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THE WORLD HEALTH ORGANIZATION: HOW CAN THE UNITED NATIONS AGENCY FIGHT DISEASE IN THE 21ST CENTURY?

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PANEL I: GLOBAL HEALTH IN THE BALANCE: THE WHO AT A CROSSROADS

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AMIR ATTARAN: Good morning everybody, and thank you for giving us your time today to be here. I'm grateful personally and grateful on behalf of the organizers that you would treat this subject as worth coming – (inaudible). I have the privilege this morning to introduce my panelists, some of whom I have met years ago, some recently, some not at all; all of whom I think are impressive. The privilege of the chair is to really talk about what the panelists represent not just in themselves, but in their thematic approach to the problem of global health.

Nicole Bates is acting director for government relations at the Global Health Council. That is an organization, a membership organization here in Washington, that campaigns and advocates on the Hill for global health issues. [The Global Health Council] Frequently represents USAID contractors and are the intermediaries between this government and the need that exists abroad. She's an MPH and I understand is working on her PhD. Good luck. (Laughter.)

Jean Luc Poncelet is at the Pan American Health Organization (PAHO). He's a physician with a special talent to explain to us the problems that arise in emergency disaster situations. To me, [this is] quite fascinating because that is the time when people begin most to think about global health. It takes a tsunami – never mind the saying "It takes a village" – frequently, it takes a tsunami or hurricane before global health becomes cognizable to the media and therefore, the population at large. He is immersed in those issues quite deeply.

We do not have Robert Rosenberg with us today, although you see his name on the program, but –

CAROL ADELMAN: I think you may have –

MR. ATTARAN: I may have an old one. Okay. Well, that makes it quite simple.

Mike Ryan is a scholar of intellectual property and politics and who has a fantastic ability that so few academics do – he does have it – [that is] to translate not only his research into journals, but into action in developing countries. He's focused on intellectual property in developing countries, more in Jordan than anywhere else I understand, and how that affects pharmaceutical markets. He has been really a guiding light in that debate, which has been very fraught as most of you will know.

I'm going to say just a few things thematically about how these peoples' work intersects with what, I think, [the] greater set of challenges in global health are. The title of this panel is "WHO at a Crossroads." Well, indeed, but so is the entire global health establishment. Foreign aid establishment is at a crossroads and if it isn't, I and others are

going to drag it there quickly because the establishment does [very much] need a more management-minded approach to be functional. It hasn't been extraordinarily functional in some very basic ways, and I'll set out in a couple of minutes here [on this topic].

The first is campaigns and targets. We have heard, on many occasions, campaign targets being set by WHO and other global agencies. The one I know best is called Roll Back Malaria, which in 1998 was a promise of the WHO, the World Bank, UNICEF and UNDP that malaria cases would be halved and deaths [would] be halved by the year 2010. We're now in 2006 – quite close to 2010 and there are no accurate statistics about whether malaria has gone up or down by any percentage figure. In other words, a promise was made and there has been no subsequent tracking of it. This is not a unique problem to malaria. In fact, it affects nearly all of the millennium development goals from maternal mortality, tuberculosis and so on. And I summarize that evidence, if you're curious to learn more about it, in the paper in *Plus Medicine* last September.

It is difficult to do campaigns that don't have measurement and therefore don't have deliverable results. Without deliverable results, it's difficult to justify the budget on an ongoing basis. Nicole [Bates], I think you talk about this because she has to justify foreign aid budgets on a regular basis. And how much nicer it would be, I'm sure, if we had actual results that we could point to rather than simple campaign positions.

Another issue that comes up with campaigning and targeting is that frequently campaigns and targets are – the edifice of them – is built on the absence of a scientific evidence-base. Evidence, of a scientific sort, in global health is very infrequently used. Myths persist. Jean Luc [Poncelet] can explain very well the myth of the dead body in the disaster situation. How many times have you heard in news report that there has been a flood, to take an example, and [that] there are bodies in the street and those bodies must be taken care of because they're causing disease? Never have dead bodies caused so much mischief as in the wake of a natural disaster. They don't cause disease. They never have anymore than any other piece of organic material – than a dead cow – would cause disease, but the totemic significance of the loss of human lives causes us to misapprehend the most urgent needs in the first hours or days of a disaster relief operation and energies [are] put into burying bodies rather than saving the living in many cases, which is a tragedy.

The use of evidence and the use of measurement, if properly done, in global health will bring about, what I hope, is [a] sort of accountability: accountability within and without the foreign aid enterprise. There has to be accountability within in the sense that those who campaigned to have malaria [halved] by a certain year are held responsible in the career sense if they don't have results to show for it. Careers should be made or broken on the basis of meeting performance targets. That is a routine private sector discipline. It is utterly lacking in the foreign aid enterprise. Accountability without simply means that results should be delivered in a timely way and if not, then funding should be appropriately drawn into question. I believe that foreign aid should operate as venture capital does. There is a certain amount of money that can be invested in aid and it should be invested in high-return projects. And if projects don't show much

of a return in lives saved, averted or what have you, whatever [the] metric is, then the venture money of foreign aid should go to another place. But this mentality, again another private sector discipline, is lacking in the enterprise as it's now constructed.

Second point has to do with core competence. In a foreign aid setting, very often you find there's a desire to do everything and it leads agencies into a sort of mission creep – not just the WHO. But I'll begin with the WHO [as an] example. It has to do with intellectual property. The last several years, the WHO has put quite a lot of effort into studying how intellectual property affects access to medicines, to seeds, to copyrights even, that might be of medical significance. And I've played a part in that; I've published in that field rather extensively, both in journals like JAMA to the medical audience and in the Yale Law Review to hit the legal audience, and what I found is that it took years for WHO to even understand intellectual property. If we could have only brought the people responsible for the program into a classroom for a few months to teach them about how intellectual property law works, I think enterprise would have responded very differently to this challenge. Michael Ryan has experiences in this area, as he has been instrumental in trying to educate the global aid enterprise on the real meaning of intellectual property, which is normally very much less than it's supposed.

Going outside of core competence, such as for WHO to tackle something like intellectual property law brings about bad results. Organizations function best – all of them – when they stay within their core competence. With malaria – my favorite topic to return to – the World Bank is in grievous violation of its core competence right now. It has spent six years trying to make good [its] promise it made to Africa in 2000 to spend – rather a lot of money – up to a half million U.S. dollars on malaria. They never did spend that money and in a tragic turn of events, it published statistics on its performance for some malaria projects, although not in Africa, which are demonstratively false. It's a painful reality that organizations not having done their job sometimes are tempted to cook the data.

The evidence of this is set out in an article that I and 12 others have published in The Lancet only two weeks ago and it has not been met with openness by the Bank, which is to me quite sad. We have tried on numerous occasions to meet with the malaria staff and never been given an audience. The Bank should focus on capital projects. It shouldn't focus on disease control. If any of you woke up sick tomorrow, you wouldn't think: "My god, I'm lying here in bed with a fever. Let me call the banker for help." When international agencies don't respect that simple lesson and go beyond the core competence, things fail. That's the crossroads we're at.

WHO at a crossroads, indeed, but so too [is] the rest of the international aid establishment. It needs to take account of results, science; campaigns and targets have to actually be measured. Science has to be used in their attainment. It has to take account of core competence. Organizations shouldn't compete with one another; they should focus on what they do best. If we bring these simple private sector disciplines to the foreign aid establishment, lessons so simple that they are taught probably on day one of business school and management school, but never heard in the corridors of power for

global health, I'm certain it will save a considerable number of lives. That is how we show our love and our caring for people – by saving their lives – not by publishing the glossy pamphlets.

Thank you. (Applause.)

Nicole [Bates]?

NICOLE BATES: Thank you, Amir [Attaran], for starting this – our presentations this morning. Good morning, everyone. I very much appreciate the opportunity to be here with you today. As you know, the reason why we're all in the room is that the World Health Organization plays a highly visible and critical role in the health around the world and so that makes the conversations of today, the presentations of today's panels all the more relevant. And so I'd very much like to thank the Hudson Institute for providing this forum for discussion.

Before I go into any details, I definitely want to lay out the context for – the context and expectations for my remarks. What I don't bring is an exhaustive review of the WHO's history, nor do I offer a set of never-thought-of-before, easily implemented solutions to the challenges that we may face. What I do offer, however, is the experience of the Global Health Council. We are a membership organization. We represent hundreds of organizations both in the U.S. and internationally and thousands of individuals who are committed to improving health around the world. The perspective I offer this morning is that of civil society.

I'd like to read four key points for my time this morning, the first being that the World Health Organization does play a critical role in health around the world. I think we would all at least agree to that, although we might differ on opinions about their performance. Second, I would say that the World Health Organization is just one of many players in health programming and health outcomes around the world. Third, that when we're looking at successes and while looking at the current challenges in health and in the broader development across the globe, I think an ideal model or one that has emerged and one that's showing promise at better partnership. So I'll spend a little bit of time speaking to that. And finally, within that context of partnership I think it's very important to highlight the role of civil society and the contributions that we make both to WHO's functioning and also to the functioning of the broader community.

So to the first point, again, that the WHO does play a critical role in health programming around the world, I think a lot of us know the history of the WHO, but the World Health Organization was created in 1948 by a number of national governments including the U.S. government. Today, WHO represents 192 member states and that's actually more than the UN itself. WHO's role has always been technical in nature. Its function, which no other entity fulfills, and its comparative advantage is in its mandate and that is to establish international norms and standards of practice as well as to establish technical merits of programs.

Another function is to diffuse practices and to provide technical assistance to countries and finally, to monitor health through surveillance of health status, but also outcomes of – outcomes of health programs, so monitoring and evaluation. With this mandate, I think that we would agree that the WHO plays a necessary role in the global community – it's that of a health organization with a global lens that plays a technical and coordinating role among governments and interested parties, and therefore it's critical in fighting disease and in promoting good health.

For all the things that it is, however, the WHO is not a financing mechanism, as we see with the Global Fund. It is not a grant-making body as we see with a lot of philanthropic entities, and it is not a program implementer as we see with national governments and other aspects of civil society. So with this understanding, it's important to consider the WHO's performance and its success or its failure in the context of its specific role in promoting health around the world.

On to my second point, which is that the WHO is just one of many players contributing to health programming outcomes. Let me be very clear, I'm not here to defend, promote, or attack the WHO. I very much, hopefully, am offering a neutral perspective. This is based on my personal experience as well as the relationship between the Global Health Council and members and the WHO and other partners around the globe, but I do think that if we were to have a full conversation about the diagnosis and prognosis of the WHO as it was outlined in the invitation for this event, it's very important to work from a shared understanding of what the WHO's role is.

The WHO, as we know, is often one of the many international bodies with the presence in countries. Its counterparts – its very common counterparts include other UN agencies, so UNICEF, UNDP, the World Bank, national governments, civil society whether they're foreign – foreign-based or actually located in countries and program implementers. At times, these collaborations were less formal kind of daily interactions trying to reduce the duplication of efforts and services because a lot of times there is overlap in terms of what people are in country to do.

At the other end of the spectrum, however, are more formal partnerships such as those that come to mind for initiatives for AIDS, like Three by Five, for TB or for malaria, like the Abruzzo targets. Many of these instances, efforts such as Stop TB, the Roll Back Malaria Partnership, the Partnership for Maternal, Newborn and Child Health very quickly come to mind. And it's important to remember that while these partnerships are housed at the WHO, they are not the WHO by themselves. As Amir [Attaran] described, even with Roll Back Malaria, they were conceived in partnership by the WHO, the World Bank, other UN agencies and national governments, and therefore all of these parties contribute to the inception and the operation of these partnerships.

The WHO's partners from across the spectrum include public organizations, national governments, private industry, academia, research and civil society and this is because we need the technical information and technical knowledge that is developed

there to be disseminated and to be delivered by those who have the mandates and the means who have that – who play that specific role.

Another point that I wanted to make was that in terms of the partnership what we see in terms of global health and what we see in terms of global efforts to improve global health is they're trying to work [in a] partnership. Again, this can be informal at times; it can be formal at others. The motivation here is that it's the stark reality that no organization in and of itself has the capacity or the skills nor the mandate to accomplish global policy or global programmatic goals by itself. Therefore, engaging with those who share priorities, which would be to improve health, but also is to bring to the table a resource is that individual or entities don't have themselves is very – is essential.

Each sector, public and private, at every level national or international, regional or local, plays an important role. Let me be the very first to say – and as Amir [Attaran] alluded [to], I am working on my doctoral degree and am focusing on partnerships and the role of partnerships, so I'll be the first to point out that partnerships and collaborations are not easy. They're very difficult; many fail. Stakeholders come to the table with different motivations that are not always outweighed by the overarching goal of a partnership or of the convening body. It takes a lot of work to make these partnerships just operate in general. The process of bringing together different sectors, different interests – and that's even before you get to the outcomes – which is why people came together in the first place. However, of all of these challenges, we see that partnerships are the preferred means of achieving goals and they can be promising. We have seen some successes, although we do see many challenges.

The role of civil society and these partnerships and also working with the WHO whether it's here in the U.S., whether it's other donor countries or other developing countries cannot be understated. When I speak of civil society I speak of non-government organizations, PVOs, universities, community-based organizations and other networks, as well as private industry. These are the people who are doing the work. They're the people who are implementing the policies and turning them into programs on the ground, and the people with first-hand knowledge of whether these programs are working and why and why not. These are the individuals civil society represents, the individuals in the organizations who are affected by and affecting health in communities throughout the world.

In recent years, there's been a groundswell of community and of civil society organizations as communities from developing countries [that] have really begun to take ownership of their own health and demand that they participate in the processes that shape health policy at the national and international level.

National governments and international donors have recognized this and actually require the participation of civil society in decision-making bodies. Therefore, in these, you see People Living with AIDS, you see community workers that are at the table and have the first pass at knowing what policies are coming down the pike. They can be the first and probably the most legitimate ones to say, "Look, this is or isn't going to work

for our communities, for our countries and for our regions." Civil society is, in fact, the world's best gauge at what is going to work when you try to reduce disease burden and improve health. This is true in developing countries, but we've also seen this in donor countries and particularly in the U.S. as civil society has galvanized around advocacy efforts to secure resources and support for the global health agenda.

I'd like to just conclude by saying that the health challenges are always evolving because the conditions that affect health, whether that be the physical, social, economic, political environment, technologies, human activities or microbes – those are also constantly evolving. So when we look at health, labels of success or failure, it might be an oversimplification of global systems that are extremely complex and dynamic. This is by no means – by no means – gives [an] organization a pass at their role or their responsibility. All must be held accountable for what they're expected to contribute to the process and to the effort.

I think a useful framing for the conversation might be what are we learning today that will be helpful and move us forward in achieving better outcomes [in health] today and tomorrow? I suggest that we have learned and are learning; I'll make four key points on that. The first is that achieving health is something that every part of society must engage in. No individual organization or their efforts can be identified as the savior or downfall of health.

Targets and goals must be progressive, but at the same time they must be realistic. And you also must have the technical, the programmatic, the policy, and the financial support to achieve these targets. We certainly don't need another declaration or another target if we don't have a complementary strategy to help achieve those.

The third point is that the WHO, as with most convening organizations, are global bodies that represent masses. The WHO has lessons to learn about coordinating global efforts, about providing good leadership, about promoting the right policies and recommendations and communicating among its partners. This challenge, however, is not unique to the WHO. I think it applies broad[ly] within the foreign assistance and foreign development community, and although I acknowledge that because of the platform upon which the WHO sits, the stakes are much higher and it must be addressed.

And finally, I think, seconding Amir [Attaran]'s comments – opening comments – accountability of partners and policies and programs is essential. We need results, we need performance and if something's not working, we need to quickly figure that out and figure out a new strategy.

Looking ahead, we cannot underestimate the importance of or overestimate or overstate the WHO's role and efforts to eradicate disease and improve health. It's just as important to assess what is happening with the type of information once it gets to countries. Are the systems in place? Are the health systems in place to disseminate this information? How does this synch with the policies of international funders and local programming? In assessing what's happened and what's necessary for the future, we

really must consider the WHO and its specific role as a technical body and we also must consider the role of its partners including civil society.

Thank you very much. (Applause.)

MR. ATTARAN: I'm going to ask all the panelists to speak in turn and if you will just hold your questions for the end, we'll have a big [Q&A] session with all the panel[ist]s together.

Mike [Ryan]?

MICHAEL RYAN: Thanks, Amir [Attaran]. Thank you, Carol [Adelman]. A great pleasure to be with you.

It is indeed, I think, the case that the World Health Organization is indeed at a crossroads and a really interesting organization for us to take a look at and think about. In order to focus our attention on a particular aspect of the World Health Organization, I thought what I would do is look at the recent report that the WHO just released in April which concerns innovation and intellectual property rights.

Now, the report exceeds 200 pages in length and – as if to illustrate Amir [Attaran]'s point about multilateral institutions in core competencies and mission creep – it shows that a commission that works for a multilateral institution can sometimes exceed its core competency and be faced with mission creep because the report would actually take a day-long seminar to deal with all the issues that it raises, which sort of go well beyond, I think, core of issues of innovation.

But in order to engage it, what I'd like to do is to just focus on a question of innovation – innovation and intellectual property rights. One of the recommendations that the commissioners [in the WHO report] make is that developing countries should play a more active role as innovators themselves. That is to say that they should seek to leverage their R&D capabilities and become more active, more engaged, and seek to contribute new drug therapies to global health.

Now, one of the commissioners points out – there's an annex at the end in which each of the commissioners gets the opportunity to criticize the report since, as you know, committees makes reports and they have to settle on an agreed overall report – and so one of the commissioners points out that he thinks actually that though they recommend that developing countries build their capacities in this area, he says the report actually doesn't do very much and talked about how to actually do that.

That's what I'd like to pick up if I could. It is the case that, as Amir [Attaran] mentioned, I have spent some time in Jordan over the last seven or eight years looking at their biomedical innovation system. But rather than talk about Jordan, for the most part I'd actually I'd like to talk about a different country and it's Brazil. I direct a center at George Washington called the Creative and Innovative Economy Center and what we do

is study innovation and creativity in developing countries. And we released in February in Geneva a report in which we looked at biomedical innovation in Brazil. And the reason we looked at Brazil was because we had understood it was the case that there was some new innovative activity taking place in Brazil and so we wanted to study that to see what was actually happening. And what we found was, indeed, there is new innovative activity.

The story about what has happened in Brazil is I think a quite fascinating one. In particular – what I will say I will use as a case study for a few short moments of remarks – is that the first drug to be innovated in Brazil was released last summer. And so, first of all, let's point out that despite the extraordinary biodiversity, despite having invested for many, many years in basic research and having really wonderful research universities in Brazil and also investing in their public capacity to conduct research, we have the first example of a drug being introduced into the marketplace, a new drug, an innovative drug, just this past year. So it makes it an interesting case study to ask why has that happened?

Now, this particular product emerges from a company called Axé, a Brazilian company with French origins. The product was something that was known as a matter of traditional knowledge in that organization for some 20 years. Indeed, one of the founders of the company was, as they say, a weekend-warrior soccer player who was as he was getting older struggling with what happens by end of that weekend, which is bad knees – you know, his knees were sore. And a local person told him that there was a particular leaf that if he would rub it, its juices – so to speak – on his knee, his knee would feel better. And so what he did was he had this company identify the compound – this was some 20 years ago – but then nothing more happened with that knowledge. So the traditional knowledge sort of, shall we say, lay foul.

Now, more recently, in fact about six years ago, the leadership in Axé finally did something about that traditional knowledge. In my interview with them, I said, "So what made you finally take knowledge that had been in your organization for so long and finally do something about it?" And they said, "Well, one of the motivations was that we actually now have a patent law." And indeed it was the case that in 1996, Brazil passed its patent law and did so in order to come into compliance with the so-called TRIPS agreement [Trade-Related Intellectual Property] – the Uruguay round agreement on intellectual property – within the context of the Uruguay round world trade negotiations.

As they said, "The challenge for us wasn't identifying the compound. We had done that. The problem was that we were going to have to make extensive investment into clinical research to demonstrate the effectiveness of the product and also ensure that the product was safe. That was going to cost a good deal of money and we were going to be unwilling to do that until we had a patent law in our own country."

So this was – I have to say to you – a real interesting conversation for me because there I was in Sao Paolo having a conversation with the Brazilian company president and I thought I was sitting maybe in New Jersey, having a conversation with an American company president. But it tells us something about the basic logic in the economics here,

which is that if you're going to invest into a knowledge-based activity, then this issue of control over that knowledge-based output is going to be important to you and that was what the patent was about.

Now, there are a couple of other things we highlight about this story, about why this happens, because it wasn't only the patent situation, although that was decisive. It's also the case that Brazilians in the state of Sao Paolo realized that they've been making years and years and years of investment into their university capabilities for research and in their public capabilities – the public labs – they weren't getting anything out of it as a matter of innovative products. And they said, "One of the problems is that we in Brazil and this is sort of, as we know, notorious how problems with financial capital as we know high inflation rates, et cetera et cetera." Meaning that getting financial capital to be invested into R&D activities has always been difficult and so the organization – which you and I would describe as being sort of like the National Science Foundation – established [a] fund to encourage public-private partnership regarding the commercialization of technology.

Now, then it's also the case that – and this is at the state level, Sao Paolo, which, as you know, is the wealthiest and biggest state in Brazil – it's also the case that the state of Sao Paolo established a development bank to encourage investment into R&D activity. Armed with a loan then from the development bank, they went out to a university and tried to solve what was their other key challenge, which is that they lack the internal R&D capability to execute the project. So they established a partnership with the university.

Now, establishing that partnership was actually tricky and difficult they said. And they said the reason it was tricky and difficult was because the people in universities didn't know very much about intellectual property rights and patents. So they said there was a lot of discussions on that. They said, "In order for us to teach them about it, we had to agree about what the royalty rates would be and all of that." They said they had unrealistic expectations about royalties and all that because they had unrealistic expectations about issues of risks like what happens if this product fails. But they said, "Well, unless we worked it out and we were able to solve a key organizational capacity problem: the partnership with the universities."

Now, just a year ago, then December 2004 – so, a little more than a year ago – the Brazilian Congress passed a law, they called it the Technology Law, that is basically aimed at trying to solve some of the problems that Axé and other companies with active R&D strategies but no products yet – patents, yes; products, no – and the problems that they were having were these partnership issues. How do we encourage universities and companies to work together toward commercializing technologies? And in the main, what they did was they specified that the universities and the national labs could and should get patents, they could and should license those technologies and it should be the case that they would be able to work out royalty arrangements, et cetera, with the private sector.

Now, what I say to you by way of conclusion is: is it the case then that the Brazilians are starting to show a way for other developing countries, whether in Africa or Southeast Asia, to begin to execute successful R&D strategies and contribute new innovative drugs to the global health system?

Thanks very much. (Applause.)

MR. ATTARAN: Jean Luc [Poncelet]?

JEAN LUC PONCELET: Thanks. Thanks very much for the invitation – (unintelligible) – it's my pleasure to have your introduction and as well as Amir [Attaran's], a wonderful one, so I will try to be at the level, but I doubt very much.

I'm working for the Pan American Health Organization [PAHO], which is the regional office of the World Health Organization and the head of the disaster program. The disaster program – (unintelligible) – the deputy director of the Pan American Health Organization, so that's who I am. Worked in the region for 20 years. Having a kind of a French accent, but not being French, I'll let you guess what – who I am, so you have something to do, you know? (Laughter.)

Just probably a couple of comments that when I hear about the WHO – there are different WHOs and so there're different parts in the organization and I always wonder how a color given to an organization when you see how composite it is. It is a mosaic of so many different things that I congratulate you for being able to give one diagnosis to such a complex organization. Just by taking the example of AIDS, Three by Five in the Americas has been a major success. It's the only region that has been able to reach the target of Three by Five – I'm not defending Three by Five – I'm just saying some of [the] evidence.

The subject of core competency is definitely a major challenge and we're challenged every day in the type of work. We have how many requests from countries, from agencies, from donor countries, from member[s] of the assembly, from NGOs, from everywhere – to extend it – to respond to those questions and "no" is frequently considered as a naught answer. The – being the head of disaster in the region – the major challenge that I have is to refuse to extend the scope of the program, to remain focused on what we have to do. That is extremely difficult to do, for several reasons.

One reason is that you see so many times that the global objective of reaching health for everybody is so closely associated to the organization. There's no difference, as people believe, that one organization can do everything in health like if WHO or PAHO can achieve everything in health. And so there's a close – (unintelligible) – where people can't understand that the organization could say, "I'm sorry, but we can only do that at present time for those kinds of things – (unintelligible) – at present time." So it is extremely difficult to resist to that one.

So I think it's the agency level, but also at, you know, programmatic level. The organization [was] created in 1902; the Pan American Health Organization joined the WHO in 1948. And there were reasons why PAHO ha[d] been created [and that is] because of yellow fever and [the] economic pressure that it [puts] on trade. So the reason [for the] creation of [the] organization [PAHO] ha[d] been already based on disease, such as yellow fever and plague.

But also I would like to comment that when the objective of these meetings has been presented – how can WHO be better able to do things – I think we forget most of the time that the real success, when success has taken place, of the organization, it is when countries have done the work. People believe the WHO has eradicate[d] small pox. I think it is absolutely wrong. It is the countries that have done so. And I think we have also [a] tendency to forget one and the other. The WHO obviously has played a leading role in that one. When you see polio in the Americas has been eradicated – (unintelligible) – [the WHO] take[s] the credit as an organization [on] that one, but I can [say] definitively, it is a country's work.

Myth and realities. I don't know what more evidence we need. It is 20 years that we have published a list of 10 myths in disaster response. We have had contact with governments, with NGOs, with researchers, social organizations, et cetera. We have had agreement. We have recommendations. What is it that we need? Or is it there are two types of evidence maybe. There is some evidence that is more evident than others. [Is] there evidence that is more economic and has more weight than others? What kind of evidence do we need?

The fact that people – that we have never seen any epidemics after any natural disaster over the last 30 years, is it not enough? What is it we need? We need what? To demonstrate that the economic impact or it has been nothing so it's not worth doing it? Or what else do we need? So I wonder a bit about, you know, what is the refusal of going ahead? And evidence-base certainly [is] a very nice way to approach it, but I think the approach will be part of it and we have to find out why [it] is that we're so resistant to it.

We continue to make vaccination campaign[s] of cholera in region[s] after the tsunami where we know there's no risk of having it, we know there's no cholera [risk, yet] we promote the cholera vaccination for it. So vaccinations [in general are] very good; vaccinations can be good for cholera and in the country [but, in the context of this case, it is not necessary]. I am just saying [there] is a resistance to go through [eliminate] that one. Why is that? I'm not sure that evidence-base will change that one.

When you see the pandemic – and just to be a bit problematic –the real issue has been obviously the number of dead that we have that, and when you see the plague during the 13th and 14th century, it's still a remnant of that one and we still continue on that – on that myth that dead bodies will represent a big threat. Obviously, when there are people dying of a disease, it's absolutely completely different [than] when people die from natural disaster. But I think now the pandemic's taking place in the state of fear.

It's taking place in the state of security issue. So I think now the pattern – the way to manage a pandemic is the WHO wants to take it as their own responsibility, that definitively, and from PAHO. I think these – the pandemic – there's a good part is a medical issue and – (unintelligible) – organization can play a big role into, but to manage the fear, to manage the economic impact it would have, to manage the security issue when military, CIA, FBI and all the similar agencies in all countries have taken such an important role. This [is a] question that we have to raise.

So I think that at [a] country level, that's what we're doing now as a disaster program is to try to focus not only on the health aspect of it – I mean the medical aspect of the pandemic – but rather to look at the coordination aspect between agencies that would put medical, national security system, natural disaster coordination that didn't exist 20 years ago. So this [is a] kind of a new approach [we] to have a look at.

And finally, to have comments on the tsunami and the earthquake. I think we have also not only to look at evidence of what ha[s] past, but also the evidence of [what] we still don't have, about what's going to happen in the future. When you analyze what has happened with the tsunami, the tsunami has shaken up the world. The reason I leave it up to you – but it has shaken up the world. The earthquake in Pakistan has shaken up the world in a very different [way] but has done also the same thing. The reaction of the international community to say, "We are the one[s] who can do best, oh, sorry, we can do better. And we will help those people who have suffered so much."

What are we trying to do? Thirteen billion dollars after the tsunami for people who have died. Is a funeral so expensive? What is the relationship between one and the other? Now, we have floods taking place every year where people survive all, have lost all their belonging[s], los[t] their hospitals, los[t] everything and they will not have a penny. So that is one thing that we have to wonder: how do we react to those kinds of thing[s]?

The tsunami has created such a big problem, sorry, such a massive reaction, that it has changed also the world's reaction. And now, there are many agencies that believe they have to do much better, be much more forceful and intervene from outside. I think if that is the lessons from the tsunami, I think we are really missing the boat.

What we believe the tsunami has shown us is that if we don't have a stronger local capacity, if we don't have a stronger national system, I think we are going to fail in the next tsunami and the next earthquake. And the big mistake [is] that there is a tendency to take now as a lessons learned from the tsunami is that we have to be stronger as international agencies to work from outside. What we're seeing is that if we don't have strong [response capacities] in [a] country, then we will continue to fail. We are going to fail together. So probably the most important message of my intervention would be to say that there's no – we will not have health globally if we don't have stronger national system[s], and I'm so pleased to see such a prestigious group here today. I'm afraid that type of group do[es] not meet in other countries, at least in developing countries, and probably – (unintelligible) – can do something about it, but that have that

type of discussion at country level to force countries within the intellectual property as a example, but on many of those other example, when nations belong, when nations become owner of their own health, then we'll see a difference. It's by having a stronger national health system that we will have a stronger WHO, not by having a stronger WHO that will have better health.

Thank you.

(Applause.)

MR. ATTARAN: Okay. It is question time. We have one, possibly two roving microphones. So feel free to address your question to anyone of the panel. We've got 19 minutes to do that.

Q: TOM BOMBELBS, MERCK: I'm going to ask my first question to you, Amir [Attaran]. And say I think you made a very good point about, obviously, organizations staying closer to their core competencies and therefore, [when] they do that the chance for success are obviously going to be greater. On the other hand, isn't it a good thing that the World Bank recognizes that health is a key component of development and therefore starts to organize some of its programs towards health in the context of development? And even though – and you and I and Mike Ryan go back a long time on intellectual property issues in the WHO – but however when you see those issues th[at] world at large saw IP [intellectual property] and trade as having a health effect, if not a health dimension to it, and therefore it's not entirely inappropriate that the WHO takes up some of these issues to see, you know, in its own wisdom whether or not there's a health effect to that. So on the one hand, you're right; on the other hand, issues change and the society's perception of them changes and how do you respond to that?

A: MR. ATTARAN: Health is an all-embracing topic. It's massive – utterly massive and one cannot or should not [in] anyway get by saying as an organization, "Here I am. I do health. Now, throw any health problem at me." It would be much more sensible to take this broad concept of health and split it into various aspects and let each of those aspects be dealt with by the most specialized agency. That's how you get to core competence. So to take the example of the World Bank, Tom [Bombelbs], I agree with you totally. The World Bank has a lot to contribute to health and perhaps some of you have read my article to mean that the World Bank should get out of health all together. I meant no such thing. What I meant was that the World Bank should get out of disease control. That's one aspect of health and I think is best to illustrate through an anecdote rather than being too academic about it. If you woke up with a fever, you would of course call your doctor and not your banker for help. But as Roger Bates sitting behind you says, and I think he's right, if you woke up with the idea to build a hospital or to build a medical school or to have a nursing college, you'd call your banker to build those things [because] those are infrastructure projects and a banker has a pivotal role to play there. [If] The World Bank is responsible for the disease control inevitably we'll get it wrong. It got it dreadfully wrong on HIV/AIDS in the '90s when the bank was advocating seriously against AIDS treatments and only emphasized prevention. It's

getting it wrong today in India where the bank continues to fund the decades old and utterly obsolete treatment called chloroquine for malaria, in settings and clinics where that drug is used on parasites that are resistant to chloroquine. Children have died because of this, to be blunt.

Now, in Geneva at WHO they know very well "thou shall not use chloroquine in India" for falciparum malaria, a deadly sort. The bank has been reluctant to take that on board, has written in the Lancet that it shouldn't be required to do that. It's a flat-earth view on science, frankly, and then if you're worried just because the bank doesn't have that core competence, but I would certainly love them to be working on building hospitals, topping up doctor's salaries, laboratory construction, and so on. Those are areas that can be useful and I hope they move in that direction.

Q: ALEX HEYWOOD U.S. COUNCIL FOR INTERNATIONAL BUSINESS: We represent American companies at the International Chamber of Commerce, at the AECD and at the International Organization of Employers. The one thing I just want you to find out is the private sector was mentioned and I think in all different aspects of the presentations in this first panel and – the International Organization of Employers is working towards getting consultative status with the WHO in Australia and facilitate private sector participation on an ongoing basis – and I'm just interested to know what you think about private sector participation with the WHO.

MR. ATTARAN: You want to take that one?

A: MS. BATES: I have a brief comment on that, thank you. I think that the private sector just as long as it's so much place and very critical role. We see this both in terms of advocacy [and] we see it in terms of programming. I know that we've also seen it in terms of drug donations for a lot of programs, so again, since no single entity can do at all in and of itself, we've seen major drug donations, particularly for the tropical diseases, from pretty much all of the big pharmaceutical companies.

We also see businesses that have their work force in developing countries starting to invest in health, in their health programs, whether it's AIDS programs or malaria programs, because they see that as an economic benefit and a return to their business in their bottom line, so private industry absolutely plays a role wherein just as the World Bank, and I'm glad that it recognizes the global helping development, we're glad also that the private sector recognizes this as well.

A: MR. PONCELET: Thank you. Just a very short word on [that] from the disaster point of view. The private sector can be marvelous. It can be extremely destructive at the same time, so I think we have not yet the solution. I would be very pleased to discuss [this] with you and your group. I think basically the private sector has an interest – a very clear one – to make money and the interest from the Pan Americans or WHO is to save people's lives and some days are obviously – their common interest that we have to refine, most – (unintelligible).

A: MR. ATTARAN: Alex [Heywood], Alliance for Youth, a war story. And now I'm taking the names out of the story because they don't matter and I want to not breach a confidence, but within the last year I was invited to co-chair a meeting on malaria in a developing country, that was really organized by pharmaceutical company that has an outstanding malaria medicine that they supply to WHO under a 10-year agreement, but that's not in the WHO. And WHO of course signed that agreement, so they are willing partners and the pharmaceutical company provides the medicine. On paper they say at their cost; in fact it's below their cost. They're subsidizing it, so here's a company that is really going out of its way to assist WHO and WHO's grateful for that help and has signed his 10-year agreement.

As chairman of this meeting I wanted someone from WHO to speak about WHO's side of how the rollout of this new medicine project was going. Nobody agreed to attend. We had 60 people in the room, from African countries predominantly, learning about this partnership with the WHO and up until two hours before the end of the meeting, the meeting that had been planned for months, WHO would not confirm their attendance. They finally sent somebody who gave an absolutely dreadful presentation because they didn't want to send someone high up or somebody who had been briefed and they only sent someone because I said: "If you don't send somebody I'm going to drive everyone's attention to this," [that] put them on the spot.

Why do I tell you that story? Because right now WHO is a set of guidelines I highly recommend to you on partnership with the private sector in conflicts of interest. It is utterly unprincipled document and it's arbitrary in its nature. So the WHO cooperates with private sector partners when it wants to and it doesn't when it doesn't want to. There's no normative basis to when the cooperation will take place. That needs to be fixed because indeed Nicole [Bates]' right, the private sector has a lot to contribute but there has to be a clear path they can walk to the front door and it can – and then be welcomed, and that doesn't exist.

Yeah.

A: MR. RYAN: Could I just add one short comment to that which is that I think that the other group of people of the private sector that we want to be emphasizing the role of the WHO include pharmaceutical companies, but possibly also those in other parts of the supply chain who can bring organizational capacity with respect to the distribution of drugs, because we have to remember that [that] information part is a critical factor here which is why Nicole [Bates] is exactly right that that's the reason for them to be in the room. But the second and ultimately decisively important reason is to bring organizational capacity with respect to distribution because we know that that is the key to the WHO's role, part of their core competency and the private sector can help them with that.

MR. ATTARAN: Sorry, I'm going to pay attention to this side of the room for a change.

Alex [Preker]

Q: ALEX PREKER, WORLD BANK: Since we're having some fun this morning, I thought I would just intervene for – I'm on the panel as well.

MR. ATTARAN: Alex, please.

Q: MR. PREKER: Sorry. I want to stay away from the malaria debate which has been, I think, set up quite well in the Lancet and which we're accidentally featuring on one of our websites this month so anybody who wants to sort of look at both sides of the debate and how the gloves-off battle is going, I'll give you the website login, and I think [there are] some fun things on there.

Let's come back to the mission issues. I think that's an important issue and I think that's one of the core things of the first panel here. The World Bank was creative following the Second World War as a reconstruction bank and that's where the IBRD comes from, the title of the International Bank of Reconstruction and Development.

And you're thinking [that] development has changed a lot over time. I mean, the early thinking was in fact that, you know, reconstruction takes place by developing roads and the infrastructure, dams and those kinds of things. And during the first 20 years, some of that actually took place, but then some time in the mid-70s early '80s people started thinking that infrastructure by itself was not enough and that if you actually wanted to contribute to development, you had to move in to human capital. And so you had this whole thinking about human capital development that came in for about 10-15 years. And I think that's where – because the bank wasn't involved in health until sort of the mid-80s and at that time we became involved in health education and other things which you might call the social sectors.

And we've been doing that now for I guess it's about 20 years and as we move into a late '90s and the turn of the century, then the thinking was, well, maybe human capital by itself was not enough either. You know, the infrastructure wasn't enough, human capital wasn't enough. We also had to look at things like good governance, whether or not public policy is working, and so that's where the issue of the good governance, corruption, whatever came back on the table.

Now, it's very interesting because under the current bank, you know – sorry, I'm finishing – under the current bank, this will determine the infrastructure, and I think some of our political panels have come back to that, you know, should the bank be back doing hospitals and infrastructure. So my question really is – I mean, if that's what we're thinking, you know – are we looking back? Did we miss something in the early part? Where are we at? I mean are we back to the infrastructure again? I mean, is that what we should be doing? Have we forgotten about human capital? Have we forgotten about some of the lessons learned?

So maybe some of these things should be revisited in the context of the development process that has taken place and then look at what the intersection between this and what WHO can do. And maybe we could have a few comments from the panelists on that.

A: MR. PONCELET: Well, maybe just a quick comment is that the fact of intervening with our best capacity and the way we see an institution that is ignoring what exists in the countries, I think that's where the problem starts. There's a wonderful network of people for example be able to rebuild the country. It – (unintelligible) – of a systematically – (unintelligible) – after that. So I think we have to build-up existing capacity and there exists some of those capacity in countries and that's why we are seeing reconstruction.

MR. ATTARAN: Back there. Yes? Yes, please.

Q: I have a question regarding the mandate –

MR. ATTARAN: Can we get your name?

Q: LAWRENCE KOGAN, INSTITUTE FOR TRADE, STANDARDS, AND SUSTAINABLE DEVELOPMENT: We look at international law and it's encroachment upon free enterprise. We look at the WHO, the current activities that are being undertaken there, to expand the mandate, redefine the scope of the convention, and see that perhaps what role – the question we ask is what role should the WHO have in creating international law, regulations, standards that would encroach upon the scope and core competencies of other intergovernmental bodies such as the WTO because we're talking here about international standard setting and the broad scope for that.

MR. ATTARAN: Okay, I'll answer briefly and then, Michael [Ryan], perhaps you could say a few words about this.

MR. RYAN: Yeah.

A: MR. ATTARAN: There is no doubt that the WHO, and that's how it's usually referred to, as the WHO rather than "the Who" which is great old rock band. "Horton Hears a" (laughter).

There is no doubt that the WHO does have a competence to conclude treaties and in its – in its constitution – yes, there is such a thing; the WHO does have a constitution. I can't recall what year it is perhaps '47, '48, '49 somewhere – '48. There is a power to convene treaty negotiations and conclude them and there is no limitation on the subject matter of that power, although it would be very untoward for the WHO to go terribly far afield. That has only been used as power once to negotiate the Framework Convention on Tobacco and it is an area where you can argue there is some inversion on the trade sphere because it affects trade in tobacco. That's the factual answer. Now, Michael [Ryan] knows much more about it than I do, I think.

A: MR. RYAN: Well, I don't know about that, but one quick comment about your question which is that in this commission report that came out in April regarding innovation in intellectual property, one [of] the recommendations that the commissioners make at the end is that the WHO should become much more engaged in regulations with respect to good manufacturing practices with respect to drugs and then also what we in the United States refer to as Food and Drug Administration-like activity with respect to regulation of innovation.

Now, it is my suspicion that those kinds of activities go well beyond the organization's capabilities, to talk again about core competencies. And so, what I personally believe is that that would probably be a wrong direction for the WHO to go. It would indeed encroach on things that might be better placed in other multilateral institutions like the World Trade Organization.

MR. ATTARAN: Roger [Bate]?

Q: ROGER BATE, AMERICAN ENTERPRISE INSTITUTE: I want to come back to the targets, timetables, and the smallpox question that was raised before. I mean, I think that the WHO can claim quite a lot of credit for smallpox eradication but up till probably health for all target setting in 1978 and of course the smallpox eradication was '77, a year later than targeted, they were running kind of commando style taking – bringing doctors into countries to deal with vaccination programs and et cetera.

So my question is, if you look at what, actually, you had a good intervention that could work in that instance, you had the buy-in of all the countries and it was moder[ately] well funded, it seems as though under that setting, setting a target to eradicate smallpox probably made sense. Whereas from my reading of most of the targets that are being set, there is not much still going into one of the means by which we're actually going to achieve this target. Now, the WHO, since it hasn't got the financing to be able to go and do that, it can work with other agencies to try and hit those targets. But a lot of them – and I think it's Three By Five in particular – I mean, some of the country – and we can argue about the Americas and whether they were going to be hitting those targets, anyway, regardless of WHO/PAHO action, but I know for a fact – and although South Africa has a very mixed to appalling record and treatment in HIV, the South African health minister wasn't even consulted by the WHO. And that is surely not the way to build a target, because regardless of what the programs that [you] have in place, you shouldn't be setting a target for a country without consulting with the health minister of that country. I wondered if you could comment on that and maybe Nicole [Bates], too.

MR. ATTARAN: Nicole [Bates]?

A: MS. BATES: I won't say how old I was in 1987. I'm sorry, I can't speak to smallpox directly or that effort, but I mean I do agree, I think as I said on my remarks, you know, a lot of times there are targets that come out of these meetings and gathers internationally and they're declarations and I won't say that they are unfounded. I mean,

it's a matter of community will. It's a matter of political will behind these, but you do need evidence, as you stated, that you saw in smallpox and you need also the strategies that will help you to achieve those targets. So, you know, if you set a target, if you don't make the target it's somewhat irresponsible to just keep bumping it back. You need to figure out what went wrong and then come up with newer strategies to achieve that, or you will find – you know, was there epidemiology – you know, did we misdiagnose the problem? Did we misdiagnose our resources? And if we have, come back, reshape that and figure out what is achievable and make sure that you have the backing – the financial backing, the political will. You absolutely cannot affect health in countries without engaging the national governments, without engaging the national communities – the local communities to help make that happen.

MR. ATTARAN: Yes.

A: MR. PONCELET: For the target has been set by other programs, I certainly would not comment on that and refer to the specialist in that field, but the comment I made is not that the WHO doesn't deserve any credit at all for the smallpox eradication. What I mean by that is that the real credit has to be given to the organization -- is that to be able to put people together and to build a consensus with the countries.

The major problem that we have in several places is when you don't have the consensus being created with a country, that is where you start failing. And so the participation of the country is absolutely critical to any success and, I mean, that if you focus too much on the body that is in Geneva or Washington or wherever, [then] we will not be able to achieve much.

I think that the real capacity of the organization is when it is built with the countries and using the capacity of all those ministries of health and has organization to be able to achieve – (inaudible). And so that include setting of the goal, including their own capacity of working together. So that's – so to recenter a bit, definitely we have a choice, a financial tradeoff, but we could have done it without the contribution of the countries.

So and – (unintelligible) – find that other people are much more specialized in that one, to identify. The only comments I can tell you is that for the Americas, definitely, that there is credit given and even some other place where the target has not been reached, but it has been better discussed in some region than in some others. And that's the reason I think why some of those targets have been reached.

MR. ATTARAN: Okay. I'd love to answer your question. We are out of time. Thank you.

MS. BATES: The woman back there, you had your hand up for quite a while.

MR. ATTARAN: Can we make it quick, please? Short questions, short answers?

Q: RICHARD HANNEMAN, SALT INSTITUTE: We are the private sector that is trying to partner with the WHO, and for 15 years and we've been involved with salt iodization worldwide. Jean Luc's right about the WHO Geneva being different than the components of the mosaic is so true because PAHO is great and Geneva is been almost impossible to pull into partnership.

In fact, [Geneva] only agreed to work in a network that UNICEF was leading; [they] wouldn't work in a partnership. And one of the other things that hasn't been brought up that I think is very important about the private sector engagement is that it makes for sustainability. They have the incentives to be doing things that do make sense long term and we've had a lot of efforts for over 50 years that I saw and it's been a question of the great enthusiasm, five years later it's done and ten years later it's undone. So thank you very much for bringing this up.

A: MR. ATTARAN: I'm going to answer that quickly and take the chairman's prerogative to wrap up. The Salt Institute has – salt manufacturers, I should say, have done quite a lot in salt iodization had made a massive difference to global public health.

Because we have had had a couple of questions this morning about the WHO's ability to cooperate with the private sector, I did mention in an earlier answer there's a policy on cooperation that governs conflict of interest that isn't highly normative, it isn't very helpful. If I gave you the document, could we put it on the Hudson Institute website? Okay, because the WHO normally doesn't release it but I have a copy of it and we will put it on the website so everyone can see it and I hope that those of you from the private sector who have a desire to cooperate with the WHO can study that document and [try] and advance it beyond what it is.

A: MR. PONCELET: I'm sorry to go over -- I just want to make [it] clear that I never even imbued that PAHO is better than any other party. (Laughter.) So that can be – (unintelligible) – and I just mention that – (unintelligible) – I just took one example of a region; there are many examples in many of the regions so – (chuckles).

MR. ATTARAN: Thank you.

(Applause.)

(END)

HUDSON INSTITUTE

THE WORLD HEALTH ORGANIZATION: HOW CAN THE UNITED NATIONS AGENCY FIGHT DISEASE IN THE 21ST CENTURY?

THURSDAY, MAY 11, 2006
10:15 A.M.

PANEL II: MAKING GLOBAL HISTORY:
HOW THE WHO CAN LEAD AND SUCCEED

CHAIR:
CAROL ADELMAN,
DIRECTOR, CENTER FOR SCIENCE IN PUBLIC POLICY

SPEAKERS:
MARY PENDERGAST,
FORMER DEPUTY COMMISSIONER, FDA

EDWARD BURGER,
PRESIDENT, INSTITUTE FOR HEALTH POLICY ANALYSIS
DIRECTOR, EURASIAN MEDICAL EDUCATION PROGRAM

ROGER WILLAMS, CEO,
UNITED STATES PHARMACOPEIA

Transcript by:
Federal News Service
Washington, D.C.

CAROL ADELMAN: I'm first going to start with Mary Pendergast, who is a president of Pendergast Consulting, which is a legal and regulatory consulting firm, and you have her bio here along with everyone else's. Mary brings a wonderful perspective of government experience and private sector experience. She was executive vice president at the Elan Corporation, so she really knows the pharmaceutical industry, how it works, and what makes it work, and she was also the deputy commissioner at the FDA and then in the Office of the General Council at Department of Health and Human Services. She is now involved with Johns Hopkins at the Public Policy Center on genetics and public policy and received all of her BAs and law degrees from Yale University.

My experience in working with Mary [Pendergast began] when the [Berlin] Wall fell, and I was in charge of our foreign aid program to Central and Eastern Europe. She was a real champion of quality and safety, because we were starting up relationships with the Eastern European countries and Russia, and it was Mary [Pendergast] that was in there making sure that the high standards were being enforced. She's also been a champion for that in developing countries as well. And since so many of our issues with the WHO, at least in terms of those that are concerned about problems with the WHO, revolve around this stepping out of core competencies into patents, into pricing and prequalifying drugs that later have turned out to have to be taken off the list because there was no check on whether there was any proof of bioequivalence, we really want to – the first question, Mary [Pendergast], I want to ask you is, given this entire issue with the prequalification scheme at the WHO and HIV/AIDS drugs and the fact that drugs were prequalified and put on this list for HIV/AIDS and then later, almost a year after, if not longer, the WHO had to disqualify eighteen of these drugs for lack of proof of bioequivalence, my general question to you is, should the WHO be regulating drugs, and what characteristics does a drug regulating authority have to have, and does the WHO have them?

MARY PENDERGAST: Let me give a two-part answer, first based on my experiences when at the Food and Drug Administration trying to help Russia and the former countries of the Soviet Union deal with the new reality they had, which was to deal with a market-based economy as opposed to a command and control economy. I spent ten years working with the NIS – Russia and the NIS - trying to help them learn how to become regulators in a market economy, and I think it was a very fruitful experience for me as well as them.

One of the things we helped them do was write core laws, write good manufacturing practice regulations, and teach them how to institute the building blocks of a regulatory system in their governments. And I would like to echo the comments that people made earlier today that you really need to develop the capacity at the country level. The WHO is never going to be able to do this alone, especially as it moves into the chronic diseases.

Now, as to your specific question about procurement, there are structural limitations on the WHO's ability to do a good job in making the particularized scientific

decisions to ascertain whether or not a particular drug made by a particular company in a particular way is safe, effective, and of high quality. And I think that we saw that in the procurement with HIV.

What are their limitations? It's not because of lack of trying, it's not because they're not well-meaning, but there are structural limitations. They're not a regulatory agency and they are not formed through any system of laws. They're a voluntary membership organization and they have to make compromises based on the needs of their members. They can not compel data and they can not punish companies that lie to them, fail to let them do inspections or otherwise, so they have their hands tied behind their back.

The reviewers are not from countries that are experienced in demanding high quality data and high quality data sets, and so they do not impose uniformly high standards. They also have structural problems with their impartiality. As you know, the WHO not only looks to see whether drugs are good but also recommends the use of those same drugs, so they are recommending something and then saying that it's okay. Well, as we know from the Food and Drug Administration's 100-year-old history, you can't have those particular conflicts.

It also doesn't have the resources to do it right. Currently the FDA spends between $3 and $6 million reviewing every drug before it puts it on the American market. The WHO just doesn't have the resources to do that, and even if they did I would argue those resources should probably be spent elsewhere rather than duplicating the work that the other major regulatory agencies of the world do. So I would suggest the other two problems we had with the procurement is that their decisions are not transparent, unlike those of the FDA. The FDA puts up on its website the reviews it did, the data it reflects and the decisions that they made and why they made them. The WHO is not transparent and it's not accountable, and so you have a system which is doomed to have problems.

I think that the WHO took an enormous and positive step when, with respect to HIV drugs, they decided that if the FDA had prequalified the drug that they didn't need to do so. In other words, if it's good enough for the United States, [if it has] gone through the FDA review, it's probably good enough elsewhere. I would submit that the WHO should continue with that model and look to not just the Food and Drug Administration, but also the other major regulatory agencies in the world, partner with them and not try and do it [by] itself.

MS. ADELMAN: Thanks, Mary [Pendergast]. Please, anyone raise your hand if you want to step in on Mary [Pendergast]'s questions, I've got – or answers and comments and I've got a couple more questions for her as well.

Mary [Pendergast], with the – now there seems to be a mission creep with not only prequalifying HIV/AIDS drugs and other drugs for infectious diseases, but the mission creep appears to be coming in the area of chronic diseases. Are there going to be any special, even more serious obstacles if the WHO starts moving into the quasi- or full

regulation of drugs for chronic diseases, due to higher complexity or any other factors that we need to be alert to?

MS. PENDERGAST: Well, I think that with chronic diseases we have HIV as a model. It's not just an infectious disease; it's also a chronic disease. And when you have chronic diseases, what are we learning? What are the problems with Three by Five? It's not so much that there aren't pills. It's not about pills. It's about the other things that you need in a chronic disease environment. You need to have [a] diagnosis. You need to have testing over and over and over again. If you have heart disease and you're on a blood pressure med, you have to be checked every couple of months to make sure it's still working. You need to have steady-state clinics with steady-state healthcare workers with steady-state records so you can follow a person, not just the one shot, not just the blitzkrieg of polio day, but rather follow the person day by day, month by month, year by year.

You need to also have a steady supply of drugs, and that requires an infrastructure all its own that is very different than the infectious disease model. So what we saw with HIV is what is coming for the chronic diseases, so if the WHO does it – I'm not saying I think it's a great idea, but if they do it I think what they should realize is that, again, it's a capacity building problem and that they need to work to build the countries.

I think that with respect to the drugs for chronic diseases, they are already out there. There are thousands upon thousands of generic drugs for all the basic cardiovascular diseases, for diabetes, for that kind of stuff. It's not like we're making this stuff up. These diseases have been around in the developed world for a long time and rather than bother with prequalification, we should look to what the rest of the world is using.

But I guess what I think about it my husband and I have two children who are now in college, and our mantra has always been that we're not trying to raise children, we're trying to raise adults; that the end of the ball game is for us to have raised adults that can go out and live in the world. And I think that that's – with respect to chronic disease, that's what the WHO has to think. It has to think that it's going to eliminate its job country by country, as they have the capacity to do this work for themselves.

MS. ADELMAN: Thanks, Mary [Pendergast]. Are there ways that the – oh, we have a question in the back. Let's take questions as they come up.

Q: RICHARD HANNEMAN, SALT INSTITUTE: Thank you for your invitation. Dick Hanneman, Salt Institute. I sit next to Mary [Pendergast], so I better be careful here. If we are talking about policies and not pills and you're getting in to the area of chronic disease, one of the things that has always bothered me, and particularly bothered me in the context of a recent report 9.16 from the WHO on obesity and disease, chronic nutrition, et cetera, is the focus on intermediate factors; for example, blood pressure.

When you were at FDA, I remember writing to David Kessler and saying that a study published in the New England Journal had pointed out that low renal activity was associated with good cardiovascular outcomes and high renal activity – high cardiovascular events, and pointing out that low-salt diets created high renal activity and thus could we focus not on the blood pressure or insulin resistance or renal activity, but on the outcomes.

How do we focus on outcomes like we would if it were pills for policies, because you put these experts together, put them in a room for three hours and they come out and endorse a policy that then is taken to all the health ministers in 192 countries?

MS. PENDERGAST: I'm sure that part of that answer is way beyond the scope of my expertise, but I mean, don't follow the lead of the United States. The answer to these chronic diseases is not really the pills at the end of the ballgame. The real strides in chronic diseases are going to be made with the prevention. I mean, why bother thinking about blood pressure pills if you haven't stopped people from smoking cigarettes? They're the leading cause of problems with cancer, heart disease and they exacerbate diabetes. There are some basic public health things that need to be tackled first before we worry about the intricacies of IP [intellectual property] and precisely what pills people are going to take.

I see the WHO as being able to have a lot of influence of those basic, core messages about exercise and a good diet – not a salt-free diet, but a good diet; not smoking; doing the basic kinds of things that are going to make major strives in public health, not the pill at the end of the day.

MS. ADELMAN: I think that's very important because one of the WHO – when they started getting into the food regulation business, one of their key recommendations was to put a tax on single commodities and of course it was the idea to tax burgers, it was the idea to tax sugar and salt and of course immediately a few single commodity producing countries got involved and told them to stop that nonsense, as in Cuba and others. But I mean it seems like the approach with the WHO is too often one of the regulatory, top-down approach of trying to deal with problems that way rather than looking at what the in-country problems are, at least from my perspective.

Mary [Pendergast] just a few – did we have any more questions over here? Just one question: Is there a role for – since you're advocating that we should be strengthening drug regulatory agencies in these countries, not setting up a whole new level and layer of regulations at the international level, can the FDA or the EMEA [European Agency for the Evaluation of Medicinal Products], which is a European drug regulatory authority, play a role in training here? I mean, how could we play a more positive role in making that happen in these developing countries?

MS. PENDERGAST: Well, I think – yes, [the] FDA does now do training. I know it's working right now to train some other regulatory agencies. Obviously there are resource constraints on the Food and Drug Administration and I'm sure there [are]

resource constraints on the EMEA as well. I think that in order to tackle things like counterfeiting you're going to need to have some core laws, some core regulatory agency in every country of the world. But do they have to make individualized decisions, each of them, over and over and over again? I would recommend that they rely on each other they way that the ICH is the United States, Europe and Japan – they've come together [in] the Pick Program, which is where regulators around the world are gathering together to share their inspection reports. I think there is a lot – in the same way that there's partnerships in the public-private way, there should also be partnerships in the public sector as well so that as little work as possible is duplicated. But, yes, every country is going to have to tackle counterfeiting. There's no doubt about that.

MS. ADELMAN: Let me move on to introduce Roger Bates, and we can still put questions to Mary [Pendergast] later on but we'll -- not Roger Bates, Roger Williams. (Laughter.) I was looking at Roger Bates and --

ROGER WILLIAMS: (Off mike.)

MS. ADELMAN: – thinking he would have to make a presentation. Roger Williams, down at the other end of the table, is an M.D. and is the CEO of the United States Pharmacopoeia. And while I have some ideas – I know individual activities of the United States Pharmacopoeia, I was asking Roger [Williams] what's the best way to describe the United States Pharmacopoeia, and I'm sure he'll do a better job at this but basically, this is the organization that sets the standards for medical technology including devices, including drugs, and so it has an extremely important role here in the United States. And Roger [Williams] has really taken that to a new level with working more and more with the WHO and setting up a site in India, and I think Roger [Williams'] been a real pioneer with drug quality and safety and doing studies in some developing countries. And getting to Mary [Pendergast]'s point about counterfeit drugs, he has really looked at this issue and I'm going to ask him to talk a little bit about that as well.

He's served in the Food and Drug Administration. He [received] his medical degree from the University of Chicago and when he worked with the Army Institute of Research did anti-malarial drug research, so Roger [Williams] comes to us with a very broad background.

And, Roger [Williams], I'd like to start out with you. Would you give us just sort of an idea of the magnitude of substandard and counterfeit drugs in the world and what you think the impact is and why we should be more involved in this? I mean, my belief is that this has been a huge area and it's been growing and there hasn't been enough attention paid to it. I know when I started looking at it about 15 years ago and [if] I [had done] a Google search, if Google was in existence then, I [would have] found only about three or four good studies on it. Now, you helped raise this, but to me this has been a big area, one that the WHO should've been doing more work on, so I'd like to ask you that as your first question.

MR. WILLIAMS: Okay, Carol [Adelman]. I'm delighted to be here. I'm going to answer Carol [Adelman]'s question and also springboard back to some of Mary [Pendergast]'s comments. And I'm going to call up the WMA, the World Medicine's Agency.

Now, you might ask yourself, why don't we have it? Or you could ask yourself do we already have it? Is it that giant complex of new buildings that sits down in White Oak that is your Food and Drug Administration? The story of the world is [that] there are about 200 countries, and only about a sixth of those have anything like what you would call a competent authority. And even amongst those sixth, there's nothing like the FDA. I would argue the FDA has more resources than all the other regulatory authorities of the world combined. I'll make that point and somebody can challenge me on it, but it really truly is an astonishing creation and we're celebrating its existence over a hundred years.

Now, the way most drugs are approved in all the countries of the world is that they'll look to a competent authority, and the first one they look to, of course, is FDA. Now with that little theme in mind, I'm going to circle back to Carol [Adelman]'s question, but I will say that I've started with an understanding that there are huge gaps in drug regulation and standards for medicines in the world, gaps that we can hardly conceive of in the United States.

But you have some glimpses of them in the United States, and [they are] your dietary supplements. I don't know how many of you are taking your dietary supplements regularly, but the United States FDA does not have strong authority over dietary supplements. There's no pre-market review and even 12 years after the law was passed there [are] no GMPs, there's no inspection, and there's no enforcement. So when you're out there reaching for your Echinacea, just think [that] that's the [same] way it is in India for their Lipitor. So nothing is black and white in the world; there are degrees of things that are the same and things that are different.

Now, into these gaps are stepping activities, and Mary [Pendergast] mentioned one of them. PICK is sort of an international inspection effort that acknowledges the fact that most countries of the world have no inspectors, and as a matter of fact, I don't know if you know it, but Europe doesn't have a central inspection authority. It's handled at the level of member states, so even though you've got the beautiful EMEA sitting in a nice building on Canary Wharf in London, there is no central inspectorate in Europe the way the United States has. And I'm always amazed at those inspectors who are out there looking all over the world constantly at the drugs that are coming into the United States. So PICK is an example of a group that's filling a gap.

I will argue that World Health – and I know the guy who created the prequalification program was filling a gap, and what he did was – I'm going to say was to create for these HIV drugs and other medicines, he created a generic drug approval process at the level of the WHO. Now, I know all about the generic drug approval process because I ran it for 10 years at FDA and I will argue, depending on where you sit in the world and who you listen to and what you believe, you could say he did a noble

thing. I will certainly agree [that] he is completely under-funded. It's not a World Health core competency and the real question is, should he be doing it?

Now, I'll also congratulate Mary [Pendergast] because Mary [Pendergast] created an alternative pathway, which was an FDA fast-track approval process for the fixed-dose combinations that are being used now throughout the world, and a lot [of] companies are using that fast-track process to get their fixed-dose combinations approved for use in Africa. These are tentative approvals in the United States because the United States has very vigorous IPR processes.

Now, there are other ways that people are filling these gaps. USP, for example; if you go to your friendly drug store you'll see a special mark on some but not all dietary supplements where we're actually reviewing the manufacturing process, see if they conform to good quality standards, and if they do we give them a little special mark. So the next time you're buying your Echinacea, look for a manufacturer who's paid us – there is a user fee for this – for that little extra mark that says, yes, we think that they're paying attention to good quality.

Now, the last thing I'm going to come to is to answer Carol's [Adelman] question, which is in the midst to these gaps the world is awash in junk and there are a lot of counterfeits, there are a lot of sub-standards and there are a lot of similars. I know and love the Hatch-Waxman Law because I lived it for 10 years. My standard joke about Hatch-Waxman was that there were 10 people in the country who understood it and nine of them were suing the agency – (laughter) – but it's a great public health law and it's worked in the United States and the rest of the world is copying it – copying it slowly. But certainly World Health, when they created their prequalification approach, copied our Hatch-Waxman activity. And to the extent they're doing it all, at least they have some sound framework for their understanding of what they are supposed to be doing.

But before we had Hatch-Waxman in the Unites States, we had a lot of similars. Similars are ones where you don't know if they're bioequivalent or pharmaceutically equivalent to the reference-listed drug, and the reference-listed drug is the pioneer drug where somebody spent a lot of money to establish its safety, efficacy, and quality.

Now, if you go to Brazil – I was glad to hear the comments about Brazil – Brazil has a lot of similars and I don't know that similar yields the same safety and efficacy that the pioneer does. Before Brazil passed this law, there was something like 47 [different] Omeprizols on the market, and I had no idea that they were all interchangeable, but yet they're legally marketed and Brazil would not say that they're substandard. They would just say that they're branded generics, but they're not interchangeable generics.

So, Carol [Adelman], in answer to your question, there's a huge amount of junk in the world. I would probably say most of what the world takes is junk. God help you if you're in Russia and you have to take a medicine. And I don't know how we solve it. I started about telling you about a World Medicine Agency. Does anybody want that?

Well, some people would, some people not. We actually proposed to that CIPAH commission and I heard gasps on the phone as we talked about it.

MS. ADELMAN: Any media questions for Roger [Williams]? But thanks, Roger [Williams], for getting into the similars versus generics issue because it has been very – people were talking and were writing about and were critiquing the WHO on prequalifying these drugs. Our main critique was that they were prequalifying drugs that were similars and not real generics. And real generics have to be shown that there is bioequivalence there; similars do not. And so that's why we were calling for let's have transparency, accountability, let's show you your studies and results. And they ultimately did that and began to look at that. And when they did they had to disqualify, but I think that that is the big issue. How do you – when you talk to the WHO, what do you say about that, Roger [Williams]?

MR. WILLIAMS: Well, I do talk to the WHO about this. I always emphasize my mantra, which is pharmaceutical equivalence and bioequivalence. And pharmaceutical equivalence means you've got the same active drug substance, and "same" is one of those wonderful English words where you have to be very careful with it. But some of these molecules are extremely complicated. They have multi-viral centers. They're unstable. You know, can I digress a little bit, Carol [Adelman]?

MS. ADELMAN: Sure.

MR. WILLIAMS: If you think about your bread…I don't pay attention to my bread, but it doesn't last too long even when you put it in the refrigerator. It gets stale. You throw it out. Now, medicines are far more complicated than bread and you're asked to maintain their stability in the marketplace for three to five years. The way people do that is through very careful quality studies that Mary [Pendergast] knows all about and very careful storage studies. So that's what pharmaceutical equivalence does. Is World Health paying attention to all that? I can't say I know.

[The definition of] bioequivalence is, "does it perform equivalently". You can have a lot of drugs that look great when you test them in the lab, but if the drug doesn't get out of the medicine [and] into the body, you're got big trouble.

MS. ADELMAN: We have a question from Amir [Attaran].

AMIR ATTARAN: Hey, Roger [Williams]. Thanks for the talk. Let's stipulate for the sake of argument – just for the sake of argument that a WMA is a bridge too far. Right now it's just not going to happen, and that the WHO doing medicine regulation takes them into an area where it's at the fringes certainly of their mandate. Could there be a third way down the middle where in developing countries where there already are groups – political groups of nations like the SADC, Southern Africa Development Community, like ECHO was in West Africa, multi country groups. Could we have for each of those a medicines regulatory authority the way that the European Union now does?

Does that make sense to you? I think it does make sense. I've spent years trying to propose it to USAID and they usually never e-mail me back on the idea. No one seems to take it seriously, but if it works why don't we pursue it?

MR. WILLIAMS: Amir [Attaran], I really like the idea, and actually that was one of our conclusions; you know, that if you couldn't get the whole ball of wax why not go to these regional harmonizing bodies like ASEAN and the Gulf States and SADC, and see if you could coalesce them into some common action?

And then the next step, of course, would be to coalesce the coalescence. So, you know, maybe it would be something that could happen in 50 years. But I would argue [that] this is critically important to the United States. This junk is coming in the United States. We all know it.

All right, let's talk about compounding. Compounding in the United States is sort of the old way of getting medicines, and it's about 5 to 10 percent of the prescriptions in the United States. A compounding practitioner can reach to India and buy a bulk drug that has never gone through the FDA approval process or a GMP inspection. So if I tried to scare you in your dietary supplements, I'm now trying to scare you on your compounded medicines.

Borders are porous and they're becoming increasingly porous with the internet and mail-order pharmacy. I think a lot of this is in the interest of the United States.

MS. ADELMAN: Thanks, Roger [Williams]. Let me introduce out third panelist and then we'll take continued questions. [His name is] Dr. Ed Burger, and we're really, really delighted to have you here today, Ed [Burger]. He is a distinguished physician and scientist, president of the Institute for Health Policy Analysis in Washington, he has his M.D. from McGill University and a Masters and Doctor of Science from Harvard, and he served on the faculty of the Harvard School Public Health and was a professor at the George Washington Medical Center – Georgetown, excuse me. And he currently is also directing the Eurasian Medical Education Program, which is a wonderful partnership, and I hope you will tell us a little bit about this, with the American College of Physicians. And they've already trained over 7,000 Russian physicians. And you're working, I think, in a lot of areas, primarily chronic care, and of course he's highly published, and worked in the White House Office of the President's Science Advisor in the early '70s, so he's seen these issues. I'm sure you are no stranger to these tensions and conflicts with multilateral organizations.

I hope that you can help us today really understand what new ways the WHO is going to have to learn on how to work if they're going to do better with chronic diseases, and I want to start off with my first question to you. With the record on AIDS and malaria that we've seen – this disappointing record – are you worried about whether they can handle chronic diseases from your work in Russia and working with the WHO, what

do you think needs to be changed in order for this to happen? And any other comments – I told that he could say whatever he wanted to whatever question I asked him, but –

ED BURGER: There's an invitation. Thank you, Carol [Adelman]. Let me thank you and let me begin by very briefly summarizing what we've been up to for the last 10 years. Our beat is Russia, in fact, and we set out formally in 1997 to establish a program for continuing medical education for Russian physicians in partnership with the American College of Physicians. For the few of you who perhaps don't know the American College of Physicians, it's 115,000 internal medicine positions in this country of long standing – 1915 – whose major activity in the United States is continuing medical education for internal medicine physicians here. And they accepted this challenge.

What we have done was to embark upon an experiment, which was based upon a question we asked ourselves, and given the enormity of the health challenge in Russia – 11 time zones, a hugely overbuilt system, an expenditure of no more than 3 percent of GDP that dropped precipitously in the late '90s and whose health indices were similarly depressed - the question we asked was, what could one do that would really make a contribution in that setting?

And the issue that stood out was a substantial isolation of the medical profession there from Western medicine and Western medicine science for 70 years. Russia is not a third world country. Russia has all kinds of – a legacy of great strength in the sciences both biological and physical, and a healthcare system never as good as its apologists suggested, but nevertheless extensive and with a strong overlay of prevention.

So the experiment we put in place was to suggest that we concentrate on bringing skills and experience and knowledge to share – and we don't use the word training – share with out colleagues in a series of Russian regional centers across the country from Tula to Yuzhnosakhalinsk in Khabarovsk in the Far East. We picked them out because there was an academic medical center outstanding in Russia and because the political and professional and the academic leadership in those areas wanted this program to take place.

It turned out [that] the farther [we were] from Moscow, the more eager the physicians [were] to catch up. We picked out a series of clinical foci for the program which correspond to the major contributors to the excess mortality in Russia. Overwhelmingly, the thing that kills more Russians - and Russian males in particular - is heart attack and stroke, [with] cardiovascular disease and diabetes behind that. The prevalence of hypertension in Russia is the same as it is here: it's 27 percent of the adult population. We pick up about 50 to 60 percent of our hypertensives; they pick up eight [percent]. It overwhelms everything else as a major contributor to excess mortality. And it's a preventable, remediable affair as we and others have shown. So cardiovascular disease, diabetes and tuberculosis were the original three clinical areas; laterally, HIV/AIDS, and I will come back to that.

The vehicle is American and some Western European internal medicine physicians trained in particular areas who are good teachers and who are sensitive to foreign medical cultures on a voluntary basis to spend time with their colleagues in their programs of continuing medical education to which they hue more rigorously in fact than do we. Over the life of the program now, we are approaching about 8,000 Russian physicians who have been in those settings in Russia, and we've also brought over here about ten groups to centers in the United States for more intensive experience.

We have considered this program as much of a security issue as a humanitarian one and I'll come back to that. The issue of chronic disease – chronic noncommunicable disease, as I say - waxes very strongly over there. What has happened in recent years [is] that the momentum of enthusiasm behind the issue of AIDS has crowded out the support for concern [in regards] to the matter of noncommunicable chronic disease. And so it has – the momentum behind AIDS and doing something about AIDS, which began perhaps with the National Intelligence Council's fifth wave report a few years ago, has overwhelmed the USAID's support, so that all of the support from the USAID bound for Russia for health essentially is put in to HIV/AIDS.

It has been, I will say, an eminently successful experiment to the extent that we have been able to demonstrate both changes in physician practice patterns and where we've been in majors of short term complications with cardiovascular diabetes – of cardiovascular disease and control of diabetes and hypertension. And the – let me just turn now to the issue of the role of the World Health Organization, which is what you asked about.

The World Health Organization did a great service first of all a few years ago by the publication of the report, "Macroeconomics and Health", which set a tone, a rationale for doing something about chronic noncommunicable disease. This was a project of Jeffrey Sachs which described the fact that health is both an independent and a dependent variable, and that in the case of Russia, for example, it is predicted [that] Russia will not be able to achieve its full economic potential without doing something about this particular problem about its health. The World Bank – ironically, the World Bank as you know has had a loan of $150 million planned for almost ten years for HIV, AIDS and TB. Interestingly enough, the department and the person who has been in charge of that took note of the fact of the importance of chronic noncommunicable disease and headed an effort to make known the importance of that burden on Russia and the result is a report called, "Dying Too Young," which is very good, very analytic, and concentrates as much on the economic negative consequences of this burden of disease as it does on the biological matters.

I'm happy to say that as a result of that a business group forum in Moscow now has taken up this issue and is putting in place a series of programs for both Western and Russian businesses in Russia to follow the lead of that particular initiative. These are some bright lights that I think the international financial institutions and the World Health Organization – the UN associated agencies have done and I think they ought to be taken in to account in considering that.

MS. ADELMAN: I'd like to put out a question to all the panelists and to the audience as well. I want to take us from Russia to some stats for more developing countries and the differences in cardiovascular disease rates or death rates per hundred thousand versus death rates for HIV/AIDS, TB, and malaria combined. In China, the death rate per 100,000 is 260 [for] cardiovascular disease, compared to 12 for HIV/AIDS, TB, and malaria. In India it's 405 per 100,000 for cardiovascular versus 75 per HIV/AIDS, TB, and malaria.

In Nigeria, there of course because of the resurgence of AIDS and high levels in Africa, it's 490 for HIV/AIDS, TB and malaria versus 410 for cardiovascular diseases, but it's still interesting to me that the CDDs are so close to the infectious diseases and of course, as Mary [Pendergast] rightly pointed out, AIDS is really for treatment purposes a chronic disease as well.

And another stat that has come out of some of the data is that China will forgo $558 billion in national income over the next ten years due to heart, stroke and diabetes. Whenever I have been at world health assemblies, I have talked to groups like the International Council of Nurses, the World Medical Association, International Hospital Foundation – these are the associations that represent the physicians, the hospitals, the doctors – I hear from them that they have a lot of trouble busting into the WHO, being considered and being sought – their expertise being brought in and being used; and these are the medical service delivery systems along [with] the scientific organizations and physicians groups and private sector corporations and private medical schools here that are going to be the organizations that really know how to best treat chronic diseases.

And the WHO has pretty much focused on ministries of public health, which are now consumed [and] overwhelmed with AIDS money, and some of them were hearing stories about ministries of health in Ethiopia sitting there with $100 million World Bank loans and Global Fund grants and [being un]able to spend them. So I guess I want to get to the heart of [is] one of the important questions of this conference: what does the WHO have to do with this pandemic of chronic diseases coming upon us, and the relevance of this? How are they going to have to change their way of doing business to deal with this better than they have with infectious diseases?

So I'd love to hear from those of you who have experience in the field and from others in the audience as well. Pardon this podium here.

DR. BURGER: I give out an anecdote of success, and the success that I'd like to describe was a program that the United States government in fact supported in the '40s in Latin America.

MS. ADELMAN: I hope we have more recent success than the 1940s, but it's nice of you to remember these things. (Laughter.)

DR. BURGER: It's illustrative of your very point, though, and it was successful probably because Nelson Rockefeller was in the White House at that point. He was a dollar-a-year man and he had the support of President Roosevelt. This was a program for health in all 18 Latin American countries that lasted over ten years. It was enormously successful in the sense that it built hospitals and clinics [and that] it trained people at both ends of the axis. It operated through a series of what were called sambesios in each of the ministries of health in all of the countries with an understanding that each of the countries would take over the financial support at the end of the period.

And notably it operated with an enormous amount of assistance and contribution from nongovernmental professional organizations, advisors, and individuals. It had great continuity and it was sold to the Congress every year on the basis of security until the last few years when it was described as a matter of economic development. Nelson Rockefeller made no friends in the State Department apparently during that period of time, but the program stands as a model.

It was repeated more modestly in Greece in the late '40s, but we haven't done anything like that since that period of time. The points that I would make are that it relied heavily upon good professional contributions over long periods of time both for advice and for those actually in the field. It operated through an organization that was extra-governmental [in] that [it] was set up for the purpose, and it is well remembered there, I think, by those who do remember and by those who took part in it as a monument that has not yet been repeated since then.

It actually oversaw the construction of physical facilities – clinical facilities, hospitals and clinics. It trained nurses and physicians at both ends of the axis. It provided a great deal of advice on public health matters, water supplies, sewage and so forth, and its professionalism and continuity were I think key points.

MS. ADELMAN: Yes. Nicole [Bates] – I mean Kate [Schecter]. I'm sorry.

Q: KATE SCHECTER, AMERICAN INTERNATIONAL HEALTH ALLIANCE (AIHA): Kate Schecter from the American International Health Alliance. I'm getting a little bit ahead of myself here, but since it was already brought out I think I might as well just jump in. I think we have done some of what you're describing, so we improved the model that – (off mike) – has promoted. I think that there's a tension that's coming out in the room over the course of the morning between what you and I have promoted and spent many years doing, which is to draw upon the expertise in the United States and the desire – this sort of almost missionary belief that the American medical world has that we have a lot to offer and we get hundreds of volunteers to go and provide their knowledge and skills and to receive people through the United States.

But in the context of WHO and its perception of what expert technical assistance is and what we're doing, I think there is a very strong tension. I've been told a number of times by Beltway-bandit consulting companies that we're dealing with amateurs and that these American medical professionals who offer their services are not really part of the

development – for lack of a better word – industry. So I just want to throw that out as something that I'm interested to hear your response to.

MS. ADELMAN: Does anyone else want to comment on that? Mary [Pendergast] or Roger [Williams]?

MS. PENDERGAST: (Off mike) – WHO tackling chronic diseases.

MS. ADELMAN: Okay, well let's have a comment on this tension. Ed [Burger], do you want to, or any other of the audience members, and then we'll get to Mary [Pendergast] on the WHO.

A: MR. BURGER: Well, first of all, Kate [Schecter]'s program is the one jewel of the effort of [US]AID, I think, in the last several years. It was begun as a hospital partners continues to wax as a major challenge to these members because they – there is a lobby, and they make a profit.

AID finds it convenient to let large contracts to a few people to in turn go out and find talent to do what they do. The same thing has obtained in the rule of law. The one jewel of a program for the Rule of Law Program is the American Bar Association's program called the Central Eurasian and East European Law Initiative. They have to fight for their position every year, in fact, in the same sense, because the Beltway bandits in fact say there ought to be a place for the profit-making world to do what they do. And I commend you all to Susan Raymond's comments about these matters, which are germane. It is a matter of that kind of politics, in fact, that obtains.

MS. ADELMAN: I think the tension is very well put. There is a very distinct difference between those who think that the only people who could really work in developing countries are people who, you know, are development experts, as opposed to the technical expertise. And, you know, to my mind when you go to developing countries, they want to have people who know how to run a hospital, not somebody who's consulting on that. They'd rather have a hospital manager. They want to have peer-to-peer relationships. It doesn't mean there's not a role for, you know, the Beltway consulting firms, but I think that, you know, this tension between, well, we need people who know how to work and move around in developing countries versus the real top-notch technical expertise is rather sanctimonious, and what the developing countries want is the expertise. That's for sure.

MR. BURGER: You've had to fight for your own position at – over your period of time, with exactly the same role.

MS. ADELMAN: Right.

Q: (Off mike.)

MS. ADELMAN: Yeah, well, I think – and we will turn it over to the panelists. I'm talking too much. But, I mean, WHO has always emphasized prevention and has always worked in ministries of public health. They have not gone out to the professional medical societies [or] the private sector, unless it's companies giving you money, and then it's, you know, "your money, our agenda," is the way that works, usually. But the fact is that the – you know, their entire attitude has not been to really incorporate that element in a big way. And I think that this is not what the ministries of health do. They do not do it. It's the hospitals, it's the schools, it's ministries of higher education, it's private physician associations [that do it], and, you know, I think it's not going to happen at all unless the WHO learns how to move out.

But, Mary [Pendergast]?

MS. PENDERGAST: Well, I would just like to throw a monkey wrench in, Carol [Adelman] – here, but –

MS. ADELMAN: All right.

MS. PENDERGAST: I'm not a 100 percent certain that the WHO should try to tackle the noncommunicable diseases, at least not just yet. I realize that they have an enormous disease burden in the world and that and it will come to grow, but it's the World Health Organization, and what is the one thing we all get affected by? The infectious diseases. And I think that we can't let the WHO move towards the noncommunicable diseases unless we're pretty confident that we have got the infectious diseases under control, because we are one world in that respect. I'm not sure we're there yet.

My second concern is that somebody has to be the advocate for the poorest countries of the world, for the poorest people of the world, and I think the WHO plays that role. And I think that it's going to be a mistake, again, to turn a bit to look at the noncommunicable diseases, which are the diseases, frankly, of self-inflicted wounds by people's diets, [by] exercising, [by] smoking. So I'm a little concerned about that.

And then in the WHO report on noncommunicable diseases, it keeps saying, well, half of the noncommunicable diseases are under the age of 70. That's true, but only a quarter of them are under the age of 60, which means that the communicable diseases at least at this point are not yet having a huge effect on the productivity of the countries. And I think that as countries move into productive economies, they ought to take a little more responsibility on their own to solve these problems. The drugs are out there, and you know, it is going to be the mission of countries and academic centers and clinics and doctors to provide the infrastructure for chronic disease.

So I'm a little worried about [a] mission shift here, and that the stuff that the WHO – the world part of it, the poorest part of it, the infectious part of it – since that's hard, it's intractable, it's no longer sexy, it's no longer new – will [leave] behind. That's my concern.

(End of audio.)

HUDSON INSTITUTE

THE WORLD HEALTH ORGANIZATION: HOW CAN THE UNITED NATIONS AGENCY FIGHT DISEASE IN THE 21ST CENTURY?

THURSDAY, MAY 11, 2006
11:30 A.M.

PANEL III: WINNING THE WAR ON DISEASE: REMAKING THE WHO FOR THE 21ST CENTURY

CHAIR:
HENRY GREENBERG,
ASSOCIATE PROFESSOR OF CLINICAL MEDICINE,
COLUMBIA UNIVERSITY COLLEGE OF PHYSICIANS AND SURGEONS

SPEAKERS:
GERARD ANDERSON,
DIRECTOR, CENTER FOR HOSPITAL FINANCE AND MANAGEMENT,
JOHNS HOPKINS UNIVERSITY

KATE SCHECTER,
PROGRAM OFFICER, AMERICAN INTERNATIONAL HEALTH ALLIANCE

ALEX PREKER,
ECONOMIST, WORLD BANK

KATHY HEBERT,
HEALTH POLICY FELLOW,
U.S. SENATE COMMITTEE ON HEALTH, EDUCATION,
LABOR AND PENSIONS

Transcript by:
Federal News Service
Washington, D.C.

DR. HENRY GREENBERG: I started out as a Peace Corps doc[tor] many years ago in West Africa, and for the last 10-15 years have come back to my interest in global health, primarily in chronic disease, and worked with Ed Burger for many years, was one of the soldiers he sent out, as it were.

I'm going to first introduce the panel very quickly and then I'm going to give some remarks. The panel will each speak very, very briefly. I'd like to keep most of the session to questions.

Kathy Hebert, who is on my left, is also a cardiologist and a practicing cardiologist. Her area of expertise is congestive heart failure and she's worked setting up various programs of management in different areas of Louisiana. She's now an RWJ [Robert Wood Johnson] fellow in Washington on a Senate committee. And I've actually asked her to come up and talk to our group at St. Luke's Roosevelt on the inside scoop in Washington. And we'll get to do that.

Alex Preker is an economist. We've heard from him earlier. He's at the World Bank, has worked with the WHO, has participated in many of their writing sessions on some of their major papers and has already been a little provocative and hopefully will be so later on as well.

Kate Schecter we've also heard from, from AIHA, has a lot of on-the-ground experience in Russia and the Caucasus, I think understands the roles of chronic disease, and has looked at the impact of these illnesses on society; and what the diseases mean in terms of economics and development.

And lastly is Gerard Anderson, who is a professor of public health and of medicine at Johns Hopkins, and has extensive experience in how to finance the systems that take care of these diseases. And they are expensive, and I think his insights will make my amateur status very apparent.

But let me just make a few comments. I didn't know exactly what the format was here. I didn't know I was chairing the session until a day or two ago. We've heard some of the data, you know, how prevalent chronic diseases are around the world. They are clearly the dominant killer worldwide and vastly more so in everywhere except sub-Saharan Africa. Contrary to what Mary Pendergast said, they have a huge economic effect. In "Race Against Time," which we published under Jeff Sachs at the Earth Institute at Columbia a few years ago, we showed that in the five countries that we looked at, in working-age populations the mortality from heart disease is two-and-a-half to five times that of what it would be in the U.S. In a study on women's health that our group published, I think in the International Journal of Epidemiology, that the mortality from chronic disease in women under the age of 35 is astronomically higher than the sum

total of birth complications leading to death and HIV. It's a real problem. If the goal of global health assistance is economic development, chronic disease is where you've got to be.

Now, when I started doing this I wondered why there was very little funding, and [US]AID was not interested in funding our group at all once it got into chronic disease. And if you go on the Web pages of [US]AID, the major foundations that do global health assistance – Gates, Soros, Rockefeller, Ford – there is not a farthing for chronic disease. Zip. Nothing. So if we get very critical of the WHO, you know, there ain't nothing left out there.

I would run into medical students who are getting MPH degrees at Columbia, and I'm listening in 2000, 2001; they're talking about the same course material that existed in schools of public health in 1970. So I went on the Web page of all the major schools of public health in the United States, and looked to see: is there was a concentration in chronic disease the way there is in epidemiology, global health, et cetera, et cetera? There are no concentrations in chronic disease in any school of public health in the United States. The closest is Yale, which calls its epidemiology concentration "the epidemiology of chronic disease" and, in fact, most of the curriculum is chronic disease. Half the curriculum at Yale in global health is chronic disease and the others have virtually none.

So that turns out to be, if I remember my data, 1.2 percent of the graduates of MPH programs have exposure to chronic disease and about 80-85 percent of graduates are non-MDs. So these folks, without any medical background, fill up all the slots in all these wonderful organizations and know nothing about chronic disease and can't learn it; they don't have the medical background. So they keep doing what they were taught.

So there are two possible reasons why the chronic disease model isn't embraced. It's also not very sexy. I can agree with that. And the idea that it is self-induced is not helpful. The issue is economic development. We in this country have dramatically reduced the impact of chronic disease by pushing the impact of the disease 30 years later. So we let people raise their families, finish their careers. We do leave a problem for people who look at Social Security. It's a separate issue.

So I went on the WHO Web page to see what they do with chronic disease, and lo and behold, one, they had this report in last September on chronic disease. Their annual reports for three of the seven years of this century impinge on chronic disease – the one on manpower, risk factors, and mental health. You can find out that diabetes is a major problem, economically, around the world, and in the top 10 countries in which diabetes is a problem are listed Bangladesh, Indonesia, Pakistan and Brazil. So this is not a problem that is left to the rich. You can find out the data on cardiovascular disease and what its impact is. This is all on their web page. And then of course there is the Framework Convention on Tobacco Control, which, a few days ago, got its 127th member: Albania. And I found out also that Myanmar has just announced that they are going to ban smoking in public in 2007. I think the smoking war is actually going to be won, and in

part the WHO is going to deservedly get a lot of the credit for that, and that will have a major impact on chronic disease.

Now, why don't they handle it well and why doesn't anyone else even consider it? And part of it is our own isolation. I mean, I graduated medical school a long time ago, well before my panelists here. Even then it was very clear to me that preventing chronic disease was simply part of the woodwork of medicine. It came out of the Framingham study, which was started in the late '40s. And I just assumed that the whole world assumed that that was part of the curriculum, and it isn't. I mean, Framingham, in a sense, didn't even move to Europe until the '70s, when Pekka Puska introduced the North Karelia project to reduce heart disease in Finland. And it's just now coming online in the rest of the world; people have not understood the model. When I was working for Ed [Burger] in Russia, we actually got a single polyclinic in Kazan to manage hypertension. We enrolled 200 people, they followed them, they looked at all their risk factors. And we lowered blood pressure and changed no risk factors because it was very clear that you need a whole system to treat chronic disease, not simply a blood pressure cuff.

But when we published the paper, being a good academic, we looked for other studies in the Russian polyclinic system, other studies in Russia on chronic disease. There are none. As best I can tell, the Russian polyclinic system, which is a very effective system – they can get to everybody. They can count anything they want to. There has never been a study in the Russian polyclinic system on chronic diseases, not because they're not interested; it's just not part of the medical culture outside the U.S. It's coming, but I couldn't find anything in English; my Russian colleague and co-authors couldn't find it in Russian.

So the question is, what about the WHO? Well, we've all heard that they don't meet their goals on "Three by Five," and things like that, and I suspect – I know how difficult it is to try and get half a dozen medical residents to agree on something; trying to get 192 sovereign countries to agree has to be next to impossible. I think what happens in that cauldron is that they come up with nice plans that please everybody and they don't quite get the goals. You can't do chronic disease the way you can do vaccinations. You can't send a SWAT team in, like we did in Afghanistan in 2002, and vaccinate people. It means a long-term commitment. You've got to have infrastructure, continuity, all of the things that were mentioned on the last panel. I would argue that takes intrinsic commitment by the host country. It cannot be done by external aid alone.

So maybe the role for WHO is to say, here's a problem, here's the data, here's the rough data for your country; are you interested? We can help. We can help with expertise, we can help with city planning to put in bike paths, we can give you guidance on clinical trials and measurements and outcome and finding out what the true impact of a stroke is in your country, whether it's a self-employed taxi driver or a corporate employee, and make the measurements. You can solve the problem. But you have to put the first dollar on the table. And maybe the nickname for the program would be, "Second Dollar Down." The UN, the WHO does not do things; it leads by exploration and

support, and then helps host countries do something that they want to do, because you can't do it – you can't do it any other way, and the WHO will be like anyone else: they're not going to be able to do it on their own. They're going to have to do it with the support and commitment of the host country. It has to be part of the national budget; it can't be a grant cycle. You can't have a grant cycle for 50 years of chronic disease management. So that may be a role.

So, I'm going to stop, hopefully having annoyed or offended a good number of people here. I've asked the panel to introduce themselves to us and what they do, because they're all related to this issue. And then we['ll] have a discussion on the WHO's role in chronic disease.

So, Kate [Hebert], we'll start with you.

DR. KATHY HEBERT: I currently am a Robert Wood Johnson Health Policy fellow serving on the Senate Subcommittee on Bioterrorism and Public Health Preparedness, and have been spending the past couple of months working on reauthorization of the BT [Bioterrorism] bill and trying to redo the United States public health system. They asked me to work on that and then to work on world peace – (laughter) – which I wasn't sure which one would be easier. But in my former life I was a cardiologist in the Louisiana state healthcare system, which is one of the oldest healthcare systems in the United States and is the fifth-largest healthcare system. I mainly take care of the patients in the charity hospital system, [who] are indigent patients. The mean income of our patients [is] $11,800 a year. So, it's been quite a challenge and we've overcome just about every obstacle. We were told we would never succeed, and so I will share with you a quick success story.

In the JAMA [Journal of the American Medical Association] article comparing the quality of care of Medicare beneficiaries – this article comes out every two years – and most recently Louisiana ranked 51st – and that's because they included the District of Columbia and Puerto Rico – and so 10 years ago I started a heart failure disease management program in the charity system, and if you look at our data, Louisiana data for our private hospitals has patients being discharged at a rate of receiving the right drug 57 percent of the time. The best state in the United States was actually Vermont, with patients receiving the right drug 81 percent of the time. When my indigent population – for those of you who are from the World Bank and are bankers – I was given a total investment of $45 to buy a teaching tape in 1996, and that was the extent of the investment for my program. And that 12-minute teaching tape taught my patients and their families everything they needed to know about congestive heart failure. That, along with partnering with the pharmaceutical companies who are now giving out free medicines for patients who make less than $20,000 a year, we were able to give out $50 million over the course of our eight-hospital system to these patients, and we now have our patients at 96 percent use of the right drug, which would actually beat out Vermont and everybody else and put Louisiana at the forefront on congestive heart failure disease management.

So if you're interested in dollars, for $45 investment, the first year return on investment was a $500,000 savings at our hospital because we decreased admissions by 72 percent. If you're interested in other things besides money, we actually dramatically decreased mortality. And the other interesting thing we did was we eliminated any racial or gender disparities. And actually, black women have the lowest mortality out of the four groups in our program.

So, one of the things I've learned up here on Capitol Hill is that there's always unintended consequences of your health policy. You may start off with the best of intentions and then, further down the line, there's always the things that you didn't anticipate. And my issue with that is, when Reagan and Gorbachev brought down the walls, that might be a good thing, but one of things that happened was with the countries in the Caucasus like Georgia, who gained its independence, they also had collapse of their healthcare system, and those healthcare systems were set up pretty similar to our state system in the charity hospitals in Louisiana.

And so one of the things that we've been involved with is a grassroots effort of physicians there who have come to me, asking us to share with them our knowledge. We may not be able to bring them the money for the medicines or the money for the textbooks, but one of the things we can do is with those countries that do have access to the Internet, we can bring them knowledge. And I've brought a guest here with me who actually has a company here in the United States that partnered with the publishing company Elsevier, and has a nursing school online here in the United States at 1,500 hospitals in the United States to try to end the problem of 100,000 nursing shortage that we're facing in the United States. With us having contributed to the brain drain of other countries by bringing people here to train them but they never go back, this is one thing that we can do to have the reverse brain drain, by bringing the knowledge to people in other countries by developing nursing schools; schools of public health that don't exist in these countries, and increasing – you know, updating their books and tools in their medical schools as well.

So if there's one thing that the World Health Organization can do to address chronic disease – if they can't supply the medicines, at least supply people with the knowledge to be able to do chronic disease training in those countries.

HENRY GREENBERG: Alex [Preker]?

ALEX PREKER: Well, thanks very much for letting me have the opportunity to share a couple of thoughts with you this morning.

First of all, I'm here on my own name, not as a representative of the World Bank. So I just wanted to make sure that everyone understood that.

One of the issues that came up this morning is, you know, what should the World Bank be doing in health? And I think that's a very important question: why should the World Bank be involved in health? Our main mandate is economic growth and poverty

alleviation; so what does that have to do with health? Well, I alluded to it in my intervention this morning. It's got to do with human capital, and to what extent do we contribute to human capital through the health sector? And I would argue that there is a very good reason for the Bank to be involved in health from four different perspectives.

First of all, health has a very big impact on health expenditure, and health expenditure spills over into public expenditure. So, like it or not, countries that are spending 10 to 15 percent of public money, of government money, on a particular sector, we have a business in looking at what that money is being spent on, how well it's spent, and what the outcomes are. So from an economic point of view, yes, we do have a good reason for being involved in health, and we should be involved in that. And we should be having a very careful look at what's being spent in the health sector.

Second of all, health has a very significant impact on labor productivity. Labor productivity translates into all sorts of other things. People with malaria are not productive, people with HIV/AIDS that get out of the labor force – [so] it has a very negative impact on labor. Children that don't learn when are growing up because they have worms or they don't – they have trouble concentrating, don't get good education and later on, [this causes] a very serious labor problem. So we have a reason to be involved from that side.

Third of all, health causes very serious problems with poverty. People in ill health end up with lower incomes and it contributes to poverty levels. And finally, there's a link between health and growth. It's a weak link, and currently there's a trend to compare health with infrastructure, your -- (unintelligible) -- regressions, your R-squared, is weaker in health than it is in infrastructure, and because of that some people would argue that we should be spending our money on infrastructure and not health, because of the R-squared. But I think, hopefully, we can think beyond R-squared and we can also think of some of the other reasons why we should be involved in health.

So I think there's very good reasons why we should be involved in health. The question is, what is it that we should be doing as we're involved in health? There, I think the critics have a good point, is should we have a unit in the Bank that deals with health financing? Probably, yes. Should we have a unit in the Bank that deals with good governance and public expenditure? Probably, yes. Should we have a unit in the Bank that deals with labor issues related to health? Probably, yes. Do we have any of those units? No. Do we have a unit in the Bank that deals with malaria? We have scores of people that are, right now, dealing with malaria, that are hired to do malaria. Do we have a unit in the Bank that deals with HIV/AIDS? We have a huge – we have a Director of HIV/AIDS that's at the same administrative level as the Director of Health. We have a huge unit in HIV/AIDS. So what it is that we are actually doing in health and how is it that we're maybe doing things that other organizations have a whole organization dedicated to?

Okay, so what does all of this have to do with chronic diseases? Well, when I first started in the Bank, I was hired actually not as a development expert, but as a

Western/European health systems expert, to work in Eastern Europe. And in Eastern Europe, one of the big problems they had in Eastern Europe was chronic diseases. They had Communist systems that had initially been set up to deal with infections diseases. I'd probably disagree a little bit with previous panelists who said, you know, the WHO should get out of chronic disease and just deal with infectious diseases. I think that's short-sided. And what we saw in Eastern Europe was whole health systems that were set up to deal with infectious diseases and had not adapted at all to the fact that people in Eastern Europe had grown older and were suffering from chronic diseases. She had very maladapted health systems in Eastern Europe. And that's how I sort of started my Bank career.

Now, what we are seeing – I'm now working in Africa, which is about as far as you can get from Eastern Europe as you can imagine — but what I see is, in Africa people are dying from cardiac disease. They're dying from chronic diseases. It affects labor productivity. It affects their ability to be involved, to fight off poverty. So there is a very strong connection between chronic diseases and what we do.

Finally, mission creep. It's interesting; I did, a couple of years ago, one of the executive government programs in Harvard. And, at that point, one of the lecturers was Michael Porter. Now, I think in private industry, organizations are told to adapt, to be flexible, [and] not to be rigid. But international organizations are told that whenever we adapt or we move, we have mission creep. So, let's think a little bit about mission creep. What does it mean? How do you adapt in a new world to new context, even as a public agency – and you can consider the Bank a public agency. So, two thoughts: yes, we should be involved in the Bank. I don't think changing orientation, or mission creep, is a bad thing. It depends on where you're heading with that mission. I think sometimes we may be heading in the wrong direction.

HENRY GREENBERG: Okay, I think we're going to get a lot of questions afterwards. (Laughter.) I like it.

KATE SCHECTER: Well, first of all I want to thank you for allowing me to step in for my colleague, who was supposed to be speaking today but unfortunately is very ill.

As a number of other people have said, they weren't really sure about what they were supposed to do and I am the least sure of what I was expected to do here today, since I found out about this last night.

I just want to ask you bear with me for a few minutes while I explain to you the model behind the American International Health Alliance, and hope you will be able to see that there is a very strong connection here with the topic of chronic disease and how to manage it.

The American International Health Alliance was formed in 1992 specifically as a response to the fall of the Soviet Union. There were a lot of American medical establishments that wanted to volunteer to help, and instead of having a kind of scatter

shot approach where people would just go and do whatever they wanted, the alliance was put together as an umbrella organization to manage this wellspring of desire to help.

There has been a lot of talk today about partnerships. And I think that term is used quite often without really necessarily defining it. AIHA has worked very hard to define what we mean by partnership, and we try hard to maintain certain tenets so that we are actually following a model.

A couple of key tenets are volunteerism, trying to get away from the consultancy model, and tapping into, as I said before, you know, this desire to help. We require that the partnerships are not short term; that they last at least three to four years, sometimes five years. But at the same time that there is a long-term – well long-term, by development standards, commitment, there has also got to be an exit strategy. So from the very, very beginning, there is discussion in the partnership about sustainability and how this thing is going – I mean, once the funding is over – how it is going to sustain itself.

I know this is a very, very, over-used term, but we really are looking at demand-driven programs so that instead of just going in because the disease of the moment is what the funding is for, we are really trying very hard to look at what the demands are on the ground. And we have been lucky in that we have not had contracts; we have had cooperative agreements with USAID. And that is a mechanism which has allowed for this demand-driven tenet to grow.

A couple of things that came up this morning about evidenced-based practice, getting people to be more sort of interactive, that is something – those are a couple of things that were part of the very initial, early-'90s ideas behind the program. Initially it was hospital-to-hospital partnerships, but then, as you mentioned, there was this focus on poly clinics and getting into primary care. And so a lot of our work in the last few years has been on developing primary care.

As a part of that initiative in primary care, we worked very hard on creating and understanding about eminent-space practice and also developing clinical practice guidelines. And what happened is that within the partnerships there was a demand and a need to deal with chronic disease. I have been studying the former Soviet Union my whole career, and we have known about adult male mortality crisis for 20 years. I mean, this is – I know it's new in some ways, but it's really old news for people who have been looking at the former Soviet Union.

And actually in the name of transparency I have to say that I did use to work at the World Bank, and one of my first assignments was to write about chronic disease in Russia. And this was a while ago. (Chuckles.) You know, and everybody got very excited about it briefly and then of course it went, as many papers do, onto a shelf some place.

So I am presenting this model as a peer-to-peer, demand-driven model that has worked very well in terms of dealing with chronic disease at the local level. I have many, many examples. We have 116 partnerships that we have developed throughout the former Soviet Union and Central and Eastern Europe, and many successful hypertension control models, diabetes programs, asthma programs, cancer screening and some actual treatment programs.

So, I mean, if anybody wants specifics I am happy to give them but the idea here was to convey to you that there is a model that has been working for a while that has addressed the local needs, that has kind of tapped into a number of things that have been said today about countries need to respond equally; it can't just be the WHO coming in and helping; there has got to be a kind of investment on the part of the country, and this has worked very well.

The only thing I wanted to say is that in this whole argument that Alex [Preker] was talking about was the development of human capacity and what they call the social sectors in the bank. Now that I am outside of the bank, I am seeing that it really is very, very important that the bank not only do infrastructure. I have an example in Georgia where the World Bank came in without really having a demand, a very clear demand, and built a huge hospital with the most advanced technology that is totally unsustainable. There was very little work done on thinking about who was going to manage that hospital, how it was going to be – okay, finance that – just didn't happen to be part of their agenda or who was going to train the people who would work in it.

So, you know, if you just sort of say, well, they can only do infrastructure, you're going to get into that kind of problem, and there needs to be, as somebody said this morning, a partnership with other organizations as well.

DR. GREENBERG: Kate [Schecter], thank you, but could you write up what you have done so that when those of us look for references on who has done what, there is an extent literature?

MS. SCHECTER: We are working on it. We are working on our website.

DR. GREENBERG: No, no, no. It's not the website. If you are going to participate in the public health world, you have got to publish it in the public health literature, I mean, otherwise it's another flower in another desert unseen again. And then another academic at the end of the end of the table, Dr. Anderson.

DR. ANDERSON: Yeah, my wife tells me that the only thing I could ever be was an academic. And you will hear that I'm basically a dabbler as I start talking over here. I have been basically a domestic person who has sort of now gotten me into the whole issue of international work and specifically on chronic disease, and I got in there because I essentially saw first in the United States – and then I will talk about the rest of the world – that basically all of the expenditures, all of the utilization is about chronic disease in the United States and Western Europe and increasingly around the world.

And basically what I see is a healthcare system in 1900 to 1950 in the United States and most of Western Europe that was really focused around infectious diseases and we designed our healthcare system to take care of tuberculosis and those kinds of things, and I think we did a reasonably good job in the United States and in other places. Then around 1945, 1950 we said, whoops, we have done a pretty good job on that; what we have [now] is heart attacks and acute illnesses. And so we redesigned in the United States and in Western Europe and in lots of other places a healthcare system to take care of heart attacks.

And somewhere around 1990, maybe it was your World Bank report or something like that, but essentially what we discovered was chronic disease, and I have been sort of discovering the impact of chronic disease for my entire career at Johns Hopkins and before because it is the major reason – it is 80 percent of the hospitalizations in the United States. It is 80 percent of the doctor visits are related to chronic diseases. And increasingly that is true in Western Europe.

And if you look at the World Health Organization report, Mary [Pendergast], what you will see is that the economic burden of disease, the economic impact of disease outside of sub-Saharan Africa is greater for chronic diseases than other things. And so that is essentially where the dollars are. And if you are going to try to improve productivity, if you are going to try to improve health status, you have got to go where the dollars are. It's not as much as in AIDS; it's not that we have got to stop doing AIDS work, stop doing maternal and child health work, but we have got to do this creep that Alex [Preker] talks about as well to do it.

The problem I see is, that it's not the economic burden; the problem why donors aren't excited about [chronic disease] is that it's not likely – chronic disease isn't likely to endanger people in the United States or Western Europe. We are not going to catch hypertension; we are not going to catch – but we will catch AIDS; we will catch a whole variety of things. So I think it's more that then it is the economic burden because I think the numbers are pretty clear on that. It's just that we are not – most of us aren't up to speed in terms of the numbers.

Let me defend public health for a minute and then attack medicine. So let me – no, we at Johns Hopkins have only a few courses in the whole issue of chronic disease if you look at our catalogue, or whatever. However, if you also look at our courses, we actually recognize that chronic disease is the major reason why people are sick, get hospitalizations, do all sorts of things. So chronic disease is in all of our courses. It is not a special area. It is the critical area that we have in most of our courses. So if you are going to take a course on the U.S. healthcare system, if you are going to take a course on the U.S. healthcare system, if you are going to take a course on the international system, you are going to hear a lot about chronic disease, because you can't [not] – you have to.

Now, let me go in and attack medicine. Since you attacked public health, I'll attack medicine. Essentially I look at five things that – do we do a very good job in

taking care of chronic disease in the United States or any other country. And the first one is research. Do we know very much about research on chronic disease? Well, yes we know a lot about hypertension; yes, we know a lot about any specific disease, but what do we know about people with multiple chronic conditions? And the answer is not very much because if you pick up The New England Journal of Medicine, what you are going to see is a study that excluded most of the people that had the co-morbidities.

So now if you are a practicing physician taking care of somebody who has hypertension, diabetes, congestive heart failure and Alzheimer's and four other things and you read that clinical study, all of those people are excluded from your clinical study, and so you are making it up as you go. And we wonder why we have such practiced variations in the United States and other industrialized countries is because the research infrastructure that we have in the United States has basically not recognized the multiple chronic conditions and that is true in most of the countries around the world.

We have [a] payment system based upon an acute-care model and it takes care of an episode very well, pays for an episode very well, pays for an episode very well, but if you're dealing with chronic conditions, it's continuity of care that matters, it's care coordination that matters, it's electronic medical records that matter, all of those kinds of things that matter. We don't have a system oriented around those things in the United States. The Britons are starting to worry about this. So if we are going to train the rest of the world how to do this, we better have a payment system and a financing system that works as well.

The same thing with coverage – most of the stuff on coverage if you look at Medicare rules, if you look at U.K. rules, if you look at Australia[n] rules in terms of what do we cover, what we do cover is the particular cure. And the rules about medical necessity are all the person is going to improve. That is not chronic conditions. Nobody improves with Alzheimer's. You have got to essentially have a different mindset with chronic conditions and we have got to have a different mindset.

And finally the delivery system that we talk about, we talk about it in terms of silos most of the time. Ed Wagner – working with the World Health Organization has come up with a chronic disease model which has seven components: an informed, activated patient, support for self management, delivery system support, clinical decision support, clinical information and resources and policies to support that. We don't have it in the United States; we don't have it in the U.K; we don't have it anywhere a system that does those kinds of things.

So we have got to certainly get the prevention going, but we also have to have a medical system in the United States, in other places that really is oriented around chronic conditions before we start trying to export it.

DR. GREENBERG: Thank you. Before we take questions, just one quick – I agree with all of your comments, except if we have to wait until we get our system right

before we do anything else anywhere, we will never get there because we [haven't been] getting it right here for a long time.

Okay, it's now open. Identify yourselves very quickly and if you have a specific panelist you would like to aim [a question towards], please go ahead. Yes, sir.

Q: AMIR ATTARAN: Hank, may I please make a quick comment about non-communicable diseases but then have an unrelated question for Kate [Schecter]?

A quick comment about non-communicable diseases is I think it is an absolutely misleading thought that they are totally avoidable and that they are conditions of [the] guilt[y], that if one has led life in the wrong way then one will suffer from a non-communicable disease.

The clearest example to me of this is the case of whether one supplements food with things like foliate or iodine. Now, for 400 milligrams of foliate per day, you can prevent a baby being born and encephalic, that is to say, without a brain, or with spinal bifida, an exposed spinal cord. To live through spinal bifida, it's incredibly painful and handicapping. Neural tube defects like spinal bifida and anencephaly are not communicable diseases; they are non-communicable. Are we seriously proposing that the WHO should not have a role in safe pregnancy and the safe delivery of a child? That is preposterous. Are we seriously supposing that the child has committed some original sin to be born without a brain? Come on. And so I –

DR. GREENBERG: Only in Washington.

Q: AMIR ATTARAN: I can't accede to that reasoning at all.

The thing that brings an issue within the WHO's mandate are not – is if it is health, first; and second, not an issue that is dealt with in a more specialized and capable way by another agency. The point is not to be dogmatic about what is health and what isn't; the point is to simply to assign each task to the agency best suited to deal with it. And sometimes there are issues that the WTO is better to do. Other times there are issues that UNICEF perhaps is better to do, and we should respect those divisions of labor and not have mission creep that go beyond them, but we shouldn't draw hard and fast rules if it is an infectious thingy it is the WHO and if it's not then it's somebody else's – no way.

Now, Kate [Schecter], I wanted to ask you a comment about your comment on infrastructure saying you weren't so certain that the World Bank ought to get out of the infrastructure – pardon me, ought to be in the infrastructure business – you weren't so certain they ought to be in the infrastructure business because you cited an example of a hospital, I believe it was in Georgia, that was pitched in advanced level of care, had all of the bells and whistles, and was not really what the country needed. Is that – let me query that: is that a question of whether – is that probative of whether the bank should be in infrastructure or not, or is it simply to say that that was the wrong kind of infrastructure to build? I think it's probably the second point, but I want to ask you.

A: MS. SCHECTER: I think it gets back to what Alex [Preker] was saying before. I mean, if you start to divide the sectors that the bank can be involved in and ones that it can't, you run the risk of what they did in Georgia. Now, if the bank had been more cognizant of the other aspects of this hospital, I think we wouldn't have got into the situation we got into where they were then going out and looking for others to fill those gaps, training, finance management, things like that.

Now, that was one example. I have seen plenty of examples where the bank has been more cognizant of all of the pieces and things have worked better or from the very beginning there has been a partnership with other organizations that have strength in a particular area like capacity building or something like that. No, what I worry about is if we get into this argument that the bank can only do X, then you do run the risk of them doing the infrastructure part of it without really thinking about the other pieces. I will give you an example – I was going to try to avoid this –

DR. GREENBERG: I would say to that same question – I mean, I would worry about an organization that did that, being incompetent and dumb doing anything, including finance. I don't think that is an area of mission creep; I mean, that is just dumb; I mean, there is a difference.

The question is, is the organization suited for building structures. That is question one. Question two is have they built the right kind of infrastructure?

A: MS. SCHECTER: Well, I mean, you know, every example has a long history and so I am not sure that I am. I think there were reasons why that hospital was built originally, which command changed over time so that by the time that I got to that project, it looked like – we call it the big pink elephant. I mean, it's just sitting out there, and by that time it looked like the bank shouldn't have been involved in infrastructure at all.

So I mean, I don't know that I am complaining to – I think what Alex [Preker] was saying before is a good approach, which is to think about the other areas that you were describing as opposed to dividing it by disease, by having a bank department that deals with HIV/AIDS or a bank department that deals with malaria to be dealing with health financing perhaps for – whatever the other areas that were that he –

MR. ANDERSON: Let me just try to answer that because you were saying – I was just in Georgia looking for USAID – as to what they should invest in, [what] kinds of things. And I think the answer for me on this one is that elephant probably was a bad investment. It wasn't appropriate for Georgia. That doesn't mean that it wasn't appropriate for – an investment in infrastructure in another setting wouldn't have been absolutely appropriate. I just think given the needs of Georgia, given the history of Georgia, it was probably just not a wise investment there.

Q: UNIDENTIFIED: Alex [Preker], you're an economist, and as all good economists you want to be flexible, adapt to understand systems. One of the problems, and the reason that as a critic of the bank of a mission creep as I am, is that unlike a market system where you have feedback loops so you try a new product or try a new area and it fails and you go out of business – the bank doesn't go out of business when it goes into the wrong areas, in fact, if we – the point I was raising earlier about targets and timetables being set, if you go through the list, it is like, failure, failure, failure, success, failure, failure, failure, failure, failure, probably failure. I mean, that is what we are dealing with and this repetition of the same kind of areas, even where they go into new topics.

So I think that dealing with mission creep is not so much about being flexible and not adapting, it's making sure that the agencies are complementary because they are not going away. I'm economist too and I believe in competition but should you really have the WHO and the World Bank competing over diseases or should they be complementary given that they are agencies which are not disappearing?

DR. GREENBERG: How about this, Alex [Preker]? Make it short?

MR. PREKER: Well, I mean, I agree and I think in some ways the WHO and the [World] Bank are complementary and we shouldn't rule that out. But I would say there is a very big difference because if you are looking at a private enterprise, this bottom line – and that is how you are measured in terms of your success. So you either make profit or you don't make profit. If you don't make profit, you go broke; it's very simple. Public agencies don't have that clarity.

Public agencies, you have a mission that you're supposed to achieve and achieving that mission is not always black and white. So the bank's mission is poverty alleviation and economic growth, and different people may have different opinions about what contributes to that online mission.

And that is a thing where we run into some problems because in many ways it has to do with social policy and people's choices and social policy, and that has a lot to do with politics and it has a lot to do with – we are not in fact – and the bank is supposed to get involved in it because we are not supposed to get involved in the politics side of things. And yet part of our success is going to depend on whether or not pool games are politically successful.

So what we are seeing – and I think this is – I won't give a long answer, but what we are seeing is our management gets very sensitive to the political noise that is out there, okay. And they want to respond to that political noise in an appropriate way that makes it seem like we are doing the right thing. And the unfortunate thing is that sometimes drags us into a way of operating that isn't what we should be doing because what we should be doing in malaria is not necessarily taking a bunch of malaria projects to the board. What we should be doing about malaria is making sure that malaria in our client countries goes down. We should be making sure that HIV/AIDS, that people have

access to effective services; it doesn't mean that we should be measuring whether we are taking 10 projects to the board on malaria or HIV/AIDS. And that is where we get confused between the outcomes and the inputs and the outputs.

DR. GREENBERG: Over here.

Q: AARON [last name not given], IMPERIAL METRONIC: I just have a question regarding if there had been studies done, say, at the World Bank or the WHO linking sustainable development to chronic diseases. My intuition is that there have not. I would like to ask the panel if there should be because to my mind as a non-economist, it seems that if you can turn the brain drain into a brain gain by keeping, say, the best and most competent doctors from those countries who go abroad to study and then make their lives, you are talking about economic development or loss of economic development. I was wondering if this would be a topic worth a study. Thank you.

A: MR. ANDERSON: What I think the challenge is – I think we have got information showing that there is a problem that there is a lot of potential for taking care of chronic disease and improving economic productivity. The challenge is showing this program or this type of program will in fact have a great economic impact. That is one of the things that I am looking for right now, something that WHO could do, World Bank could do, USAID, European Union could do, [the] research community can do. There are not a lot of good success stories out there that have been sustained for any seriously long period of time. We have a number of problems that for five years ran, that saved some money, that seemed to have had an improvement in outcomes, and then the program ended, funding ended, and the country didn't pick it up. And so what I am looking for is sustainability.

DR. GREENBERG: Well, I think that is right – I mean, my argument is that the first nickel down has to be from the country itself and it has promptly got to be put into its own ongoing budget – it can't be sustained by external money.

Over here. Tina [Cleland]?

Q: TINA CLELAND, HUDSON INSTITUTE: And my question is [if] the WHO were to embrace chronic disease in a serious way, what would be – if they were to embrace chronic diseases in a more serious way – what would you see as the top-four action steps they would take as evidence that they are embracing this issue seriously?

DR. GREENBERG: That is –

A: MR. ANDERSON: I don't know if I'm going to have four; I'll start out with one or two. Essentially I think they are already doing a fair amount in prevention, but I think there is clearly a great deal more, and that is clearly their historical strength so I think they should play on that. The second one, I just sort of mentioned it in passing, but just to reiterate it, is I think that they should have a set of success stories that, you know,

this program in Georgia was eminently successful and is potentially exportable outside of Georgia and here is why.

DR. GREENBERG: I think part of what they need to do – or needs to be done and could be done by an agency like that is to create a very good database. When you look at the WHO data, it's the best out there, but it's not good. And what is the impact of these diseases on a given country? And I think what HI [Hudson Institute] – what the [World] Bank or the WHO could do is support the kind of training of professionals who can do the kind of in-depth, public health assessment of what the impact of the disease is; i.e., state the problem so it's very clear what the specific impact is, where you are, and that data should be compelling enough to get the country to say we would like to do/deal with that because that is a big problem.

Yes.

MS. SCHECTER: One thing that I didn't mention that we have been doing with the WHO is we have developed what they are calling a knowledge hub in Ukraine. There are three knowledge hubs in Central and Eastern Europe and the former Soviet Union that are focused on dealing with HIV/AIDS. One in Croatia is dealing with secondary surveillance and teaching epidemiology and surveillance to all of the countries of the region. Another one in Lithuania, I think it is, is focused on harm reduction and programs that work in harm reduction. And the one in Ukraine is focused on care and treatment.

The main idea behind it is to develop standardized curricula that will be used by everyone throughout the region so that when people are being trained in treating with ARVs, that they are all doing it by the WHO standards. Now, we won't discuss – we won't get into an argument about whether those standards are, you know, the best or whatever, but I think that the model is a very strong one. It is working very well in the former Soviet Union and there has been a real ratcheting up of numbers of teams trained – the whole concept of team approach has just leapt forward without any real argument. And all of the different countries of the region are adapting these curricula and using these trainings through the knowledge gaps.

DR. GREENBERG: I can't wait to read the paper. (Laughter.)

MS. SCHECTER: I'm not – you know, I am just saying that this an approach which could easily be used to deal with chronic diseases.

DR. GREENBERG: The last question right here – I have been ignoring this poor gentleman all morning and then I think we are going to break for lunch. Right, Carol [Adelman]. Yes.

Q: MICHAEL ROSENTHAL, DEPT. OF STATE: Thank you. I will try to put this in the form of a question. I am also, like Dr. Preker, on my own nickel.

I have just returned from a tour of duty at the International Atomic Energy Agency. I am little hesitant to mirror image into what the WHO does because it may not be the same. But I did have a reaction to – I thought many of the comments during the morning – that was, hmm, everyone thinks the WHO should go out and do this, but the WHO is not an autonomous actor; it's an intergovernmental organization with a executive board and a world health assembly, and a budget that is provided to them by those member states to do certain things.

And it's probably a no-growth budget for many years now. If they get extra budgetary contributions, they are undoubtedly earmarked with particular projects of interest to particular donors, and they operate under very ridged financial rules, at least the IAEA does. And sometimes mission creep is just innovative people within an organization trying to get around the fact that the budget for 2006 was planned beginning in 2001 and it didn't accommodate something that needed to be done at the time.

So all of these constraints – and I think folks should think about how to organize the governance, if you like, of international organizations if you wish them to do the kinds of things or some of the things that you want them to do in a responsive and evidence-based and flexible way.

And I can't resist one advertisement though, which is, in response to Dr. Greenberg's remarks about – but I want – not a response or anything. The International Atomic Energy Agency is itself a health organization to a very limited degree. It spends about $25 million a year through its technical cooperation program at the response of its member states and in response only to a first dollar down by the member state in the health area.

Most of that has to – the majority of that is in the area of cancer therapy and IAEA working together with the World Health Organization, the American Cancer Society, the National Cancer Institute and others has just launched a program called Program Evac for Cancer Therapy, which is intended to promote international global cancer control – (inaudible) – not just therapy around the world. Sorry for advertising but folks have some response to how to deal with the lack of autonomy of the organizations and the staffs, I would be interested in that. Thank you.

DR. GREENBERG: Okay, thank you very much. We have probably run just a little over. We have solved the problem, though, right, Carol [Adelman]. It is all done? Just write it up, send it off, we are done. Okay.

(END)

HUDSON INSTITUTE

THE WORLD HEALTH ORGANIZATION: HOW CAN THE UNITED NATIONS AGENCY FIGHT DISEASE IN THE 21ST CENTURY?

THURSDAY, MAY 11, 2006
12:30 P.M.

LUNCHEON KEYNOTE ADDRESS:

DR. GAIL WILENSKY,
SENIOR FELLOW, PROJECT HOPE

Transcript by:
Federal News Service
Washington, D.C.

MS. ADELMAN: (In progress.) She has her Ph.D. in economics from the University of Michigan and is very active with – a real opinion-maker, policy-maker, and change agent in this town because she takes what she knows and does what Hank Greenberg was admonishing people to do: publish, get out there, and get your views out there. And that is that is Gail Wilensky. So, Gail, we apologize for still having people get their plates, but we know you have to catch a train. The first thing is, I only have – I've been asking questions of panelists, Gail, and I have one question to ask you before you talk, and that – as the result of your crutches and your knee – she got this little injury playing tennis and my only question to Gail is, did you win the point?

DR. GAIL WILENSKY: I did not. (Chuckles.)

MS. ADELMAN: She did not.

DR. WILENSKY: But my partner, who I've been playing with since graduate school, has been so chagrined by my injury that he has been calling or emailing about once a week to see how I am doing. I told him I expect to win in our next game. It has been an ongoing rivalry since 1964 and I can't say I've had the best of it during any of those years.

Jerry Anderson and I have known each other for many, many years and have had mostly discussions about views of the health care sector in the U.S., but as he mentioned, he has become increasingly active in the international area. I actually had started very early when I was still in graduate school – did a two-year project on Nigeria and its use of quasi-governmental entities as a mechanism for economic development. So I've had this latent interest in international issues basically my whole professional career, although most of it is been focusing on domestic health care problems with financing and the delivery system, et cetera.

This is a very interesting general area of attempting to transform the WHO for the 21st Century, a general theme of this meeting, and I have been thinking about what I might say to add to this morning's discussions for the last week. I've been less physically active than normal, since my ACL repair a week ago. And so I have had more time to think and read and I have been doing a fair amount of thinking about this. And there are some interesting similarities in terms of focus between what is going on in the U.S. and some of the developed world, and then some areas that are quite different for the WHO.

We use terms like "the need to transform health care for the 21st century" in the U.S. all the time. There is a lot of interest in trying to harness information systems to transform health care. We regard information systems as a transformative mechanism, use of electronic health records as a way to bring both greater efficiency and more

portability to how and where health care is delivered, and as a mechanism, for example, that might be very important in building virtual networks in a health care system that remains very un-integrated such as ours.

So the concept of this transforming health care for the 21st century really plays quite well. Most of the Western European countries have been thinking about also using electronic health records and information systems, and the realization that while we have many areas where we differ in terms of institutional features, there are some areas where we have surprising similarity. One of them, which people tend not to focus on much in the U.S., is growth rates in health care spending in the Western world is hauntingly, frighteningly similar across the spectrum – across the G-8 countries for sure.

We always think of ourselves as being an outlier, and when it comes to spending per capita – [in] absolute terms – the U.S. indeed spends quite a bit more than its next closest neighbor, Switzerland. Those are Jerry Anderson reported data. But the problem that we need to focus much more on, the area that will really get us in the future, is the growth rate in spending, which for the U.S., as you probably have heard and otherwise will hear ad nausum over the next 10 or 20 years, has been 2 percent higher than the rest of the economy since the 1960s, and that is a very scary concept.

So we are worrying about transforming health care for the 21st century. Europe, even though it's starting from a different level of spending, is facing some of the same kinds of concerns, is worried about how to try to get more efficiency, more consumer-oriented, consumer-centric health care delivery, to use the Institute of Medicine['s] term. But it is also clearly an area for the WHO as well. And one of the ties – and it was an issue I understood for the middle-income countries, it was only in the last week I understood this was really true for the developing world as well – is the one that you have been spending so much time talking about this morning, which is the rising dominance of chronic care.

We know in the U.S. that that's basically where our health care money is going [to]: diabetes, congestive heart failure, COPD, et cetera. HIV has now actually moved more into the chronic disease, for us at least, rather than the acute disease that it had started out. But there is no question for the U.S., and I think most of the Western world understands, that chronic care is the dominant area of health care concerns and we need, as Jerry [Anderson] and others have said, to recognize that we will need a delivery system that is reflective of care that doesn't go away. The clearest example of how much we haven't gotten this isn't even the examples he had used in the payment silos. Just think about hospice care. Hospice care, which is one of our real successful additions to Medicare, was based on people dying from cancer. That is, this was something you might choose to do in the last six months, move to palliative care, not [to] have to be in an institution. It has a lot of obvious appeal. It doesn't appear to save money, but it has a lot of other obvious appeal. Its real problem is that it isn't at all designed to deal with the way many people are now dying, which is a combination of chronic care, and you don't know when the last six months is likely to be. It's likely to be just at the end of a

downward sloping curve, and trying to figure out exactly what that curve looks like and how fast it is going to slope at the end has been very difficult.

No question about this being a major issue in the middle-income countries. I was interested in Alex Preker's comments about how these issues of health care begin to impact on areas [in] economic development. In an area that I have been trying to develop at Project Hope, we are going to be looking at how chronic disease like diabetes or congestive heart failure is impacting in an increasing way the middle-income countries of Central Europe, which have low fertility rates, some migration, the blessing of having people living longer, and the need to recognize that they need, not only to train their health professionals to worry about treating chronic care disease [but] to make the communities and the individuals more aware. That is kind of traditional Project Hope activity. My push in this is to say – and we need to make sure that the ministers of health and the ministers of labor or social welfare are also brought in because if they don't allocate resources in the ways that are consistent with treating chronic care, which is frequently out of the hospital, it is not going work. And, oh, by the way, you better to check your pension and labor laws and make sure that as you have aging populations and low fertility rates, that you're doing things to keep people into the labor force longer or you are going to be able to have the kinds of problems that France and other – Germany, are going to be facing and are facing in a very strong way.

So the impact I think on chronic disease, this has been a medium-hard message to sell, I would say, in my experience. Explaining – although the numbers do a pretty good job. When you look at the projections for diabetes in 2010 for Poland, for the Czech Republic, for Hungary, for the Ukraine, for some of the former republics of the Soviet Unions, the not really poor ones, the numbers kind of jump out at you that it is likely to be a pretty significant problem.

What I am surprised to hear more is that in sub-Saharan Africa and other parts of the "real" developing world – that is what we traditionally think of as the emerging country world – that chronic disease is having the increasing dominance it is having there as well, that if you make it through the child survival/infant mortality and you are not hit with the immediacy of HIV/AIDS, that these chronic diseases are a major health threat even for sub-Saharan Africa. And that really, when you bring them together, is what ties the need to focus on chronic disease in a much more serious way for any international organization, particularly for those who have any interest in the middle-income countries, but even for the emerging countries. And that, to me, was really an eye-awakening moment, to realize how common this increasing dominance of chronic disease really is. In part, it's speaking to the successes of our other activities, so while you have this, congratulations, now you have to face the problem that we have in the U.S. – you know, we didn't use to worry about Alzheimer's the way we did now when people were conveniently dying of stroke or cancer – it is the consequence of some of the success of early childhood disease eradication or at least reduction and some of the infant mortality that even these emerging countries are focusing now on chronic care.

In trying to think about what and how could the WHO respond to this, I was trying to think back about what has defined the major success of the WHO? And I think when you look at the history of the WHO in terms of smallpox eradication, in terms of their efforts with regard to river blindness, other major public health activities, it is very hard not to say that there have been areas in which the WHO has been extremely effective and impactful to the rest of the world. But the fact is the world has changed, and if the WHO wants to continue to have the kind of impact that it has had and the kind of success that it has had, it really does need to recognize that the world had changed and so it will have to change. Now, that is not in completely and in every way, but is to some extent.

So how has it changed? Well, we are becoming much more of a unified world, like it or not. That was very true and became very clear with the SARS flare-up. We might think that we can have, even in the infectious disease world, a disease that is over there somehow, but people who are over there and got contaminated by that infectious disease could well be almost literally in your backyard within a 24-hour period. So with the rapid people migration and movement that occurs, with communication that occurs, with those pesky birds with avian flu who just won't stay out in the Far East and keep migrating toward the West, clearly are going to show up in our area at some point.

The notion of thinking about very compartmentalized problems just doesn't work very well, and it is the communicable disease that doesn't work very well. In terms of the broader issues that we have been talking about today, it also doesn't work very well because of the issues that Alex Preker was raising, which is that health is a vital part of human capital and human capital development. Therefore, it is going to be a vital part of economic growth, and economic growth becomes all of our concerns because of the rising importance of international trade.

Now, there are some people who take a more kindly view of that aspect of globalization than others. My view is that while there are some negatives that you need to make sure that you can accommodate, basically we are all much better off in the movement toward globalization. In any case, that is where we are moving and not likely to be moving back. And that really does bring these issues that we have been talking about in terms of chronic disease, role of individuals continuing in terms of their labor force and the productivity that they will have, and how that will impact on the economic growth of the country, is more than just their concern, their country's concern. It's their country's concern first, but it does have a broader issue in terms of what happens.

There was this concept which I found very interesting of should the WHO be accused of engaging in mission creep if it were to more explicitly and more formally include something like a focus on chronic disease as part of its portfolio? I did like the analogy that in the private sector we would regard it as adaptability and flexibility, but in the public sector as mission creep. I think that the answer is [that] to not do that ignores the reality of where health care is today, but it will require a clear focus, and that focus will be important or its likely to mean people don't know what the WHO is really doing

anymore, and they may not be doing some of the things that only they were doing as well, and that would be a problem.

There has been large changes both already occurring with regard the WHO's view. That's probably most obviously seen in the commission that Carol [Adelman] mentioned that I've been on for the last year, and that's the Commission on Social Determinants of Health. Basically, for non-clinical people, I usually explain that as focusing on all the non-medical stuff that impacts health. That's what we are looking at. So, how poverty, the treatment of women, environmental conditions, access to health care also – but how all of these together impact on health. Michael Marmot is our chair, so we of course spend a very large amount of time talking about the impact of social gradients on health care and health, but it is to my mind, which I am usually pushing back some – but to my mind the really important addition has been to recognize that health and well being depend on much more than medical care, obvious, but this was really a very explicit recognition that you are not likely to favorably impact health if you ignore this.

Carol [Adelman] also mentioned I am a trustee for the United Mine Workers Health and Retirement Fund. These are mostly widows since the miners tend to die relatively early – mine workers who tend frequently to live in West Virginia or Pennsylvania, in not easily accessible places. And since the fund is responsible for all of their care, very broadly defined, it has a great incentive to go look sometimes, when it looks like there may be preventable accidents happening. So it will go into the homes and build some ramps and supports, for example, for somebody who is having repeated hip or other bone fractures, both to help the individual and to help the fund. One of its more recent activities has been to arrange for some transportation because there was an astronomical amount of ambulance use for people who had no way other than an ambulance to get from their home to their physician's office. In no way was this regarded by anyone as an emergency other than the fact that they weren't going to get there, so to arrange transportation. Although we did discover that one person's nephew owned an ambulance company and she had literally 365 ambulance rides a year, but that was a different problem.

What we are doing now in terms of the Social Determinants of Health is going out to different parts of the world to see how governments are looking both at what is generally called the gradient – social gradient issues. I keep saying that in the U.S. we understand it as disparities more. There has been a lot of emphasis on health disparities in the U.S. In seeing how that relates to social determinan[t]s – poverty and living conditions and other social areas – and what the government is willing to, considering, doing about it, and so there [has] been an attempt to try to get country partnerships involved. The commission has been to Chile; that is where it started. The president has been very active – the president who just stepped down has been very active in this area. His minister to France, who was the previous minister of health, is on the commission, at least temporarily in his place. Egypt, India, Iran, in January; we will be in Kenya next month.

And they have been, for somebody like myself, very interesting visits to try to have a better sense about how serious some of these governments are, what they are doing. There is nothing like going to either a place like India or China to recognize the enormity of the problem of thinking about reaching out to these huge populations to put in place better access to almost any kind of health care: public health, acute health, chronic health. Anything is just so difficult because of the sheer numbers.

The India [trip] was particularly interesting for me because we met, as we frequently do, with all the top governmental leadership. The prime minister is a Ph.D. economist from Cambridge. He was elected, as I understand, in large part in response to what had been some questionable dealings in the previous government – [he—the prime minister] is regarded as a very honest individual and not much of a politician, clearly would like to do the right thing for the health care sector. But India spends a paltry amount – 1 or 2 percent – in terms of its GDP on health care through the public sector.

So the concept of trying to make major inroads and differences in countries that have such vast unmet needs is really daunting. And this to me was one of the areas that seemed to me appropriate to a group of individuals who have talked so much, as you have today, about partnership possibilities and what that might mean in the future. It is just very clear when you go to a place like India that their health care is not going to occur only through their public sector. I mean, it is so small relative to the needs of the individual. And it is in an area, as is frequently the case, where there is a nontrivial private sector of health care that is growing and there is a nontrivial entrepreneurial part of their health care sector reaching out to their privileged populations or those of nearby countries.

One of the things that I think organizations like the WHO is going to have to consider – which will be very difficult for them – is how to think about rationalizing arrangements that are ongoing anyway between the public and the private sectors as they exist or as they potentially could exist, how to rationalize the work of NGOs or other groups that might want to partner with a country, corporations, in a way that meets their needs and meets the needs of the country that obviously understand how to try to partner – that is, take money from the World Bank or from [US]AID or any of the other multinational donors that may come their way. But it's clear, relying strictly on the governmental structures that are in place is just to miss where much of the action is and where much of the action appears likely to be in the near term.

When I think about this, I have sort of good-news and bad-news views about the WHO. The good news is that this Commission on the Social Determinants of Health occurred because the current general director agreed that this was a key area that the WHO needed to move in. So this would not have – this did not happen because it was imposed by somebody on the outside. This was really embraced by the current general director, Dr. Lee, at the WHO, and I think that says a lot, that it is a very different activity having a commission talk about the social determinants of health. I was very surprised when I got an invitation to join this commission – was very blunt about saying why in the world do you think you would want to have a market-oriented economist from the U.S.

on this commission? But after some extended conversation said, okay, you know what you're getting into. I'll be glad to see whether I can make some contributions to it.

So the fact that the WHO was willing to undertake this – I mean, more than willing. That this was really a major initiative, driven by the general director, I think says that they recognize that the very narrow traditional focus isn't going to work, and that is promising. It will take some real sustained pressure to help the WHO put itself in a position where it might consider how to really partner with other areas. It does not do that easily and naturally is, I guess, the most diplomatic way that I can think of to say it.

There is the recognition, internally and externally, that health is more complicated that infection and/or communicable disease, and that you can't ignore these other areas. I think the challenges will be how to try to rationalize what is going on anyway, to make it integrate more effectively with the movements of the WHO or the national governments would like to see happen. I think it will be very important if they have any thoughts about why partnering, to remember to keep advocacy out of their activities.

A second reason that the WHO has been so effective in its early activities in public health is they were clear of any such involvement, at least in my view very heavily focused on direct public health. It is easy, in my role as a commissioner, to see how they get pulled by some of the civil societies who deal with them, who want less than nothing to do with the private sector or any of the corporations that might want to try to partner or help, but I think it is just foolishness to think that this is the most effective way to resolve the problems of these poor and middle-income countries, and I'm hopeful that the good will of the people involved – and they do – and the leadership people that I've met are all people of good will – will allow themselves to ignore or deal with in other ways, some of the individuals who are so against any kind of such concepts of partnering.

So I think it can happen. I think the WHO really can begin to modify its focus. It won't be easy. It's showing some encouraging steps in that direction by broadening its traditional area of activity, but it is clear we don't know yet either what will be produced, or, more importantly, what if any effect it will have. So a very interesting time for the WHO, and of course the rest of us interested in health care for the 21st century. Thank you.

(Applause.)

MS. ADELMAN: Gail (Wilensky), thank you for leaving some time for questions, so I'll let you all pass this around, but what question would any of you like to raise?

Q: (Unidentified) Basically what you talked about, we have infectious disease, and that spreads across boundaries very easily –

DR. WILENSKY: Right.

Q: – whereas social determinants of health doesn't really spread across boundaries. Chronic diseases don't spread across international boundaries. Are you seeing a harder sell for social determinants for health or chronic diseases because it doesn't cross borders?

A: DR. WILENSKY: No, I think the harder [part] is getting the metrics that you can make an impact. My sense is that's really the area that if and when we can show that we can intervene in chronic disease through disease management or whatever strategy we want to use, and actually lower the use of health care, make people more productive, change – that's why I've been pushing and saying that's not going to do any good if you don't look at the labor laws and the pension laws as to whether or not they're going to come in.

I think people – when I've been having – I'm still relatively early at trying to get this project off the ground – people seem to get it, but the question is, will you be able to impact it? I mean, the nice thing about infectious and acute-care disease is that because it has a clear start and stop, it's easier to do that set of metrics. So I think that's going to be the challenge, but I may tell you I was wrong if I get to the point of saying, no, we've got some good metrics. It's harder than that.

I don't think it was by and large that people were so afraid they would be personally impacted. I mean, it's not that it's not there at all. I think it's actually more than that.

Q: RICHARD HANNEMAN, SALT INSTITUTE: Thank you very much. It was a very enlightening statement, especially about partnerships, and I just wanted to share [something] quickly. Two weeks ago I was in Delhi. We launched a nationwide UNICEF-led – not WHO, which wasn't even present that I know, but the minister of health of course was there – partnership to promote salt iodination because India is now the worst problem area in the world. And then two days later I met with all the salt producers in India to do it.

So there is a real willingness when – and I would make one other point – when there is a proven outcome that's going to be beneficial. I've been part of the WHO consultations where there hasn't really been respect, but there hasn't been respect both ways because I don't think there was respect for the interests and sincerity of the food industry on one side, and I don't think there was respect on the part of the food industry for the science since there was no health intervention that had a proven and demonstrable health benefit at the other end.

So if you aren't credible when you make the recommendation – and it's just not enough to be for prevention; you have to be for some specific intervention, and if it's not evidence-based, then you kind of lose us in the private sector.

DR. WILENSKY: Yes, and that's as well it should be. The needs are so great, the available assets so small, that's not an unreasonable requirement. But it is – again,

it's different – I've spent a great part of my life partnering with groups in one capacity or another. If it's not your history and your focus, it just takes some getting used to.

Q: MICHAEL ROSENTHAL, DEPT. OF STATE: In the experience of [the] IAEA – this is not evidence based or science – but the introduction of a radiation therapy cancer treatment center in, say, a country in Africa becomes an agent for promoting awareness, education, and prevention. And so even though it looks like you're doing treatment, it actually has an effect of prevention.

So in a way, the dichotomy that you hear of, oh, you should spend all your dollars on prevention and forget about, perhaps, treatment, doesn't really work in this case. And if you were going to come up with a metric that measured the impact of treatment, ideally it would also have some way to take account of this other impact of education awareness and the preventive effect. And even more complicated, if the cancer treatment people can get people to stop smoking to reduce lung cancer, you reduce many, many other diseases as well. So I'd be interested in your thoughts, though, about metrics. You touched on it a little bit.

A: DR. WILENSKY: Well, let me first say the part about the many roles that healthcare can play, I mean, that's basically been Project Hope's mission for these almost last 50 years of rather than being explicit providers of healthcare directly, it's going out to train the trainers, train people who – or build facilities so that there will be places that people can receive help, and that they will do themselves out of a job in setting that up, on the grounds that there are – that you can do both, that you deliver care while you're doing, frequently, something else, as is in the case for the cancer treatment area.

The focus on the – I mean, I'm an economist by training, so the notion that you are likely to make much headway without having good metrics just belies – when you move away from that, then you're raw politics. And I've lived in Washington the last 30 years; I don't know that I'd want to say I understand raw politics, but I've certainly seen it around me. It really is the other way to try to get decision-making done, and it's why people who are going in at the get-go need to understand that this is likely to be their most convincing weapon, to be able to say here is what's going on now, here are the kinds of ramifications of not dealing with some of the diseases that are out there. Here is what reasonably you might expect to be able to produce. The very least you'd have to do is be able to say, we think it's important but we actually can't provide any credible metrics to back it up.

This issue about do you do preventive or do you do chronic care treatment or do you do active intervention is always a delicate balance because it's very easy, if it's not you or it's not your people, to say I know what's best for you, but there is this delicate balance about if you're trying to sustain a long-term relationship for a country, you can try to get them to migrate to your more enlightened way of thinking, but if they really think there are some areas that are more important for them, you ignore it at your own peril. But I think that the metrics is just a really critical part of any sustained, long-term involvement in a partnership.

MS. ADELMAN: I'd like to just go back to the last question, because I know you have to go, Gail [Wilensky]. We, today, heard just a broad array of people working with organizations that are doing wonderful partnerships and working with physicians overseas, professional medical societies, teaching hospitals, not your usual partners with the WHO, and from what we know and what we've heard, you know, these have been some very successful endeavors. And what is your sense of the hope for the WHO ever being able to move out of the model of just working with – (inaudible) – and working more with these private organizations, including corporations who are – all of these healthcare – (inaudible).

DR. WILENSKY: I don't know that I actually know the organization well enough. It's very hard to get bureaucracies – national bureaucracies are really tough, but they pale in comparison when it comes to working with international bureaucracies. So they have their own histories and ways of doing things.

It may be on – it's hard to imagine a wholesale migration away from that. It might be possible on specific activities like this – I mean, this Commission on Social Determinants of Health has a lot of unusual attributes. So you may have some specific activities that veer away from the traditional path – unless and until, I suppose, they found they were really not as relevant as they wanted to be, and then the only thing that drives international bureaucracies even harder is to stay alive. So if they felt ultimately and vitally threatened, I'm sure they would be surprisingly creative.

(Laughter.)

MS. ADELMAN: That's a very optimistic note to [end on]. (Applause).

(END)