

HOUSE OF LORDS
MINUTES OF EVIDENCE
TAKEN BEFORE
AD HOC COMMITTEE ON INTERGOVERNMENTAL ORGANISATIONS
CONTROLLING THE GLOBAL SPREAD OF INFECTIOUS DISEASES

TUESDAY 22 APRIL 2008

International Federation of Pharmaceutical Manufacturers & Associations,
15 Ch Louis-Dunant, PO Box 195, 1211 Geneva 20, Switzerland

DR HARVEY BALE JR, MR GUY WILLIS, DR STEFANIE MEREDITH,
MS RYOKO KRAUSE and MR ERIC NOEHRENBERG

Evidence heard in Public

Questions 753 - 799

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Present

Avebury, L.
Desai, L.
Jay of Ewelme, L.
Soley, L. (Chairman)
Whitaker, B.

**Memorandum submitted by International Federation
of Pharmaceutical Manufacturers & Associations**

Examination of Witnesses

Witnesses: **Dr Harvey Bale Jr**, Director General, **Mr Guy Willis**, Director for Communications, **Dr Stefanie Meredith**, Director of Public Health Partnerships, **Ms Ryoko Krause**, Director of Biologicals and Vaccines, and **Mr Eric Noehrenberg**, Director of Public Health Advocacy, International Federation of Pharmaceutical Manufacturers & Associations, examined.

Q753 Chairman: First of all, thank you very much for your time. As you know, we are a Select Committee on Intergovernmental Organisations and our particular interest is the contagious disease question at the moment. Let me say, first of all, that the comments here will be noted by our shorthand writer. That will be produced in our report and sent to you in transcript form for you to correct any factual inaccuracies. I would also very much welcome it if, during the course of the questions, all or any of you feel you want to say something, please do so. If we do not cover some of the things that you think we ought to cover, then please say so and, indeed, when we finish this session feel free to write to the Clerk at the House of Lords and make any further points that you wish. Perhaps I could start by simply asking if you could introduce yourselves as to your jobs, so we know who does what. That would be helpful. Then I would like to ask a little about the organisation itself.

Dr Bale: Thank you. Perhaps I should start. I have been here for 11 years as Director General of the IFPMA. I will save the comments about what IFPMA is and more specificity until a little bit later. I am Harvey Bale. I am originally from Philadelphia but have lived in Switzerland for 15 years. I have done two stints in Switzerland. Eric, why do you not start at your end?

Mr Noehrenberg: I am Eric Noehrenberg. I am Director of Public Health Advocacy and Director of International Trade and Market Policy at IFPMA. I have been here almost nine years, very much involved in the whole question of patents and access to medicines. My primary responsibilities are discussions with the World Trade Organisation, World Intellectual Property Organisation and also the World Health Organisation in respect to patents and access to medicines primarily.

Ms Krause: My name is Ryoko Krause. I am Director of the Biologicals and Vaccines. I have been at IFPMA for eight years now and deal with all the technical, scientific and regulatory issues related to the biologicals and vaccines. Most of the work that I do is with WHO, and right now with all the vaccine initiatives with GAVI and UNICEF.

Dr Bale: I would emphasise her coordination of our Influenza Vaccine Supply Taskforce, given that you have avian influenza on your agenda.

Dr Meredith: I am Stefanie Meredith. I think I am the newest person at IFPMA, I have been here for a year and a half. I am the Director of Public Health Partnerships. I have come to IFPMA to work with the industry in developing partnerships, collaborative partnerships, with the aim of improving healthcare outcomes, access to healthcare. I came to this from a background working in major public-private partnerships, the Mectizan Donation Program, that you may know of, the Lymphatic Filariasis Donation Program, and a background in tropical medicine.

Mr Willis: Good morning. I am Guy Willis, Director for Communications at IFPMA. I have been with the organisation for nearly three years. One of my responsibilities is documenting the partnerships that the industry is involved in for the developing world.

Q754 Chairman: Thank you. My next question is just to get a clearer view of who the IFPMA represents. Is it all the companies? Can you just say a little bit about that, if you would not mind?

Dr Bale: In fact, up until 2005 we represented only associations. We had 55 member associations around the world from China, Russia, India to the US, Europe, Japan. We have membership now, which began in 2005, of 25 research-based pharmaceutical companies. Historically, this industry has been concentrated in Europe, North America and Japan. We also received our first Indian company, Nicholas Piramal, in 2007. It shows you that pharmaceutical industries are growing internationally with regard to the research capacity. We are a hybrid of company members and associations. From the UK we have both AstraZeneca and GSK. We have a number of the US companies, four Japanese, and we will add another Japanese company in the next few months, and we are hoping to get more companies in the future from developing countries.

Q755 Chairman: Are there any of the large players, the large drug companies, outside your organisation?

Dr Bale: Only one or two. One for example, like Johnson & Johnson, which is a very diversified company into hospital products, diagnostics and a number of different areas, is a member through the associations. In fact, more than one because they are in a large number of national associations. Nova Nordisk, a Danish company, is also not a member of IFPMA. If you think of all the rest of them, Sanofi-Aventis, GSK, Pfizer, Merck, Lilly, etc, Takeda from Japan, the largest Japanese company, they are all members.

Q756 Chairman: Do you see the IFPMA as being the organisation that gives a voice to the whole industry and serves as the organisation that negotiates with the various health bodies around the world? Is that how you see yourself?

Dr Bale: Yes, although we will mainly negotiate, advise, inform or consult with or be asked by the international agencies. Our main interfaces are with the World Health Organisation, number one. We also interface a lot with the World Intellectual Property Organisation, the World Trade Organisation, UNAIDS and GAVI. We were very much at the founding of GAVI. Medicines for Malaria Venture, all of the international disease-related or health-related organisations, in some way or another we have interaction with. At the national level the health agencies, for example the Department of Health in the UK, our member in the UK, the ABPI - the Association of British Pharmaceutical Industry - would be the interlocutor there. For example, we assist on global issues. I was in London last week talking to the DFID people about a project that they are launching next month called MeTA - Medicines Transparency Alliance - and Alexander will be there and his team and, together with a number of NGOs and governments, we will be launching the whole question of how do we bring greater transparency into the pharmaceutical supply chain. That is why we are here, in fact. When I first came 11 years ago I was advised by *Script* magazine that I should take IFPMA away from Geneva and put it somewhere else. But, when you ask the question where else would we be, the only other location would be, perhaps, Washington or New York, but that would still be far too parochial in the sense that most of the international agencies are based here. UNESCO is in Paris, the World Bank is in Washington, but the bulk of them are here.

Q757 Chairman: Thank you for that. Let us start with this general area, if we may, because obviously we are aware of the needs of drug companies to make profits and the need to invest in future research. We are also aware of the desperate need to deal with some very difficult

diseases and the need for vaccines and drugs in that. We are aware of some of the things you are trying to do, but it would help us if you talked us through how you see it from your perspective. We have heard a lot from other organisations about the need for drugs dealing with these diseases around the world, the need for vaccines and so on, but we have not heard it from the industry point of view.

Dr Bale: Thank you for the opportunity to provide evidence to the Committee. Simplistically, we think of it in terms of three As. The first is availability, that is to say how do we get drugs in existence. One of the great failings in the last couple of years was a project to develop an HIV/AIDS vaccine. It will not be a complete failure at the end of the day, I hope, but how do we get products in existence. Availability is the first one. Secondly, it is accessibility. Once we have these drugs available, how do we get them from Point A to Point B. This is not a simple matter because of the problems of logistics and lack of infrastructure in many developing countries. The third issue is affordability. If they are available and accessible but not affordable, then, again, the system has failed. How we approach it is in all three areas. I will just make a few introductory comments and ask my colleagues to expand. The question of availability really means investment in R&D. Today the global pharmaceutical industry is investing nearly US\$60 billion worldwide in new medicines and vaccines. I would say 85-90 per cent of that R&D is carried out by companies in developed countries, the OECD, Switzerland, UK, France, the US and Canada, and the rest in developing countries. This means we have to have good regulatory systems, good intellectual property systems, good systems of communicating the innovations to doctors who prescribe the medicines, since we do not deal directly with patients, and a good economic financing system. In the UK you have the NHS and other countries have similar or different systems. The basic system is one of finance, intellectual property, regulation and communication. Again, the question then moves to accessibility, and here we are working

with organisations. Stefanie has a project that we are beginning to work on in the Gambia about supply-chain security, how we build the supply chain and, on the other hand, how countries develop the necessary clinical facilities, the hospitals, keep nurses from moving away from developing countries and coming here to Europe or the USA. The brain drain from developing countries is an enormous and aggravating problem these days. That is the accessibility issue. Affordability: a large number of our companies, especially in the critical areas, such as Malaria, Tuberculosis and HIV/AIDS, have differential pricing programmes, which is to say that, depending on the company, they will take a no-profit approach or a below cost approach to pricing in the poorest countries. They will try to make up those losses in the developed countries, and in the middle-income countries they will have some differential pricing that varies according to the company. Tiered pricing, which is what we call it simplistically, is a very common practice, especially with the critical diseases, the ones that are global issues. This has been a traditional practice in the vaccine industry, even going back for a longer period of time than in the drugs field. Another way is through donations. Stefanie mentioned the Mectizan Donation Program for onchocerciasis and we have a donation programme underway for lymphatic filariasis. Companies are giving away medicines for leprosy, measles vaccines, et cetera. We have a company in Germany giving away mother-to-child transmission of HIV/AIDS drugs, a drug called Navarapine which is given away by Boehringer Ingelheim to some 45 developing countries. The way we try to facilitate this is first information. As Guy has indicated, we put together a volume, and I think there is a copy on the desk here, of the kind of partnerships that we try to foster. Then we are trying to communicate this as much as we can to the WHO, as Eric has mentioned before in his work with them, to make sure that people are aware of this. The kind of work that Ryoko does in vaccines is working with GAVI, because with differential pricing you still need funding, because generic products as well as brand-named products are simply not affordable

to millions and millions of people around the world. It does not matter whether the product is an originated product or copied product; if you are going to spend \$200 to \$300 per year for AIDS treatment, very few people in Africa or India or the South Asian continent or many people in Latin America will be able to afford that level of expenditure on healthcare.

Q758 Chairman: Or second-line treatment for TB, which is presumably typical?

Dr Bale: Yes. Here is an area where the generic industry is not very present because many of the second-line drugs are very difficult to make. We have a partnership programme that is described in this booklet from Eli Lilly that is engaged in technology transfer to companies in South Africa, China, Russia, I think the other one is in Brazil, around the world to try to build capacity to develop these very difficult-to-make drugs. There are two tuberculosis drugs for the multi-drug resistance issue which, of course, is the reason we have to go to second-line TB. It is a combination. With that, maybe I could ask Eric, Ryoko, Stefanie and Guy if they want to expand on that, if that would be permitted.

Q759 Baroness Whitaker: Could I just ask for clarification on tier pricing. Is it possible to avoid somebody buying them in a country where they are cheap and smuggling them into a country where they cost a lot more? Do you take measures against that?

Dr Bale: This happened a few years ago with GSK. It happened because GSK was under a lot of pressure from countries to get the medicines into Africa. Medicines were shipped, but what was not done at the beginning, which has since been corrected, was there was no differentiation in the boxes and packaging and tablets. Today, what is done typically is that you send the medicines in - for example, Coartem, an anti-malarial drug, which is sold in developed countries and sold very cheaply, relatively cheaply although it is still an expensive product, is sold at cost in developing countries in a different tablet size, so you can tell the difference.

Q760 Baroness Whitaker: So the authorities can pick it up?

Dr Bale: Exactly, differentiation in boxing, packaging and in the tablet itself. It has to be approved by the regulatory authorities, of course, and it has to show the same efficacy, it is the same product, we are not selling a product to the Third World that we would not ourselves want to consume in the First World. You still have to try to differentiate that product along those lines, otherwise you get what we call parallel trade and re-exportation of the product and the product is lost to the supply chain.

Dr Meredith: I could, maybe, add something not on the tier pricing but on the donated products. As Harvey mentioned, there are four major drug donation programmes and all of these donation programmes are long-term, the companies have committed to donating the drugs for as long as needed, which is very different from the small-scale donations to clinics and emergency relief. When I worked in the Mectizan Donation Program, we did have problems because the drug is extremely effective, it is very safe, free, but it was not available on the market; and occasionally we had massive diversions which had to be managed and managed carefully. That is the same for our other drug donation programmes. What you have to put into place is very careful distribution channels. Once it has been nipped in the bud, there has to be good communication about the fact that drugs are free and how to get them.

Q761 Lord Jay of Ewelme: Could I ask a question about donations, to perhaps take one example. What proportion, as it were, of the total drugs needed are donated? In the overall treatment of the disease, how important is the donation programme?

Dr Meredith: Mectizan or Ivermectin for onchocerciasis, right now more than 50 million receive treatment a year. When we started the programme we estimated that there were some 80 million people infected with the disease, but as techniques improved we discovered through better assessment methods and non-invasive assessment methods that, in fact, the

number of people infected was far greater. The coverage is probably about 80 per cent of the total who need it and the remaining 20 per cent are not eligible - they are pregnant, under-age or ill. For Mectizan for onchocerciasis, the majority are actually covered now.

Q762 Lord Jay of Ewelme: By the donations?

Dr Meredith: By the donations. The drug is not available to be purchased. It is under another label, other packaging, as stromectol for other indications and for the First World market. With lymphatic filariasis, the problem here is having funds. When you have a free drug, it is not the drug that costs the money. Boehringer Ingelheim, which donates Viramune, estimated it was maybe about two per cent of the cost of people accessing healthcare. For lymphatic filariasis, which is global, it is bigger than onchocerciasis, only a few countries have really good programmes, because the funds that are needed to distribute the drug are not widely available, so it is not a lack of the drug, it is a lack of funding that impedes progress.

Q763 Lord Jay of Ewelme: It is the distribution network?

Dr Meredith: Distribution and healthcare infrastructure.

Q764 Chairman: That is really to ensure that the drug reaches the person in a state in which it can be used effectively, is that right?

Dr Meredith: Safe and effective, yes.

Mr Willis: As Stefanie has indicated, there are certain diseases for which donation programmes seem to be the most appropriate solution. The medicines that are available are cheap, they are effective, they are relatively easy to distribute. For those diseases that Stefanie has mentioned, you only need to give one or two tablets for a period of a year, say, and then you have to go back and do it year after year. For the more complicated diseases, like HIV/AIDS and Malaria, the pattern that we see is you have new generations of

treatments, they are much more sophisticated, much more expensive, and in those cases the distribution model seems to be through the tiered pricing that Harvey was referring to. In the case of TB, the first-line treatments are old, well-established medicines, the problem is that you need to take them for a very long time and the problem is keeping patients on them. You go into treatment, you start treatment and within a month or two you start to feel much better and it is very difficult to keep people coming back to keep taking the treatment, having to do it every day in environments where it may be difficult for them to get to medical facilities. The WHO has recommended treatment which is Directly Observed Therapy, where you have to be in the presence of a health worker when you take the medicine, which is difficult to implement in countries where there is poor transport infrastructure and few health workers.

Q765 Chairman: The effects of the treatment are sometimes unpleasant, is that right or not? Somebody said to us they were unpleasant. That is the MDR one.

Dr Bale: With sleeping sickness, for example, the eflorithine and some of the other treatments are difficult to administer and some of the alternatives in the sleeping sickness regime are even worse. One of the issues we have is to try to find better formulations, easier to take, also fewer tablets. I am thinking of Coartem, where there is now a formulation where children will take a cherry-flavoured tablet which is a lot more palatable than the existing Coartem tablets, which are rather distasteful to children. That formulation is still in clinical development.

Dr Meredith: It will be out later this year.

Dr Bale: So it has just finished.

Q766 Lord Desai: As a professional economist, we always have a big debate about patents. All economists believe that they are a restrictive practice and, therefore, harmful. This is because all economists believe in a free market and, therefore, patents must be wrong.

Clearly, that must be one of the big criticisms that you must be facing because they do hold up the dissemination of medicine.

Dr Bale: As a fellow economist let me answer that. Joseph Schumpeter was one who differed with that view. I know the view though, I am a student of the Austrian school and a number of the others. The question is the trade-off between long-term competition in the case of innovation versus the short-term grant of what was, I guess, 1625, the English Monopolies Act that reformed the old royal monopolies into the innovative model that was instituted for the so-called period of temporary monopoly or temporary exclusivity. It is not just restricted to medicines, it is also true in the case of biotechnology, environmental biotechnology, et cetera, that if you do not have an IP patent system with a so-called temporary period of exclusivity you will not deliver the new medicines, new antibiotics and new biologicals. This is why, during this period of time when the companies have the responsibility, they are more than willing, as our document states, to work with countries to make sure that the patent does not become a barrier to access to medicines. This is one of the big challenges that we have. We do think that over time the costs of clinical development will change as a result of the growing presence in developing countries of clinical trials, which are very expensive. If we look at the total cost of developing a drug, which can range from a couple of hundred million pounds to £500 or £600 million, the greatest part of that cost is the eight to ten years of clinical trial testing that the drug has to go through. It is a combination of the direct cost of having these trials in place, typically in developed countries, very expensive, and also the tied cost of the money that is invested, simply what you do not gain in interest or return on that investment that you put in as cash outlays on clinical trials. Many developing countries, China, India and others, are now working to improve their clinical trial structures, which would significantly reduce many of these costs. That is coupled with the growing competition globally in R&D. R&D itself is a competitive model. It is interesting and changing the way

that the patent system affects the development of medicines. It used to be thought, and some still argue, that a patent guarantees you a profit. It is interesting that less than a third of the products that actually come out recoup their own R&D costs. The market is becoming extremely competitive, so that you have a large volume of relatively innovative medicines that have been developed over the last decade that will lose their patent status this coming decade. The estimate is in the order of US\$70-80 billion that companies doing R&D will have to compete with in the generic sector while at the same time trying to recover their costs. You are right on the patent model and I have watched both of these arguments. Personally, and philosophically, I tend to side with the Schumpeter argument, which is that the patent system helps set up the creative destruction of what has gone before through ideas and the genius of people that is applied to commercial enterprise. That patent system has successfully done that, and I think we owe a lot to the UK historically for instituting those reforms over the years.

Q767 Lord Desai: You were saying in the introduction that only one Indian firm has joined.

Dr Bale: So far, because India ---

Q768 Lord Desai: Why are they all out? What do they not think they are going to gain from joining you?

Dr Bale: If I could do a quick overview on the Indian pharmaceutical industry as we see it. There are three associations in India right now. One is the OPPI, which is our member, and it includes Indian and international companies doing R&D. By numbers of companies it is still a relatively small minority. The other two organisations are IPA, the Indian Pharmaceutical Alliance, which is an alliance of the more important Indian pharmaceutical companies, like Dr Reddy's laboratory, Ranbaxy, et cetera; and the IDMA, and there are some 7,000 Indian pharmaceutical companies roughly speaking. There used to be estimates of up to 20,000, but

a good survey would indicate about 7,000. These are very small operations and have no capacity to do R&D. The emergence in 2005 of India adopting patent legislation - and, although many people criticised it, the fact of the matter is that India has embarked on a process of applying patents in the pharmaceutical sector - is now generating to varying degrees a large increase in the R&D of Indian companies. There is no doubt it is the right way to go because in the generic sector India faces enormous competition that is now emerging from China. If Indian companies do not move, as we would say, up the value chain of the R&D away from the purely generic commodity business, they will be in big trouble. The biggest leap was done by a relatively small company, but a very dynamic and growing company, Nicholas Piramal, that took the step of applying to IFPMA for membership. The others are not quite ready for that, but a number of them are members of our local organisations in a number of different countries, although they are not ready for it on a global scale.

Q769 Lord Desai: Because of some kind of entry barrier to joining you?

Dr Bale: No. A company that joins IFPMA has only two or three commitments. First of all, they should adhere to the IFPMA ethical marketing code on the advertisement or promotion of medicines. This carries with it some restrictions that do not apply to non-member countries. I was just reading a story that Sipla, which is a major company in India, is promoting a drug for certain types of cancer which it has not been approved for. This type of activity in IFPMA would not be permitted, it would be a clear violation of the ethical marketing rules. The second commitment is to support IP protection. The third commitment is to establish and support good manufacturing practices. There are a lot of the companies in the world which do not produce products to standard and do not produce what we call safe and effective medicines. Those are really the three commitments and they are commitments that are political and moral quality commitments. Those are the only “barriers” to entry.

Mr Noehrenberg: I am also an economist. One often overlooked aspect on the question of patents and development and competition is the fact that patents create competition. Let us look at the AIDS field, for example. The first AIDS drug, AZT, was developed back in 1987 and it is a good drug and still used quite effectively. However, if that was the only drug on the market and you do not respond to it or you develop resistance to it, which unfortunately happens, you would be in very serious trouble. Thanks to the patent system, other competitors have had to find other ways of attacking the AIDS virus than by using AZT. If you look at India, for example, that has been copying and copying, they have a number of variations of AZT but none of their own innovative initiatives on it; and now, thanks to the patent system, thanks to forcing competitors to find different ways of tackling the HIV virus, we have about 26 plants on the market which are using a combination to effectively treat HIV in a variety of countries. I can see your argumentation, and we debate that quite often, but I think the creation of competition, the creation of public health benefits through the patent system is often overlooked but very important as well. The question of therapeutic competition on a variety of drugs also helps to keep prices down. If you look at the various sectors of the healthcare system treating AIDS, heart disease, cancer, et cetera, you will see that, although they are not exactly the same drug and the patent gives you a so-called monopoly over that particular drug and that particular indication, nevertheless, if someone else develops a different way of attacking the problem, the competition among those products helps to drive prices down. Indeed, when India passed the Act in 2005, Minister Nath, the Minister of Trade and Industry, said explicitly that he counted on such therapeutic competition to continue keeping prices down in India.

Mr Willis: A practical consequence of Indian patent legislation is that we are now seeing products in development for Tuberculosis and Malaria being done by Indian companies.

Q770 Chairman: I would like you tell us a bit more, if you could, about your relationship with some of the organisations, like GAVI on vaccines and inoculation and WHO generally. You have talked about your three As - availability, accessibility and affordability - and my guess is that the affordability one is the one that there is quite a battle over. I wonder how you see the relationship between yourselves and those organisations out there saying, “Hey, we want to get drugs down to people who need them in an affordable way”.

Dr Bale: Can we start with the vaccines, because Ryoko has not said anything yet. You mentioned GAVI, and Ryoko is responsible for that area.

Ms Krause: As Harvey has mentioned, all of our vaccine members have committed to work with GAVI from the very beginning. They started their work in 1999 to prepare for the initiative of the GAVI Alliance to provide vaccines to children in the least developed countries. What they have been doing is supporting the infrastructure development of GAVI initially and then contributing to provide the vaccines through a UNICEF procurement system in large quantities of high quality vaccines for those GAVI recipient countries. I think there is a lot of confusion about what GAVI does. GAVI does not give vaccines, it focuses on two vaccines for the time being. One is basic vaccines which are used all around the world for measles, mumps and rubella. Those are not procured by GAVI. GAVI is focusing only on the Hib vaccines and Hepatitis B vaccines. They are trying to expand their remit to new world vaccines coming in, which are very high-tech innovative vaccines for Rotavirus diseases, Diarrhoea and Pneumococcal diseases. Those are the new-era drugs that GAVI is starting to work on. Their success has been incredible, it brings all the funders together and uses the money and resources in a very effective way. The vaccine industries are at the table as a Partner. That is the difference between how the other organisations work with industry, because very often industry, although they come up with extremely good products, high quality and innovative products, is treated as somebody who is not contributing enough to the

developing countries. The GAVI model is an idea that all industries can work together on an equal level as Alliance partners.

Q771 Chairman: On all the other drugs that these organisations want to get down to low cost, and an enormous amount of money is now going into it, is there real tension between you and these organisations about delivery of drugs at what they would regard as a price that will deliver the right outcome to people on the ground in sufficient numbers?

Dr Bale: I think overall that is a good perspective, a reasonably accurate perspective on the issue. I would underline the point that I would derive from Ryoko's comment, which is to distinguish WHO, because when you ask who sits at the governing table, industry does not sit there, we are a non-governmental organisation. Who sits at the table are the Member States, the Health Ministers and their representatives. Who sits in an organisation like GAVI are the Global Fund and the Medicines for Malaria Venture. When you take something out of the official UN system and create a partnership, which is what these organisations are, you then find the industry typically at the table. It is a very interesting phenomenon which reflects the political structure and history of the UN as a Member State-driven organisation. We are going through debates right now with the WHO on who can sit in a room at a meeting. At the end of the day I think that debate will not matter too much, but it matters for the moment in the heat of battle. That tension is there and it is a tension between an industry that you started off by saying is in the private sector. There has been no model that has been developed that consistently can deliver \$50-70 billion in R&D over a long period of time in a commitment like this, and companies that cannot go to the capital markets and borrow the money have to raise the money through venture capital and shareholders. They will not find a bank who will lend them \$100 million and say, "Here, go develop a new drug". At the same time, it is an industry that has a large foot in the public health sector, as you suggest, in which we have to be able to justify how we deliver these medicines at affordable prices, or in some cases when

they are not affordable what can be used to get them to the people who are disadvantaged and without income. There is that tension, and it exists primarily at the World Health Organisation, I would say, where the industry is cooperating on a number of fronts. For example, Ryoko's group, the IVS, the vaccine supply taskforce, is very closely involved in preparations for avian flu. Here the problem is not the industry, the problem is one of the Member States, specifically Indonesia, which is threatening to upset the whole system of surveillance and sharing of the virus samples that threatens public health and is a violation of the International Health Regulations. We are not always the bad guy. In fact, if you ask the WHO, the more senior you go, the greater appreciation comes about as an understanding of what industry really does. At the same time there are a lot of people in the WHO who do not understand, do not want to understand, what the private sector does, it is not part of their world view. We deal with those people but sometimes we deal with them a little bit more contentiously than others. I am quite pleased. Over the years I think our relationship with the WHO has improved. There has been a better understanding, particularly under the last two Directors General, Dr Lee, who in an untimely way died, and Dr Chan. I am hoping that will continue. We have added a specific partnership function with Stefanie in the last couple of years to try and reach out and work more with the WHO.

Q772 Chairman: Does UNITAID help you in the way that they work?

Dr Bale: That is an interesting case. We are not at the table with UNITAID.

Q773 Chairman: Why not?

Dr Bale: At the beginning we had a lot of dialogue with the French Government in particular, which was really the driver of their airline tax on funding, which I understand is yielding something in the order of €300 million a year.

Q774 Chairman: It is a lot of money.

Dr Bale: We have known Philippe Duneton for years, and Jorge Bermudez is the Executive Director. On a personal level we are on good terms, but officially we are not there with UNITAID.

Q775 Lord Avebury: Would it be helpful if you were?

Dr Bale: I think so, and we would be more than willing to on technical issues, on the issues where they are going to be running into difficulties. A few organisations came about rather quickly and UNITAID was a very quick development as a result of Foreign Minister Douste-Blazy's efforts to sell UNITAID and the tax. We went to meetings at the beginning with UNITAID and I remember sitting in two or three of them. But, when it comes to day-to-day interaction or participation, we are not anywhere in the governing organisations, nor is our French industry counterpart, who is very closely monitoring and following what is going on there. We wish them well and we would like to help, but theirs is kind of a smaller version of the Global Fund. In the case of the Global Fund, we are formally at the table through the private sector membership on the board, but the UNITAID organisation has not placed that structure into existence.

Q776 Chairman: You said they will run into difficulties. Why will they run into difficulties and of what type?

Dr Bale: For example, with regard to WHO and the vaccines field, there is very, very technical information that needs to be delivered and a lot of misapprehensions and misconceptions that we have been able to address by being in the room and discussing the issues at the so-called Intergovernmental Meetings that have taken place about what is the science of vaccines. In the case of HIV/AIDS, TB and Malaria, which is UNITAID's remit, there are going to be a lot of issues around the supply of the products, questions of whether

and how fast you can develop fixed-dose combinations, which they would like to do, paediatric formulations, which is on their agenda, and fixed-dose combinations on their agenda. Industry can help with regard to the technical aspects of how to develop and deliver such medicines.

Q777 Chairman: Before I call my colleague in, is the implication that the sort of problems you think they might run into could be quite serious in terms of the failure of the drug regime or whatever?

Dr Bale: Probably even more so on the questions of delivery and quality assurance as well as the formulation of fixed-dose medicines.

Dr Meredith: I feel quite strongly about this. One of UNITAID's major foci is development of paediatric formulations where they do not exist already, and only the R&D, the research-based pharmaceutical industry, can actually do that. If you are not sitting at the table, there is not the dialogue. On the whole question around quality assurance, we know that, if you take the lowest price you are willing to offer, that does not give you the quality that is going to be needed in the long-term. Eventually UNITAID will need the private sector at the table. It is not just for drugs but also for diagnostics. They will need us. At the moment, to be honest, the reticence to having a dialogue with the private sector is coming from a few of the people on the Board; it is not the UNITAID people themselves, it is a few of the stronger voices, some of the Member States. I understand that recently they had an evaluation and assessment of a new partnership model they have developed, where there have been questions about why the private sector is not at the table, and perhaps this will lead to some changes.

Q778 Baroness Whitaker: Before I move on to generic drugs, returning to R&D I just wanted to ask you whether your members stimulate manufacture in countries where the need is greatest, bearing in mind that there is so much research in the West and so much disease in

the South. If they do so, either through their own companies or other organisations, what do they do about accreditation standards?

Dr Bale: There is some of this in the material that will give you more detail than perhaps we have time to give you today. GSK, for example, right out there in West London, has been a good example of what we call technology transfer. They very, very carefully select their partners in the case of these medicines because their reputation is really on the line here. The types of technology transfer that occur, when they make sense, do make a lot of good sense. In the case of HIV/AIDS and GSK, they have done technology transfer with Aspen Pharmaceuticals, a generic company in South Africa, to help with the distribution, because they feel that Aspen can better handle the distribution in the sodic region, the southern African area, not in South Africa alone but in the regional context. Lilly, in selecting its partners, has spent over US\$70 million to develop these four partnerships with four generic manufacturers going to India, China, Russia, et cetera, to do that. Accreditation becomes a very important issue and it is done at a very micro level. You have to send manufacturing teams, and we have had some of this in the vaccine field. There is quite a bit of discussion going on right now about how we can build capacity in developing countries and in what way. Typically, the companies will start off with a very basic technology transfer agreement, which is called filling and finishing. Basically, you are taking an active ingredient that comes typically in very large drums, cartons, and sending these to the countries where they are put into the final tablet form. If you start to develop the skills with regard to that, then later on you can go to a more refined operation. Some companies, like Merck, have developed turnkey vaccine facilities.

Q779 Baroness Whitaker: Have they saved money on R&D by so doing? Not yet?

Dr Bale: No. Typically the goal is not to save R&D in the case of technology transfer agreements. Where costs on R&D can be saved is where you can access procedures, subject

to the presence of ethical review boards, that allow the company to do clinical trials in developing countries. In developing countries you have many more patients who are available simply by virtue of the fact that these countries have not been very well-served because of lack of infrastructure, poverty, unaffordability of medicines, and colloquially they are called naïve populations, so you have naïve populations in many developing countries that are very hard to find in Europe and are simply less expensive.

Q780 Baroness Whitaker: The ethical considerations are presumably the same, are they?

Dr Bale: Yes, they are huge.

Q781 Baroness Whitaker: Identical with the ones in the West?

Dr Bale: The existence of ethical review boards is much more difficult in developing countries, where the standards have to be much more developed along the way to do many more clinical trials that are needed. A lot more development has to be done.

Mr Willis: A Dutch NGO did a study into this recently and found that most of the clinical trials that are taking place in developing countries are offshoots of clinical trials that are multi-centre clinical trials which are usually directed by companies or institutions in the developed world. The ethical standards that apply in the developed countries are, by extension, applied in the developing countries.

Q782 Baroness Whitaker: I just wanted to clarify that. What I want to ask is about generic drugs. I think you say that 95 per cent of pharmaceutical products on WHO's Essential Drugs List are not patented. Does this include the essential drugs for HIV/AIDS, Malaria, TB and influenza? Are they generic?

Dr Bale: That is a mix. They are patented in the UK, for example, and not patented typically in India or Bangladesh. A very interesting transformation took place in the Essential Drugs

List. It takes a very long time to get a drug typically added to the list because of bureaucracy, questions about affordability, et cetera ---

Q783 Baroness Whitaker: WHO bureaucracy?

Dr Bale: Yes, process. The Essential Drugs Committee, which was an observer, that meets twice a year, not very often ---

Q784 Baroness Whitaker: So are you saying you might have to wait 12 months to get on the list?

Dr Bale: At least. The HIV/AIDS drugs were not added to the Essential Drugs List until, I think it was, 2001, 2002.

Mr Noehrenberg: 2002.

Dr Bale: For example, AZT has been around since 1987 and is now generic. AZT is the one drug in the HIV/AIDS class that is now generic. A large number of the others will become generic very soon. At the same time, because India and a number of other countries did not have patent laws until the early to mid-decade, at the beginning of 1995, you have a large number of the HIV/AIDS drugs available generically. Some of these drugs are good quality drugs. You cannot and should not associate a generic product with a substandard product. There are many substandard products available in developing countries, but there are also good quality generic products that are available. HIV/AIDS is kind of the big exception to that rule.

Q785 Baroness Whitaker: I think you also say that copies of products tend not to reach the poorest peoples. Could you just spell out all the reasons for this, because this is very crucial.

Dr Meredith: Where shall we start!

Q786 Baroness Whitaker: I can think of some, but you tell me your views.

Dr Bale: What is the statistic? How many millions of children die of diarrhoeal disease each year? The numbers are staggering, yet oral rehydration therapy costs pennies.

Q787 Baroness Whitaker: Indeed?

Dr Bale: If you go to basic antibiotics, one of the biggest killers in Africa today is respiratory disease, pneumonia, upper respiratory, lower respiratory; and antibiotics are cheap. A doctor will prescribe for me erythromycin and I will happily take it, it is a very cheap antibiotic. We cannot get this product into these countries.

Q788 Chairman: Why not?

Dr Bale: Because of the delivery systems. Let us start from the top and take the worst case example, Robert Mugabe, does he care? He is extreme; but, if you ask the WHO what is the biggest barrier to access to medicines today, they will tell you it is lack of sustained political commitment to public health.

Q789 Baroness Whitaker: So there might be entry restrictions on imports?

Mr Willis: Before you even get into that, it is simply the amount of money that they spend on healthcare.

Dr Bale: You are addressing just poverty, and that is a factor.

Q790 Baroness Whitaker: Poverty means you cannot afford the drugs if they cost something.

Mr Willis: It means that most sub-Saharan African countries are spending per capita, per person, per year less than \$5.

Q791 Baroness Whitaker: So there are two aspects to that, the individual cannot afford the drugs and the government cannot afford the health infrastructure, the transport?

Mr Willis: That is just talking about what the government spends. Typically in sub-Saharan Africa the ratio is 4:1 or 5:1. Out of pocket expenses are typically four or five times what the government spends, so total healthcare spending in Nigeria is in the order of \$50 per head, but 40 of that is coming out of the pocket of the individuals concerned. That is before you get into tariffs.

Dr Bale: There is a lady here in Geneva with the Global Fund who was the former drug regulatory chief in Gambia, who says that the quality control systems in Gambia have not been updated for over 20 years, so they do not have the capacity to even evaluate which drugs are good quality drugs and which are bad quality, let alone ensure that the good quality drugs get into the systems in remote areas.

Ms Krause: During the first year of GAVI's activities they have agreed and decided to give free vaccines to 72 least developed countries around the world. It is not a matter of price. It was totally free and sent to individual countries in the proper way by UNICEF, but those countries which could adopt those immunisation schedules did not incorporate Hepatitis B and Hib vaccines in their immunisation schedules because they did not have any infrastructure for the cold chain, no delivery system and no healthcare system. They had no immunisation schedules where the people could come to be vaccinated. For each vaccine, even when it is a zero cost or one cent, it costs about \$8 to \$14 per dose to be vaccinated properly, depending on the level of infrastructure in those countries. That is the reason why GAVI Phase 2, which started in 2006, re-focused their approach on how to provide those vaccines to those countries, and they wanted to receive a country commitment. Some countries immunised the children only when it was free and, if it became a few cents, they decided to stop immunisation programmes on those particular vaccines and did not care about the children who were dying. Now they are focusing on the country to make a core payment and no government will receive free vaccines because that does not have the government

commitment. Then they focus much more on the infrastructure, healthcare system strengthening and are not giving out the free vaccines any more.

Dr Meredith: I will give you some examples. I have spent most of my life working in Africa and I am really committed to seeing something different. You can go to the central stores in, let us take Tanzania or Rwanda, and the drugs are there, there are the basic essential drugs; but, when you are in a health post that is 1,000km from Dar es Salaam, there is nothing there. The whole supply chain management is a problem. It is a problem because the person at the health post actually has no training in how to keep an inventory and order. But, even worse, if he does have the training and the capacity, and some of them do, the road has been washed away during the rainy season, the landline telephone does not work. Nowadays, with mobile phones things are changing and there is the possibility; but, if there is no transport from Dar es Salaam to Mahengi, you do not get your drugs for three months and there is nothing there. For me, one of the major problems is also trying to address building capacity for much better infrastructure and supply chain management. The same is true in Rwanda, which had \$90 million when I was working there in 2006 just for HIV/AIDS alone for a population of seven million, and at that point about 3.5 per cent of the population was infected with HIV. \$90 million is vastly over, 300 per cent more than was actually needed, but still at the health posts there were not the drugs. They had the HIV drugs but none of the other essential drugs because there had been vertical training. That is infrastructure, lack of integrated policies and we need a broad sectorial approach to improving that.

Q792 Baroness Whitaker: I absolutely endorse what you are saying.

Dr Bale: We are happy if you stay for another hour!

Q793 Baroness Whitaker: It is our job to make recommendations to bear on the UK Government. With the best will in the world they have not too much influence on the range

of tariff regimes, infrastructure, they have to choose where they can influence. To remedy this situation, to enable poor people to get generic drugs, what is the most useful thing, or things, that the UK Government can do, either at the political level or the aid level?

Dr Bale: We are starting a dialogue now with DFID. By the way, I think your Government is really a stand-out leader in this regard. Between DFID, USAID and a few other aid agencies focusing on health, this is enormous. First of all, I do think that the British Government should encourage institutions like the World Bank to focus more on these infrastructure issues. Instead of big mega-projects, like dams and telecoms and all that, that is fine but there is a bit of advocacy needed, because the UK Government is very influential in World Bank circles, and there needs to be more multilateral focus in this whole field of health. There are two issues. Not just supplying drugs - everybody seems to be keen about supplying drugs, UNITAID, et cetera. But let us get the infrastructure in place, let us build quality, let us keep counterfeits out. There needs to be a lot more focus on quality control, just as Stefanie, Eric and others have indicated. We have got to do that bilaterally, besides advocacy at the multilateral level, focusing against some of the programmes. We would love to work with DFID, for example, on this Gambia project. We would like to set up a model, in effect an exemplar, a project, a pilot, to use the Gambia, which is a small country of a million people, but still lots of problems, poor health quality control facilities, almost none. We are going to try to go in there and help. We have the skills and expertise but are not typically in a position to provide financing on a sustainable basis for 20-30 countries. It is a combination of public-private partnerships. We will bring the skills, we will put the resources in there and help get people there, companies committed, and it will cost them money. This is what we do with MMV, we get companies who are willing to devote laboratory resources to help develop a new anti-malarial drug, and it has spun on, most recently in the case of Ranbaxy in India,

who picked this up to develop the drug further. It is a combination of what we call PPP, public-private partnerships.

Q794 Lord Avebury: Is it DFID which is in the lead in the Gambia model?

Dr Bale: Right now we are at an early stage on Gambia, but DFID certainly seems to be in the lead on a number of health-related issues in developing countries. We hope to work with DFID. I would suggest DFID is a good natural partner in the case of the Gambia.

Q795 Lord Jay of Ewelme: This is a question, following up what Stefanie Meredith was saying. I guess we have all been to rural areas and seen the shops and stores where there are not the drugs but there is, let us say, Coca-Cola. My question is! is there scope for the pharmaceutical companies to work with private sector distribution networks to get the drugs through to places where at the moment other goods get through but drugs do not?

Dr Meredith: It is unfortunate that many people bring up the whole thing with Coca-Cola, including Margaret Chan of WHO, because it is completely different.

Q796 Baroness Whitaker: Why?

Dr Meredith: In the health posts that I am talking about, it is public sector. In the small private sector shops the profit margins are very small, but in Coke the profit margins are larger. They are all bottled in-country, these are local products and the cold chain is local.

Dr Bale: Coca-Cola controls it from A-Z. Coke is in charge.

Lord Jay of Ewelme: It is just that there are private sector mechanisms for getting products from Dar es Salaam to the rural areas. If that exists, why can it not be used in some way for other products?

Lord Desai: Forget Coca-Cola, heroin always gets there!

Q797 Chairman: Do not go there!

Dr Bale: Again, in that case it is the drug lords who control the chain. Our role in this is frequently we are at a disadvantage. Even if we have companies in the countries - and we have companies in Kenya, Nigeria, South Africa - they cannot get out and direct the public health authorities to do this and this. What we are hoping we can do is train them. This is where we think the value of what we can do in Gambia comes into play. At the end of the day we cannot own those health outlets.

Dr Meredith: What you are talking about is better and more innovation in distribution.

Q798 Lord Jay of Ewelme: Yes.

Dr Meredith: In fact, there are some innovative examples of essential drug franchise stores that were started in Kenya which were using something very much like this. I would recommend very strongly that we look more at expanding these franchises.

Q799 Chairman: A final word from Mr Noehrenberg.

Mr Noehrenberg: Thank you very much. Lord Jay raises a very important point. When I came to IFPMA from UNAIDS, where I was responsible for our relations with the private sector, this question was posed to me quite often: why is it that the private sector can reach out there. As Harvey and Stefanie have noted, every step along that chain in the private sector, every single person, makes a significant profit until the final end user, even out in the rural areas. What the private sector can do, and has done through organisations such as the Global Business Council or Global Business Coalition on HIV/AIDS, is to offer the private sector expertise on distribution, storage, management, in a way to get a more effective outreach into the rural areas. If you look through the printed copies of the book - that is the advance version and we are going to come out with the official printed copy in coming weeks - you will see specific initiatives which go to that exact issue, how to work with governments to reach out there. Your point is very well taken, your Lordship. The fact of the matter is that

the public sector does not have the same incentives for each step along the way to get out to the people there in the rural areas, but by true collaboration and exchanging experiences it can become more effective. That is something that could be used to promote partnerships. May I make one last point? One of the most effective ways of getting AIDS drugs out to people in sub-Saharan Africa and the least developed countries is by what is called the Accelerating Access to AIDS Drugs Initiative. It was started in 2000 by a group of five companies, including GSK of the UK, and works with five UN agencies: WHO, UNDP, UNAIDS, the World Bank and UNPF. That now reaches to well over 800,000 people living with AIDS in sub-Saharan Africa and other developing countries with quality triple therapy treatment. Furthermore, the second-line antiretrovirals offered through that programme by the companies is lower in cost than those offered by generic copiers from India and other countries. That is proven if you do analysis of statistics on prices collected by *Médicins Sans Frontières* and WHO. The companies we represent are committed to expanding access, to offer drugs at cost, low cost, even for free, as appropriate. Furthermore, they also cover the costs of transportation, insurance, et cetera, to the purchaser, whereas many of the copiers of products do not do so. This goes to questions raised by Lady Whitaker, Lord Jay, Lord Avebury and others. We are committed to making access a reality and we are doing what we can to make it possible. Where we can do it alone, it does work, but it is even more effective through partnerships with the public sector, NGOs, faith-based organisations in many places. We are trying to do our best to make it possible, so whatever can be done would be very helpful.

Chairman: Thank you very much indeed, that has been extremely helpful. There are one or two points you have raised which we will look at further that will bear further examination - the infrastructure one in a way being the most important one that we need to give some more thought to. If you do get any more ideas or thoughts, or want to elaborate one or two points

more specifically, please do so, and if you write to Mr Preston in the House of Lords it will come to all of us. Once again, thank you for your hospitality but also for your very clear answers to our questions. Thank you very much.