eager to share some of my thinking and thoughts on this with you from my years in both practical, as well as academic experience, thinking about these things. Sorry, oops.

One of the things that I was asked to address, and what I was scheduled to speak earlier, was to talk about—to try to answer the question, are our existing institutions up to the job? And although, this is a little out of place, in terms of the original schedule, I think it actually fits quite nicely into the debates and discourse that we've already had today.

I want to do four basic things with my presentation, and unlike some of the presentations that we've had before, which have been at a fairly general level, I want to try to focus on some specifics. And I want to talk about some specific international regimes, particularly that being defined as norm's [sp] rules and institutions that are relevant to the global control of infectious diseases, because it's not a blank slate. There's actually a lot of politics, diplomacy in international law that exists on, and that's relevant to the global control of infectious diseases, and I think understanding that complexity is important. So, the second objective that I have today is to describe that current landscape of these international regimes and institutions that relate to the global control of infectious diseases.

We're also interested in how globalization has had an impact on these regimes. And as you'll note, when I go into—when I talk about these regimes, part of what I'm trying to do is also go back in history, as well as to look forward, because I think we need to understand where we've been, in order to know where we might want to go, and how we might get there. And I think it's important to understand how globalization, this phenomenon that we're all interested in, may be affecting these international regimes, and what implications that has for global control of infectious diseases.

And finally, I want to ponder what the impact of the current anthrax attacks on the United States has on the future development of these relevant international regimes. I'm not going to talk in any specific detail about bioterrorism, because we have a whole panel on that. But, I think it's important to reflect for a moment about how these anthrax attacks may be affecting this larger picture. And we've already heard some worried concerns from Laurie Garrett and Jeff Sachs about how the bioterrorism situation in the United States may be affecting the global public health picture, and I'm going to be adding a chorus of concerns of my own to that.

What I want to try to do, and this is a very simplistic schematic, but I want try to use this to illustrate the different kinds of strategies that have been attempted historically in connection with controlling infectious diseases in international relations. And I'm using the terms vertical and horizontal here, very differently from the way in which they're used in public health. So, I'm going to provide a very precise definition of how I'm using it, when I'm talking about it, so as not confuse that with public health terminology.

Vertical strategies are strategies of international cooperation that seek to reduce infectious disease prevalence inside countries, and here, I've just indicated inside State A just to give a simplistic figure for that. And the idea here is that we really need to attack the infectious diseases at their national source. So, vertical strategies are, in essence, inward looking. They're not really concerned about trying to stop and prevent cross-border transmission of pathogenic microbes. And the objective, here, is to decrease the national burden of infectious diseases inside the nation state.

Contrast the vertical strategy with, what I call, horizontal strategies, and these are strategies that involve international cooperation, between states, to try to minimize that cross-border transmission of pathogenic microbes. So, here, we are concerned with disease exportation and importation. So, our focus is on the cross-border element of this. It's outward looking, in other words. All right. It is not concerned, this strategy has not historically been concerned with reducing infectious disease problems inside nation states. It's been concerned about the cross-border issue.

So the objective here is to coordinate state actions at point of disease, exit and entry. To, first of all, decrease the possibility of disease exportation, and then secondly, strengthen public health readiness at points of disease importation. So, I'm going to be using this vertical-horizontal throughout the rest of the presentation, but that's how I'm going to be using these terms. And you'll see here how the regimes, then, fall out within these different strategies.

Let me talk, first, about horizontal international regimes and infectious disease control. And the current slide is the—contains the regimes that I'm going to talk about: the classical regime, the organizational, and the trade regime. And I'll go into each of these in a little bit of detail, to explain what I'm talking about.

Let's first start with, what I call, the classical regime. And why do I call this the classical regime? Well, this is the oldest regime in international public health. This is the regime that was developed beginning in 1851, which the first International Sanitary Conference, and developed in the latter half of the 19th

century, the first half of the 20th century, leading up to the foundation, the establishment of the World Health Organization.

Now, part of why I'm taking us back to 1851 is that there is historical continuity that we need to understand with the classical regime. It begins in 1851, but it goes up to the present day, because the current embodiment of the classical regime for global infectious disease control and international health regulations promulgated by the World Health Organization, first adopted at the International Sanitary Regulations in 1951. The name was changed in '68, I believe, and now, they continue to be, in the words of the World Health Organization, the only International Health Agreement on communicable diseases that is binding on WHO member states.

The basic function of the classical regime, both in terms of the International Sanitary Conventions, and its current incarnation with International Health Regulations, I think is captured by the official purpose of the International Health Regulations, and that is, we have this regime to ensure maximum protection against the international spread of disease, with minimum interference with world trade and travel.

Now, I want you to notice there that that's a dual objective. One objective is the classic public health objective of ensuring maximum protection against the international cross-border spread of disease. But, the regime is also concerned that, when we take public health measures, we don't do so irrationally, that we do so in a way in which there's minimum interference. Only that interference with trade and travel that's necessary for public health purposes. And a lot of people forget that in this classical regime, or the public health approach to infectious diseases, those trade and travel issues have been on the agenda since day one.

Now, let me talk a little bit about the two objectives: maximum protection against international spread of disease, and minimum interference with world traffic as part of this classical regime. How do we go about ensuring the maximum protection against international spread of infectious diseases? Well, on the classical regime, there really have been two policies that have been implemented to try to obtain that. The first is, states are required to notify each other, or an international health organization, about cases or outbreaks of specified diseases. This is designed to create a global international flow of epidemiological information and data.

The second is to maintain proper public health capabilities at points of disease entries and exits. So, at ports and airports, you have public health capabilities built into the system. Minimum interference with world trade and traffic. Here, again, the idea is that trade restricting health measures need to be based on scientific evidence, scientific principle. They need to be based on public health principles, to prevent states from taking irrational measures against trade and travel. This is, also, part of the public health thoughts. If you do something that's irrational, in terms of science or public health, you're not going to do anything to protect public health. So, you're neither achieving the public health objective, and you're unnecessarily restraining trade and travel.

And I'm going to skip over this briefly, but just, in historical matters, the classical regime, particularly as embodied in International Health Regulations has been a failure. There's been a complete breakdown

on both objectives. We have achieved neither maximum protection, nor minimum interference with world trade and travel. I could spend all afternoon talking about this, but I won't. Part of this led the World Health Organization, in 1995, to conclude that they needed to revise the International Health Regulations, because of the impact of globalization, and I want to come back to that in a little bit.

The second regime, in the horizontal context, is, what I call, the organization regime, and here, I'm talking about international health organizations. The organizational regime represents efforts to create and operate international health organizations that have, as part of their mandate, the control of infectious diseases. And again, the World Health Organization is not the first example of this. We have the Pan-American Sanitary Bureau in 1902, the International Office of Public Health in 1907, the Health Organization of the League of Nations, 1924. So, these are precursors of WHO, in terms of this organizational regime, that go back to the beginning part of the 20th century.

Now, although, these international health organizations were tasked with facilitating international efforts on infectious diseases, the regime itself, in terms of the treaty, the actual international law, contained no duties, contains no duties on member states to do anything specific about infectious diseases. For example, in the Constitution of the World Health Organization, the only two concrete duties that member states have are, first, to submit period health reports on various health matters to the organization. And secondly, pay their share of the budget allocation, neither of which WHO member states have been good at complying with historically.

The organizational regime means that, essentially, public health sovereignty of member states is unfettered. In other words, the organizational regime doesn't really require us to do very much, in terms of infectious diseases. Part of this has been some of the thinking that has led people to say that, at least in the 1990s, the World Health Organization was suffering from an institutional crisis. And part of that crisis were challenges from other international organizations that are outside of this regime: the World Bank, the IMF and the World Trade Organization, and I want to come back to that organizational matter in a bit, as well.

Finally, the trade regime, or what I call the trade regime. This represents the rules of international trade law that affect the use of trade-restricting health measures for public health purposes. And I've listed, up here, General Agreement on Tariffs and Trade, the World Trade Organization, the Agreement on the Application of Sanitary and Phytosanitary Measures of the SPS Agreement, TRIPS, GAT. There are a whole number of different regimes, within the trade regime, that are perceived to have an effect on public health or potential effects public health.

The General Agreement on Tariffs and Trade, going back to 1947, recognized the right of solvent states to restrict trade to protect public health purposes. This was elaborated on through the World Trade Organization, particularly the SPS Agreement, where specific disciplines have been applied on states enacting trade-restricting health measures. There are science-based disciplines, and then, there are also trade-related disciplines. In addition to that, you have the very powerful dispute settlement mechanism of the WTO, that plays into global public health context today.

Now, the traditional trade regime, GAT, the SPS Agreement, and that sort of issue is, again, concerned about this cross-border transmission, that's the nature of horizontal regimes. But, with the WTO, we've seen the expansion of the trade regime into new areas: intellectual property rights, and now, the liberalization of trade in international services. And this is one of the—this expansion is one of the reasons why the trade regime has become such a controversial issue in global public health terms, because it's now, not only dealing with the cross-border issue, but also some of these very controversial issues, which again, I'll touch on in a bit.

Next, I want to just give you an overview on the vertical international regimes and infectious disease control, and this starts to get complicated, so I'm sorry if my little grasp is getting out of control here. But, it illustrates part of the shift that's occurring, because of globalization. The top set of boxes indicate what are the public health strategies that we need to implement inside countries, in order that they will be able to reduce the prevalence and burden of infectious diseases. And here, I've just listed environmental reform, and there, I'm talking about clean water, clean air, sanitation and things of that nature.

Public health system reform, we've talked a lot today about the importance of public health infrastructure, the need to focus on public health. And that's obviously important for getting infectious diseases under control on an international basis.

And then, finally, something that really came out of the HIV/AIDS pandemic was respect for human rights as a strategy within countries to help get control infectious disease problems. And then, all of those, then, filter down into the various, of what I call, vertical regime, which I'll talk about in a moment. All of that, then, you can't quite see it, because it's blocked by the microphone, it's supposed to have impact vertically inside the space. And so, again here, we're not concerned about cross-border transmission. We're trying to deal with the problem at its most local source, within the nation state system. So, let me just quickly go through these various regimes that I've identified as being these vertical strategies.

The first is what I call the soft law regime. And here, what I'm talking about, is guidance, for example. Our previous speaker mentioned this. The WHO is constantly putting out guidelines, best practices, recommendations for member states to implement within inside their countries. That advice is not legally binding, in terms of international law, but it can be a very effective strategy, from the point of view of an international organization, to member states if they actually follow it. But, as our previous speaker indicated, most WHO member states don't adopt the recommendations made by the organization to improve public health performance on infectious diseases at the national level.

An interesting wrinkle that we're seeing with this vertical regime, in connection with the impact of the World Trade Organization, is perhaps some synergy between the WHO soft law and what's happening in the WTO. And just let me give you a couple of examples of that.

In the SBS Agreement, for example, the SBS Agreement instructs dispute settlement panels to look to Codex Alimentarius, for example, for guidance on what are food safety standards. The WTO regime, in a sense, legalizes that nonbinding, technical advice from the WHO. In other words, the WHO has a

real possibility there of putting those recommendations in play as a matter of international law through the WTO in a way in which it couldn't do on its own. So, I see there have been some synergy between some of the organizational regimes and the South Wall [sp] regime and the World Trade Organization.

Let me talk quickly on about the human rights regime, and this really breaks down into two categories: civil and political rights, which the first two bullet points refer to. And in the area of civil and political rights, the human rights regime attempts to discipline government restrictions on civil and political rights, undertaken to protect public health. We've heard a lot of discussion lately about quarantine and isolation and a threat to civil liberties in the United States. That's what this is talking about. International human rights law developed to try to regulate how governments might restrict civil and political rights for legitimate public health purposes.

And secondly, in the area of civil and political rights, there's the prohibition on discrimination and the enjoyment of those rights in the public health context. Now, as anybody familiar with the HIV/AIDS pandemic knows, that both of those disciplines, within the human rights regimes, have been massively violated on a global scale.

The second issue here, on the human rights regime, is economic, social and cultural rights, and here, that's singled out, the human right to health. In other words, the human rights regime promotes this idea that the right to health, or the right to access to health care, is a universal and fundamental human right. And historically speaking this has been very, very powerful rhetoric for states and international health organizations. But, there's actually been very little progress made in making this human right effective—an effective part of international human rights law in the public health context.

The environmental regime, again, I mentioned earlier, things of local air pollution, water pollution, sanitation. Most of the international environmental law that we have in this regime deals with other-the classic global problems, such as trans-boundary air and water pollution, or maritime, marine pollution, ozone pollution, global climate change. And all of those, somewhat, resonate with public health, but if you actually look at the infectious disease killers that come out of environmental context, it's at the local level. And it's local air and water pollution that cause the morbidity and mortality of infectious diseases. And here, we really don't have any international law. There really isn't much interest at all in dealing with those problems as a vertical strategy, even though those are the biggest infectious disease killers.

Now, the regime that has generated the most controversy and attention lately is what I call the access regime. And here, we're talking about the controversies about access to essential drugs and vaccines and other medicines. And the real action, lately, has been here, and we've heard a lot of mention of this before. And that's really a debate about access to drugs, and its been trained then versus protection of patents on pharmaceutical products. That's likely the TRIPS debate, which everybody here will be familiar with, and it's become polarized, and it's become ideological, and it's really become one of the major controversies in global public health today. I don't want to go into that, but it's certainly one of the sore points.

But, also in terms of the access regime, we also see some developments in terms of whether or not a public-private partnership to develop new drugs and vaccines for HIV, malaria, TB and other diseases, and some of that has already been mentioned today. But, that's considered to be a new wrinkle in this access regime, as well as the global front for HIV, AIDS, tuberculosis and malaria, and some of the other policy ideas that are alive in different forums, such as the Commission on Macro Economics and Health, in order to try to improve access to those drugs.

Now, let me just talk a little bit about the impact of globalization on this, or where are these regimes going in the future? Now, I'd like to sort of try to lay out the analytical framework of this. It's my conclusion, from having worked on these issues and tried to observe what's happening, is that what we're witnessing is the death of the classical regime. In fact, some people would argue it died a long time ago, and we just are now realizing it. Or the World Health Organization, their experts haven't realized it, because they're still trying to revise it.

I sense a great deal of political, as well as legal, apathy towards the IHR revision process, not only within the WHO itself, but among the member states, and also, global civil society groups. I couldn't identify a single NGO that's active in global public health that cares at all about the revision of the International Health Regulations. I'm not even sure that WHO really cares about the revision of the International Health Regulations. And I'm not sure that's a bad idea.

Part of it is that there's just a lack of interest in it within the organization, but there are also extraordinary difficult substantial problems with trying to continue to pursue in this classical way, this idea of maximum protection against international spread of diseases with minimal interference in world traffic. And I could talk a long time about these substantive difficulties, but we sort of seemed to have run up against a brick wall, in terms of making that paradigm work effectively.

In fact, and thirdly, there are some technological opportunities that WHO is trying to exploit. Laurie Garrett mentioned some of those this morning. And to try a different approach, a different paradigm to just collecting global epidemiological data that may be more effective, and doesn't have to rely on this type of international regime reform. Again, there are controversies and skepticism about that. But, I think that's the direction WHO is going, and that's part of what I'm witnessing in terms of the death of the classical regime.

As I mentioned, too, I think globalization is also building, or has set in place with these regimes, potential synergy between the trade and the organizational regimes, within the World Trade Organization, particularly in the context of the SBS Agreement, food safety, for example. It's not a huge synergy, in the sense that there are synergies all over the place, but I think here is a potential opportunity for WHO and WTO to do some good work, because they seem to be operating on basically the same regime principles.

Again, the future, I think, is also going to be overshadowed by this very serious controversy about TRIPS and public health. I actually believe that a lot of that controversy is misguided, but the fact is that it's there, and we sort of have to deal with it. Not often mentioned is the possible frictions that are

arising in the context of the General Agreement on Trade and Services. There are great worries that if trade and health services is liberalized, that this is going to have a detrimental effect on national health care and national public health systems. And it may be another adverse impact of the WTO and the processes of the globalization on the national control of infectious diseases.

In terms of the vertical regimes, again, I think that the soft law regime, and we might have some hardening of that soft law through the WTO process. But that's really going to be driven by the WTO, rather than the WHO, except to the extent to which those two organizations can work together.

On the environmental regime, I don't see any evidence of much interest in addressing local air and water pollution, as a global infectious disease concern. The focus is on climate change, which may, down the road, have impact on public health, but the death and suffering that's happening now, there doesn't seem much interest in that vertical regime to deal with the problem that's right in front of us.

On the human rights regime, again, we have the problem of violation of civil and political rights in the HIV/AIDS context, but we also have the problem that the human rights to health, although powerfully rhetorically, remains indeterminate as a matter of international law and as a matter of this regime. It doesn't have a lot of traction, and part of that's led people to explore new concepts, connecting public health and economic development, global public health, global public goods for health, their health, things of that nature.

And finally, in the access regime, the future processes of globalization is going to depend on whether there's any raprosmall [sp] developing in this debate over the human right to access, and the protection of intellectual property rights. And, at the moment, there doesn't seem to be much on the horizon to create that raprosmall.

Now, let me just summarize here a little bit on the impact of globalization, before I turn my concluding remarks to the impact of bioterrorism. On the horizontal strategies and regimes, I think we, again, I think we're seeing the death of this classical regime. Globalization has sort of overtaken this traditional approach to global and infectious disease control, and maybe we need to try something new.

But, we've also seen a shift in the dominance from the organizational regime, the International Health Organizations, towards the trade regime. This is simply not possible to say with a straight face anymore, the International Health Organizations control what's happening with these horizontal regimes, in connection with public health. The trade regime does that in the horizontal context.

There is also, I think, we've seen a shift in the emphasis away from the horizontal strategies toward the vertical strategies and towards the vertical regimes. In a sense, if we're just dealing with the cross-border issue, we're missing part of the problem, and we really need to deal with the problem within nation states itself.

So, the vertical strategies and regimes, again, I think we're seeing somewhat of a shift towards that, away from the horizontal strategies. We're seeing a shift away from the traditional WHO soft law

approach towards an emphasis on human rights, and especially an emphasis on access as a human right. But at the same time, we're starting to see a heightened understanding of the underlying weaknesses of the vertical regimes. And here, I want to point out, and I want to come to the sovereignty problem that was raised earlier this morning, because the weaknesses of these vertical regimes, the fact they don't really penetrate down very deeply inside nation states, has to do with sovereignty.

International relations would allow sovereign states interact on a condition of anarchy. We can't force states to do some of these things. And if they don't adopt some of these things, then, we've got a problem from a point of view of global infectious disease control.

So, one of the problems that we've got with these vertical regimes is that the structure of the international system, the structure of the politics between nation states, is hostile towards these kinds of vertical efforts. And what that means is, that not only do we have a shift from the horizontal to the vertical, and then sort of an understanding that these vertical strategies aren't really getting us anywhere, that's created opportunities for organizations that have real vertical power to muscle in on global public health. And I'm thinking, specifically, of the World Bank and the International Monetary Fund. They can make countries do things at the national level. They have real vertical power, in a way that we don't have in a human rights regime, soft law regime and environmental regime. And I think that may be part of the reason why we're seeing these new actors come to the forefront in terms of global infectious diseases.

Let me just wrap up by talking a little bit about the impact of bioterrorism. I'm a veteran of the pre-anthrax debates about bioterrorism, both working with the Federation of American Scientists on the proposed protocol to the Biological Weapons Convention, but also, as an International League of Consultant to the Department of Defense, Defense Science Board on Homeland Defense Against Biological Weapons. So, part of what I'm drawing on here is not only from my academic study, but from my personal experiences working within this bioterrorism realm.

I think I'm going to try to categorize what we saw in the pre-anthrax environment. I think we saw some slow, very frustrating progress in making the United States, particularly the federal government, a little bit more aware of the importance of global infectious disease issues, and I have mentioned some of the classic seminal reports and institutions that were involved in this. But, as Jeffrey Sachs, and other people have already pointed out, that progress was pretty superficial. We had lots of disappointing responses to this idea that infectious diseases are now a national security concern. That really was more politically correct rhetoric, than it was actual policy. And I think a lot of people point to the fact, look at U.S. policy on access to antiretrovirals in Sub-Saharan Africa, or U.S. policy on the new global fund, as an indication the United States really never became engaged in these issues prior to the anthrax attacks.

And I also think that there's a lack of leadership, even on those traditional national security issues, such as biological weapons proliferation. You had a great deal of indecision from the Clinton administration about this, and then also, the sort of a summary execution of the DWC protocol by the Bush administration in July of this year.

Well, what about the post-anthrax environment then? My reading of this is that with the United States currently into biological attack, the global efforts, the need for this new paradigm, this new way of thinking that earlier speakers talked about, the need to think about infectious diseases from a global basis, I'm afraid this may suffer very badly in this environment. And what I see developing, and again, part of this is my reflection and my experiences working on this as a consultant, is that public health is going to become—will become dominated by national security concerns. And these are not often the same thing as public health concerns. And we're going to be focused on fighting terrorism and proliferation of biological weapons. So, in a way, public health is going to be taken in this national security direction.

Also, I think that the political and financial focus is going to be on national public health, for purposes of homeland security. And the rest of the world isn't going to get much attention from this. Somebody earlier mentioned, HIV agents had to turn out, but they sort of disappeared from the global agenda after September 11. Well, after October 4, with the anthrax attacks, it's been even more buried in terms of the consciousness in this country.

And also, I think many people are starting to see that U.S. responses to anthrax, particularly the threats to break the patent on Cipro, reveals the U.S. myopia, and some would say hypocrisy on global infectious disease control, particularly in connection to our attitude about other countries using compulsory licenses for access to drugs in poor countries. Not that that's the best public health strategy, but I think this has sort of really revealed the nature of our true interest in some of these public health issues to our detriment, I believe, not only short term, but also long term.

Now, let me just wrap up. The impact of globalization on these various regimes and global infectious disease control, I think, can be summed up in two points. The first is, I think we're seeing a radical transformation of the landscape of these horizontal regimes. We're seeing the death of the classical regime, sort of the withering of the organizational regime, and the dominance of the trade regime. But, also I think that we have a new emphasis on these vertical regimes. But, we haven't really done much at all, if we can do anything at all, about this structural friction in the international system, unless we try to greatly reduce that, or we engage in structural adjustment for public health on a global basis, we're going to continue to run into that particular problem.

And finally, in terms of the impact of bioterrorism on global infectious disease control, I think we're going to see, or we are seeing, a shift in the United States from a weak global perspective, to a strong national perspective on the threat of infectious diseases. And that may not be, as previous speakers have mentioned, the right way to go.

Secondly, I think we may be witnessing a shift in the United States from a weak commitment to public health, to a very strong effort on homeland security. Again, that's not the same thing as a strong national effort on public health.

And finally, I think we're seeing a shift in the United States from a tepid concern about the threat of naturally occurring diseases, the concern that we've had that diseases of others would come to our

shores. It never really became very strong. We're seeing a shift from that, to a serious fear about the intentional use of microbes, which, we realize now, is important, but it's not the entire story.

So, I have great concerns about how the recent anthrax attacks are going to affect the development and the shaping of all of these various regimes, which I've talked about, and I'm sure other people will have opinions and questions that they may want to present about that. But, that concludes my remarks, and I'll shut up and open it up for questions.

PROFESSOR BARRETT: Most of my work is actually on environmental issues, and on international environmental issues, we take a very decentralized approach, and it turns out that there actually hundreds of treaties dealing with these problems. And a lot of people are dissatisfied with this approach, too, and they say, well, everything would be all right, if we tried a different approach, and particularly, if we had a world environment organization. And I think I finally need one response to that question, that proposal. I think you have just given it to us. I mean, it's not clear that moving in that direction would be any improvement of where we stand now.

Let me first ask for if there are any clarifying questions for Professor Fidler, and if not, I'll just open it up to general questions. So, are there any clarifying questions? No? OK. Well, let's just open it up, then, to general questions to both speakers.

Yes, in the back.

MS. ELLEN KELLY: Thank you. My name is Ellen Kelly. And I work in the House of Representatives as a solo [sp]. And I do bipartisan education for members and staff on the security issues. And I know that the terrorist attack on September 11 has displaced a lot of other issues and sort of remolded the framework for where we consider national security in general. But, I have heard a lot from members about how they want to turn to issues, like global health, and developmental security concerns go out the gate with the $40 billion that we're going to spend mostly on bolstering defense and intelligence in traditional ways. I'm wondering, what can you suggest, as leadership opportunities for members of Congress on making sure these issues get included in the framework that we're going to develop to deal with terrorism and international security issues, in general now?

PROFESSOR FIDLER: Well, it's been my experience, in working on this, I'm not trained in public health or science of doctrine. I'm an international lawyer, so I can look at the public health community with, perhaps, a little bit of objectivity. And it's been clear to me that public health, historically speaking, has not been very—has not really had to play the games of politics and budgets and allocations that national security law enforcement and intelligence communities have had to play for a long time.

Unless the public health community gets much more savvy and sophisticated at playing these types of politics, they're not going—those issues are not going to walk with the billions of dollars that are being poured into bioterrorism and homeland security. And unless the public health community strengthens its voice to make those connections clear, I'm afraid that the message is going to be lost. And that's what I'm seeing. I'm seeing that the public health elements that are useful to law enforcement intelligence

national security being co-opted without there being any attention paid to the larger issue of public health infrastructure, which is, after all, the front lines of defense for any biological terrorism. It's our front line of defense for any naturally occurring disease.

Again, there's a tremendous synergy, a potential there. But, what I'm sensing, and I think Laurie Garrett is sensing the same thing, is now people on the Hill are saying, hey, public health infrastructure, they don't have a clue as to what it means, how it works, and the importance of connecting that, in a grass roots way, to national security.

We've gone off in the traditional model of national security again, and we've taken the bits of public health that are useful to us, and ignoring the bigger picture. So, I mean, I don't know that's an answer to your question, but I think that the public health community needs to mobilize, and to be able to play these politics better. Otherwise, they're going to be the weakest link in the chain of this effort to try to deal with bioterrorism, or naturally occurring diseases.

PROFESSOR BARRETT: Are people tired? Yes.

UNIDENTIFIED MAN: I'd like just answer this question. See, you said that the NGOs refused to take those drugs. Is it because of some conditions you portend? You have to have medicine. You have to have [unintelligible] shots. You have to have something with that. Or is it, you said, please have it, and do it your way? Thank you.

PROFESSOR LEISINGER: Mr. Manny [sp], we were not putting any conditions on it. As a matter of fact, we went to the WHO, and we said, we want to give you the way for elimination. We are convinced that we can eliminate leprosy, as a public health issue, over the next five years, eliminated means less than 1 patient per 10,000 of population. It's not eradiation, because you do not know the incubation time, and we have fields where we do not have the access, and we don't know what we'll find there.

When he spoke about elimination, and let me explain to that. Ten years ago, there was an international conference in Orlando, where I said if everything comes the way we think it will come, we will be out of leprosy in 10 years from now. So, in order to prevent that we have a motivational problem, with the field staff in India, is the field staff in Brazil. Let's diversify into leprosy and tuberculosis, because medically, this is very similar. Or let's diversify into leprosy and AIDS, because of the stigma this is very, or was very similar.

And I was laughed upon, because, you know, virtually I was saying elimination. And now we are where we should be, and we can do it. And what the handles [sp] did not say is more than you can imagine, imagine we would not have used this window of opportunity to eradicate smallpox, and now have HIV. What would have been the community affect of HIV and smallpox? You know, now we have a window of opportunity to eliminate leprosy and eliminate means if we can reduce the re-infection pool to be so small, then by definition, we will have less new infections. And the threat of going out of business, in my interpretation, was the reason for a very incomprehensible approach.

Now, mind you, there are three to four million leprosy patients who don't have fingers, who don't have toes, who are cured in the sense of not being infectious, but who need support economically, socially, whatever. This should be a worthwhile task to take. And wouldn't it make sense that we all do our best to eliminate this disease and infectious situations? It is so frustrating if you then run against what I cannot perceive to be something else, but an ideological resistance.

PROFESSOR BARRETT: Yes.

MS. MARIA GLENNA [sp]: Hi. I am Maria Glenna. I work as a consultant for the World Bank and IDB [sp]. And I work a great deal with NGOs. It's just my observation, as well, that NGOs have a difficult time dissolving themselves when the time comes, when the issue is solved. And I'm just wondering, I recently worked with a group on issues for the disabled, and the NGOs, running the program, are people who are disabled. And, of course, there is a great bureaucracy that has already grown. These people have their jobs due to the issue that they work on. I was just wondering if an indication of this leprosy NGO, where the people who are working in the NGOs, were they also diseased people themselves? Is this a matter of, or was it that it was a bureaucracy that had grown up and had no other issues to move on to? And, perhaps, as a suggestion, it might help if we actually work with NGOs, have alternative plans for these people whose careers are tied to a particular issue. And this could be a byproduct or something that we can be working on at the same time, as we work with them on their main goal.

PROFESSOR LEISINGER: Well, I feel sorry for those who go out of a job, because you have solved the problem. I mean, that's a problem we always wanted to have. Aren't there enough other challenges out there? Could we not expect the same amount of flexibility that is expected from everybody working in the private sector? Could we not assume that those who say they have sacrificed their life for the benefit of the poor, they would be a little bit more able to adjust themselves? Or do we have to take all the resources to pay for social plans for unemployed NGOs? And it can't be, can it?

And I'm not trying to be monicade, but there are basically two, Socrates has said there are personal certainties and there are—there is objective truth. What I'm saying is a personal certainty, so other people might have a different perspective.

But, the point is, there are two kinds of NGOs. One is a result oriented, constructive, cooperative, and they are willing to go into coalitions or alliances with others to solve the problem. And others are sitting on the fence and telling other people, what they are doing wrong, and they are the, how shall I say, the activist, as such, is the important thing for them. I can cooperate with the one; I cannot cooperate with the second one. I have to endure that second kind, because a multinational corporation is a worthwhile objective to rub your shoulder on.

And, you know, but at the end of the day, I have enough confidence in the common sense of the people that before they give money to an NGO, that they ask themselves what are they doing with the money we are spending? And then, you have the results oriented one, and you have the activist mode.

PROFESSOR BARRETT: Maybe we should have asked D.A. Henderson, not how he eradicated smallpox, but how he eradicated his own job when he succeeded in eradicating smallpox. Yes, sir, back there.

MR. JOSH FIELDS: Hi. Josh Fields of the [inaudible]. David, it's good to see you outside and even away from Barbara or Mark. I knew you in my former life, actually.

I, first of all, have to take contention with your issue about the—your statement of the Bush administration and the Clinton administration demonstrating a lack of leadership on the biological weapons, to mention protocol. I'll make a statement, and then, I'll ask my question, which is, in effect, I think the decision the administration most recently made to put the brakes and to further contemplate an ineffective protocol that you, yourself, have said undermine the international norm against biological weapons, and against the confidence and compliance in the diligence that the international community was put up against. That was a very brave move against the international pressure that they were being pushed to sign that protocol.

But, the question I have here is, given the most recent events with regards to the anthrax, how do you, and especially the FAS, feel about the ambiguities and the arguments that the administration have raised for some years about the issues involved with any uncertainties regarding compliance measures for biological and toxin weapons?

PROFESSOR FIDLER: OK. I'm going to stick to my guns here. I do think it was a fundamental lack of leadership on the part of the Bush administration. The reason I say that is, not because I think that the protocol that was proposed, answered every single problem. There were serious substantive issues, and some of the concerns that the Bush administration had about the protocol were real. For example, I'm not going to sit here and tell you with a straight face that that protocol, as drafted in the compromised chair's text, would it have prevented the anthrax attacks that we're seeing now? All right. Or would it provide a shield against bioterrorism?

Terrorists don't sign treaties, the last time I checked. All right. I think we're all learning that. All right. So, there are serious substantive deficiencies, weaknesses, problems. What I had a problem with, wasn't that substantive debate, was the summary execution with no alternative policy that was expressed. We said, we don't like this. What's the alternative? There was nothing constructive forthcoming until after the anthrax attacks on the Bush administration.

Now, we have the protocol is back from the dead. All right. But, not in the form in which it was negotiated in the 1990s. Now, the Bush administration wants to deal with trade, access and trade in biological pathogens, like we've done in the United States, CDC regulations, good idea. Criminalizing bioterrorism is a crime against humanity. All of these are—why weren't these proposals put forward before? Where was the constructive alternative to these years of negotiation? We've had a very serious problem on biological weapons proliferation.

If there was an alternative, the Bush administration didn't do a very job of communicating with its allies, what the alternative approach is going to be? How are we going to deal with the problem of biological weapons proliferation? How are we going to deal with bioterrorism? Nothing until after we have the anthrax attacks. So, I do have a serious problem, leaving aside the substantive arguments that we could have about the legitimacy of the protocol, about the way in which the Bush administration dealt with that very important multilateral issue.

I'm not going to sit here and speak for the Federation of American Scientists. I am not authorized to do so. I am not qualified to do so. One of the issues that's come up in the post-anthrax environment is if the protocol is coming back from the dead, where are we going with this compliance verification structure that was the key element before? All right. Is it wise to continue to go down that path? I still think that's an open policy question. All right. There are those of us who think that it offers potential to make some progress. It's not the silver bullet to anything. There are others who think that it's a ridiculous waste of time. All right.

We're going to have to re-engage in that debate, as well as debate the wisdom of the new policies that are coming out from the Bush administration to replace that approach with something new. But, I got to tell you as well, those new approaches to the biological weapons problem are neither new, nor are they themselves foolproof. So, I don't know that they would even pass the test that the Bush administration set for the protocol that was negotiated in the 1990s.

MR. WILSON PARSONS [sp]: I'm Wilson Parsons, student here at SAIS. And I have a question for both of you, actually, about access to medications, specifically in developing countries. Obviously, there has been a great rift between the defenders of intellectual property rights and those who say there should be universal access to any drug that would provide a "benefit to humanity."

Is there anything that could be done to try to move those two positions closer together? And specifically, I'm asking from the standpoint of one of the major arguments of the big pharma has been, there is so much corruption in the delivery process, in getting the drug actually to the people, and not having them re-exported, not having them reverse engineered, so that the patents are broken. Is there a way that a new regime could be created, or a new process, so that the drugs were actually delivered to the people for whom they were intended, and thereby create a new approach for this delivery?

PROFESSOR LEISINGER: I'm glad you're asking this question. Let me, first of all, say 95 percent of the drugs, that are on the WHO essential drug list, are off patent, the only exception being drugs for HIV/AIDS, multi-resistant tuberculosis and multi-resistant malaria. These are the exceptions to an otherwise functioning rule, and I believe that the treat exceptions as exceptions, and do not exhaust the rule to the five percent, a rule that worked for 95 percent, first.

Secondly, exceptional circumstances ask for exceptional solutions, and that if you have seen how much the pharma industry, as a whole, moved from last October to this October, then it seems to be a different world. A year ago, big pharma, Sortizay [sp], was trying to take the South African government to court, as if it could solve social problems or political problems with legal means.

What I miss is a greater concept, a greater—a more comprehensive approach to it. Today, we have the special prices for southern Africa, we, for example, don't have it for eastern Africa, and I can't see that Tanzania or Kenya would be so much better off, central or South Africa.

There are ways and means, and I think we have, and the lobbyists have given it an example of how this could be approached, for example, was differential pricing that you make a concept of Memorandum of Understanding with the World Health Organization that uses its authorities, through the National Health Authorities, to make sure the drugs end up where they are supposed to end up. You will never, under no circumstances, be able to prevent that 100 percent of the drugs are going the way it's intended.

As long as we get two-thirds there, I would be happy with it. There are ways and means that you can. You could, for example, imprint such drugs with a special WHO logo or other logo or whatever. There are ways and means of preventing misuse, but we have to try, and again, we have to look for best practices. We have to look for coalitions. And they are, what I said, NGO's have people in the field, which industry doesn't have, and government doesn't have.

And if we do that great coalition getting a lot of actors with their specific skills on the one umbrella to solve one specific kind of a problem, we could achieve at least 75 to 80 percent of what we want to achieve. And, you know, this is good news. We shouldn't aim for a 100, maybe ideally, yes. But, in reality, if we get more than 75 percent done, it will be done, and there, IPR is a minor issue. I do, I have, I understand activists who want to draw attention to the problem, by taking an issue that is related to the big profitable companies, because this gives you a picture that you can portray on the background of collective poverty. And then, we have this [unintelligible] of nothing involving. Your picture that you want, but in reality, it is not that way. Yes, prices are expensive, prices are--but if any price from any Swiss company sold in any Sub-Saharan African country is going to be expensive, if it is not under a public tenor system, or not under differential pricing system. But, both opportunities are available. Both have been proven that they work in reality. And all I want to say is, let's do it. It can be done.

PROFESSOR FIDLER: Yeah, I just want make a quick comment. The World Health Organization lists four key criteria for access. Only one of those deals with price. You can't really find much NGO activism interest in those other three, which deal with the basic infrastructure problems, which deal with the logistics, which deal with the governments.

And most of the attention is dealing with the TRIPS issue, and I agree. TRIPS is not the problem here. All right. Maybe it was useful in raising some, you know, controversy and things of that nature. But, it isn't, at the end of the day, the problem. In fact, in connection with the South Africa controversies, TRIPS was the shield for South Africa. It wasn't the problem. South Africa said, hey, look, you know, we've got a public—by anybody's definition, this is a national health emergency. All right. So, TRIPS allows us to do those sorts of things.

So, I think a lot of that has sort of been misplaced, but I think one of the—maybe one of the best people in the room to address that sort of issue is Seth [sp], because he's actually got experience trying to work with some of these issues.

UNIDENTIFIED MALE: I agree with most of what's been said, but there is one key element they're leaving out, which is critical. But, first of all, let me go back, and that is that the activist community has jumped on this, and they are now, you know, winning the war against big, bad pharma, and that is part of the goal here. The truth is that pharma certainly didn't reach out to try to get these drugs available, as you said earlier, to these countries. But, the most important thing is those countries, themselves, have not been asking for it, because they realistically are worried about basic infrastructure issues, basic treatments, basic dealing with opportunistic infections, etc. They may be able to use those drugs in the capital city, but not in the rural areas in general. So, it's been much more driven by the external activist.

The one thing that has been left out of the discussion, which is perhaps the most important thing, is the acceptance by the NORF [sp] of tiered pricing. About 20 years ago, Merck was called in front of Congress and asked the question, just a question. They weren't—they didn't get their wrist slapped or anything else. But, it was about, is it really true that the American market is paying X price for the measles vaccine? And, you know, UNICEF is buying it for it for X minus whatever. And they got so worried, that they pulled out of that kind of global marketplace for that vaccine. And I think that's really going to be the challenge, and that goes back to changing the overall mindset.

For an AIDS vaccine, the general paradigm for all vaccines has been, you produce them for the NORF, and 10 to 15 years later, they begin to trickle down to the developing world. Because, you know what? There's not a lot—there is no infrastructure for them. They are expensive. There's no marketing system. If you went to those companies ahead of time and said, we want differential pricing, and we have political support for that. Nobody's going to beat you up, but you're charging this amount up here and down here, and we want you to produce an extra 100 million doses, 500 million doses, we'll even pay for the plant. They'd do it, but that's the mindset.

So, that's the critical component. There's going to be public acceptance, and even more, you know, the companies are cheered by the public as doing their duty to provide them into south differential pricing. And that's what's not happening now. And in fact, the scary thing, is with all the noise about the drug companies, you're going to have the Gray Panthers join with the AIDS activist, and the next thing you know, the pricing goes on everything, and people start worrying about it, and that, again, kills the research and development arm. So, that's really the mentality that has to change.

PROFESSOR BARRETT: I have time for one more question, yes, Harry.

UNIDENTIFIED MALE: Is that on? Klaus, in talking about the delivery of what we've been talking about today, and understanding the complexities of Africa or Asia, etc., in terms of getting something to work, and the very great frustration of not seeing anything specific that looks as though it might work, the initiatives to raise funds, etc., going very slowly. What do you think about the role of the most significant NGOs? We see some NGOs that seem to be actively engaged, MSF being one, etc. Do

you see them as accepting a much bigger role in this kind of activity, because they seem to be well placed to do something?

PROFESSOR LEISINGER: One should never generalize. I mean, there are of the industry, and they are not the NGOs, and you have to now say distribution everywhere.

Let me answer it like this. The future will be on the side of those who are results oriented and willing to cooperate with others that act in good will. The future will not be with those who are militant. The future is not going to be with those who sit on the fence and keep on criticizing, because everybody, in an environment of underdevelopment, in an environment without institutions, without infrastructure, with lack of education, everybody who is actively taking a role there is going to make something wrong. This is part of the game.

Now, if we go together on the learning curve, and if we benefit, if we share what we know from each other's niche of skills and experience, the learning curve will be much, much better, than if we compete with each other or if we fight each other. The public acceptance, the appraisal of big internationally active corporations as good corporate citizens that have a reputation of, not only being of the profits, but having a better bottom line, will very much depend on whether they are flexible with regards to unorthodox solutions for the poor. And at the same time, the NGOs will be measured, whether they deliver, or whether they talk only.

PROFESSOR BARRETT: Thank you very much. I'm going to have to stop the questions there. I want, first of all, to thank our speakers for an excellent session. Thank you very much. I'd like now to invite you to take a coffee break with us. At 3:35, we'll begin a session that, when I organized this conference, I was worried there may not be much interest in. And that is on bioterrorism and biological warfare. But, until then, we can enjoy coffee.

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