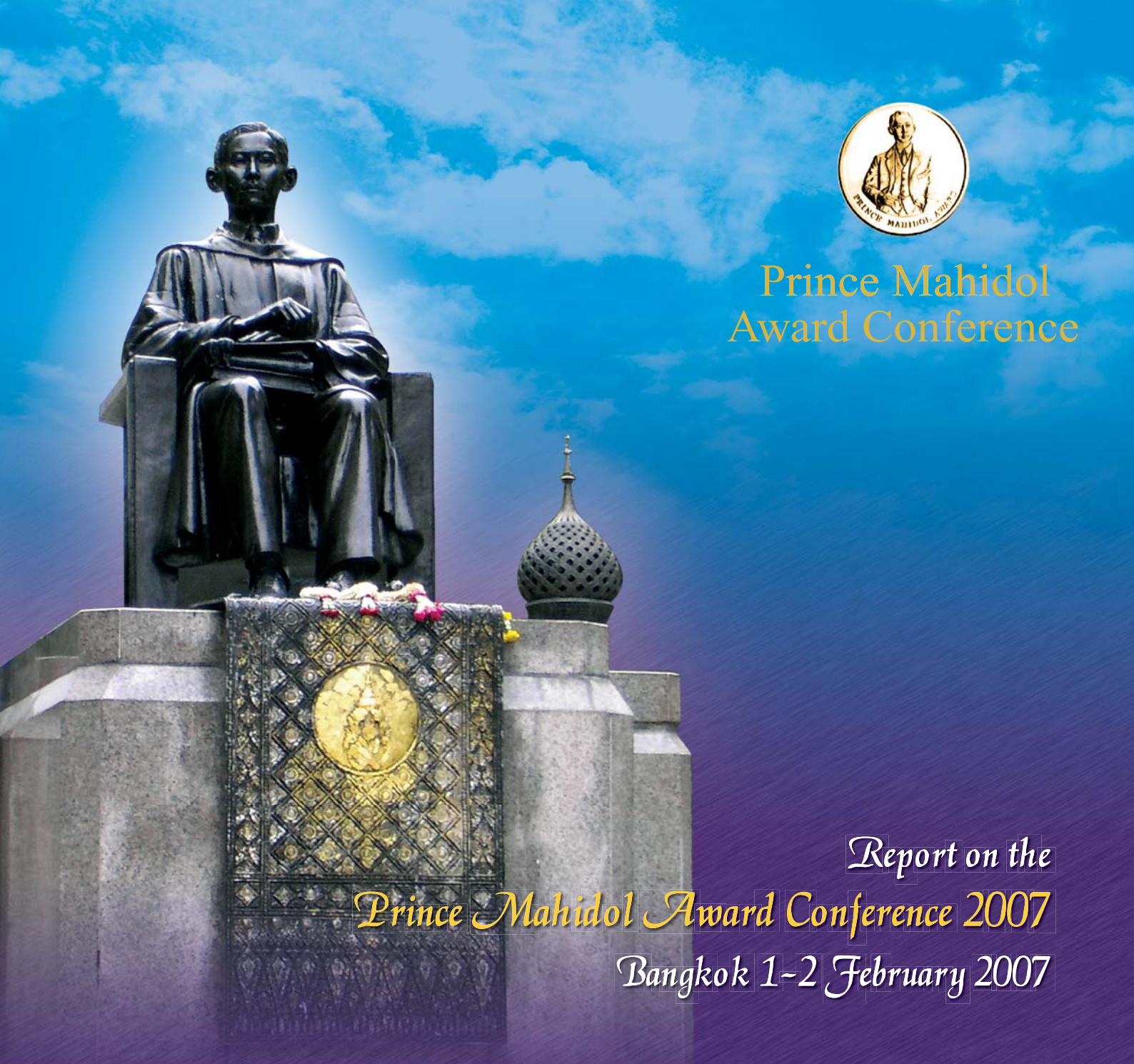

Prince Mahidol
Award Conference

Report on the
Prince Mahidol Award Conference 2007
Bangkok 1-2 February 2007

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Prince Mahidol Award Conference

COMMEMORATING THE FATHER OF MODERN THAI MEDICINE

"The 1st of January 2007 marks the 115th Birthday anniversary of His Royal Highness Prince Mahidol of Songkla whose lifelong contributions extended to various fields, especially medicine and public health... To commemorate His Royal Highness' contributions, the Prince Mahidol Award Foundation was established on January 1st, 1992 to honor individuals and organizations, regardless of race or nation, for their beneficial accomplishments in medicine and public health. As an international award, it thus stands as a symbol of harmony and efforts for a healthier and safer world..."

- H.R.H. Princess Maha Chakri Sirindhorn, Chairman of the Board of Trustees and President, Prince Mahidol Award Foundation

The Prince Mahidol Award Conference of 2007 was devoted to the worldwide issue of improving access to Essential Health Technologies, with a special focus on neglected diseases and the problems of reaching neglected populations.

These are matters to which many organizations and individuals concerned with human development and the health of society have devoted attention. Some of the principal organizations involved, notably the World Health Organization, the World Bank, UNAIDS, civil society groups (Médécins sans Frontières), the Rockefeller Foundation and the health care industry, joined with the Ministry of Public Health, Mahidol University, Siriraj Medical School, and Prince Mahidol Award Foundation in organizing and planning the Conference; the speakers and participants included some of the world's leading experts in the area of health policy and development.

CONTENTS

Prince Mahidol Award Conference

Report on the Prince Mahidol Award Conference 2007 Bangkok 1-2 February 2007

Four of the most distinguished scholars and scientists are conferred the Prince Mahidol Awards for 2006 :

In the Field of Medicine:

Professor Stanley G. Schultz, MD.

Professor Stanley G. Schultz, MD. is the former Dean of the University of Texas Medical School at Houston in Texas, U.SA. He is now Professor of the Department of Integrative Biology Pharmacology, University of Texas Madical School at Houston, Taxas, U.S.A. In the 1960s, Dr. Schultz and his team demonstrated that glucose and sodium absorption in the small intestine was intimately coupled, and glucose could facilitate the absorption of sodium and water. This pioneering work provided the scientific foundation for the use of the oral rehydration solution consisting of salt, sugar and water in the treatment of dehydration in diarrhea patients. Since the early 1970s, the ORT has continuously benefited the lives of millions of children each year all over the world. Dr. Schultz is also known to be a great teacher, receiving several teaching awards including Teacher of the Year award from the American Physiological Society.

In the Field of Public Health:

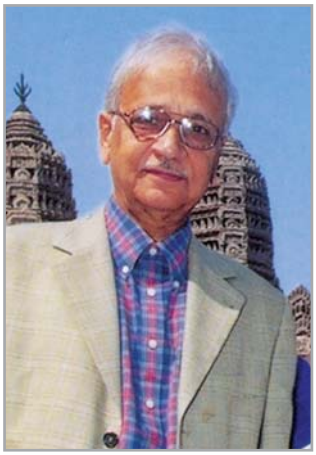
David R. Nalin, MD.

David R. Nalin, MD. is the former Director of Vaccine Scientific Affairs. Merck Vaccine Division, Merck&Co. Inc., West Point, Pensylvania, U.S.A. Dr. David R. Nalin, was assigned, in the 1960s, to the Pakistan-SEATO Cholera Research Laboratory (CRL) in Dhaka, East Pakistan (presently, the capital city of Bangladesh) as a research associate at the US National Institutes of Health (NIH). Dr. Nalin, Dr. Richard Cash, and their colleagues successfully tested the efficacy of an oral glucose-electrolyte solution, later known as oral rehydration therapy (ORT), to be used instead of intravenous fluid for the treatment of patients with severe cholera. This new treatment was tested in Matlab and then used by the Johns Hopkins University International Center for Medical Research and Training (ICMRT) in Calcutta in the refugee camps during the Liberation War of Bangladesh in 1971. Later as a WHO consultant, Dr. Nalin has helped establish a number of highly successful national programs on the oral rehydration therapy for diarrhea diseases in Costa Rica, Jamaica, Jordan, and Pakistan.

Richard A. Cash, MD, MPH.

Richard A. Cash, MD, MPH. is Senior Lecturer on International Health at the Department of Population and International Health, Harvard University School of Public Health, Boston, U.S.A.

As a young clinician, right after finishing his internship in New York City, working at the Pakistan-SEATO Cholera Research Laboratory (CRL) in Dhaka in 1960s, Dr. Cash had been involved in the first scientifically-proven successful clinical trial of testing the oral rehydration therapy on severe diarrhea patients. The trial has become a landmark for subsequently applying this treatment around the world.



Dilip Mahalanabis, MBBS, DCH, FRCP.

Dilip Mahalanabis, MD. is the Director of the Society for Applied Studies, a non- governmental research organization, in Kolkata, India.

Dr. Dilip Mahalanabis started his work on oral rehydration therapy in 1966 as a research investigator for Johns Hopkins University International Center for Medical Research and Training in Calcutta. During the Liberation War of Bangladesh in 1971, Dr. Mahalanabis used the ORT in the refugee camps which accommodated 350,000 refugees, in West Bengal. Dr. Mahalanabis instructed his staff to distribute the ORT for the treatment of over 3,000 patients. With the ORT, the death rate dropped to only 3% in comparison with 20 -30% using only intravenous fluid therapy. This was the first large - scale use of oral rehydration solution in a disaster situation. As a result, it gained the International health Organizations recognition and its application was spread worldwide.

Professor Stanley G. Schultz, MD

David R. Nalin, MD

Richard A. Cash, MD, MPH.

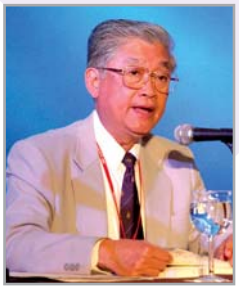
Dilip Mahalanabis, MBBS, DCH, FRCP.

Message from Chairs of Organizing Committee

The Prince Mahidol Award aims at recognizing distinguished researchers or scientists who discover or develop new technologies and those who make the inventions available for wide public use. Thus, the theme of the 2007 Prince Mahidol Award Conference has reflected clearly the goals of both the World Health Organization and the Prince Mahidol Award Foundation. It also reflects the concerns of many other development partners, including the World Bank, UNAIDS, foundations, academicians, industries and civil society groups. They all actively participated in organizing this conference.

This conference booklet reflects their strong commitment and wisdom. We hope that the outcome of this conference will enable participants and participating organization to further strengthen their joint efforts in achieving greater access of medicines for all. This is essential for the achievement of the Millennium Development Goals (MDGs)

We would like to take this opportunity to thank all the contributors and the honorable participants to this meeting, particularly the World Health Organization and the Royal Thai Government who co-host this conference. We would also like to express our thanks to other organizations, foundations, NGOs and industries for their active involvement and support. Finally, the real hard work of the Secretariat Team are highly appreciated and recognized.



Prof. Dr. Vicharn Panich

Chair
Organizing Committee
Chairman, International Award Committee, PMAF
Bangkok, Thailand

Dr. Howard Zucker

Co-Chair
Organizing Committee
Assistant Director-General, WHO
Geneva, Switzerland

Background

A series of major studies have in recent years profiled the problems of ensuring access to health technology throughout the world. In 2005 the United Nations Millennium Project published its detailed study of issues relating to Access to Medicines[1] and advanced a series of proposals. In 2006 the World Health Publication issued the report of Commission on Intellectual Property Rights, Innovation and Public Health; established at the request of the World Health Assembly in 2003, the Commission's task was to include an examination of "...the question of appropriate funding and incentive mechanisms for the creation of new medicines and other products against diseases that disproportionately affect developing countries."[2]

Both of these studies, as well as other authoritative sources, have stressed that the issue of "access" to health technology must not be looked at too narrowly. While pharmaceutical medicines tend to be at the center of the picture, the challenges relate equally to other means of diagnosing, preventing or treating illness. What is more, at least four phases of effort need to be distinguished and their success assured:

- the basic *discovery* of the product or method; in some instances, for example many tropical diseases, a much needed remedy or vaccine does not as yet exist.
- the *development* of the product or method to the point where its suitability has been demonstrated and it can be introduced into health care ("reduction to practice")
- the *delivery* of the product or method to the community, ensuring that it reaches the ultimate user, without the intervention of barriers such as those created by distance or cost.
- a process of *information, education and motivation,* often necessarily directed as much to the ultimate user as to the health services, to ensure that the method or product will be widely and appropriately used.

[1] UN Millennium Project: Report of a Working Group on Access to Medicines. United Nations, New York, 2005

[2] Resolution WHA56.27, calling for the establishment of the Commission.

On all these four fronts there have up to the present been significant shortcomings, sometimes reflecting a lack of interest or effect, and in other instances attributable to indifference, poor priority setting, lack of finance or the presence of unappreciated obstacles that need to be identified and overcome. Even where a solution to a problem has been found, there have sometimes been unforgivable delays in implementing it. The present Conference devoted attention to all these points, especially in the light of documented examples, and sought to identify appropriate steps to ensure progress.

BUT HOW CAN IT WORK ? AN ELEMENT IN PERSUASION

An excellent example of an effective yet simple innovation enjoying wide access is that of Oral Rehydration Fluid (ORF), subject of the Prince Mahidol Awards of 2006 to Dr. Richard Alan Cash, Dr. David Nalin, Dr. Dilip Mahalanabis and Prof. George Schultz. The basic discovery was that a simple mixture of salts and sugar in water could relieve dehydration in infants with severe diarrhoea and save lives on a large scale. The mixture could be prepared in the homeor producted cheaply by any manufacturer without a need for prequalification. No patent was taken out on the formular, meaning that the discovery was accessible to all especially when housewives were empowered to prepare home based ORF. However even the use of this important innovation was for a time delayed by opposition from some experts who doubted its credibility, particularly in view of its unusual simplicity, and argued that the treatment must be primarily anti-infective. Its use was ultimately much stimulated by the fact that work by Prof. Schultz and his team had elucidated the mechanism of action.

Promoting discovery

The discovery of new remedies has largely been undertaken during the last century by industry, often with success, though the rate of success has slowed in recent years. This is in part due to the technological hurdles involved in improving on past innovation and on existing products, and in part to the fact the remaining challenges (such as Alzheimer's disease) tend to be more complex than those successfully tackled earlier. Where neglected diseases are concerned, a major obstacle to progress is the lack of an effective market or of other forms of encouragement to invest in the necessary research; one may regard this as representing a failure both of the market and of the public sector. There is now an immediate need to stimulate innovation, to seek new ways in which progress can be achieved, and to ensure that investigation is properly directed to meet the world's most pressing needs; too many of the new products which do enter the market are directed primarily to treating the ills of the industrialized world. While the outcome of projects obviously cannot be predicted, many analysts claim that a disproportionate amount of research initiated within industry is essentially directed to the creation of close analogues of existing drugs (so-called "me too products"), rather than to achieving major leaps in real innovation. Many accept this, but others point out that the cumulation of incremental innovation itself often results in significant advances in healthcare and the health of the population and should not be dismissed as irrelevant.

Many of the more important advances in fact have had their roots in basic discoveries made in academic and public health institutions, followed by development in industry. This highlights the need for investment in academic research if an environment of innovation is to be created and maintained. However, it should be noted that academic research, though necessary for innovation, is not of itself sufficient, and some form of industrial development is usually required to translate innovation to practice.

THE NEED FOR LATERAL THINKING IN DISCOVERY

Ivermectin (Merck) was developed as a veterinary drug and proved dramatically successful in a range of parasitic animal diseases. In man it had proved disappointing against hookworm and tapeworm. However, two experts familiar with sub-Saharan disorders realized that it might be useful in Onchocerciasis (river blindness) that affects some 18 million people. It indeed highly effective and safe, has since been provided free of charge to more than 62 million people, and could ultimately help eliminate the disease entirely.

- From a presentation to the Conference by Prof. P. Roy Vagelos

Approaches:

1 Broad collaboration between international agencies, governments and consumer organizations can do much to ensure that scientific effort is appropriately directed and that public money is made available where necessary to support it, either directly or by ensuring that successful discoveries are further developed and made available.

2 Currently the market (whether private sector or public sector) primarily dictates the demand for (and hence the direction of) innovation. However, in recent years public sector and philanthropic investment in R&D through public private partnerships (PPPs) have leveraged "in kind" investment from the pharmaceutical industry, the latter in part reflecting considerations of corporate social responsibility. This entire process has led to the creation of significant pipelines of products for several diseases, notably malaria and TB.

3 A proposal is being advanced by some advocates that one should disconnect reward for innovation from market return and develop an R&D treaty concept in which financial rewards for an innovation are attuned to the degree of novelty and social importance of the new product rather than to its level of "market" use. Detailed proposals to render such an approach effective still need to be developed and tested.

4 Further study and encouragement is needed to drive innovation to on the treatment of neglected diseases or in fields in which existing products are unsafe or have ceased to be effective because resistance has developed.

5 Governments have only rarely been willing to provide subsidies to industry to undertake such work, particularly since the finances of companies are as a rule not disclosed to the public, e.g. expenditure on advertising and promotion, which may be quite substantial and may much exceed the sums devoted to research. However, examples where subsidies or analogous mechanisms have been developed include the recent emergence of PPP's and

orphan drug legislation in the USA. Recent regulatory rules in the EU (article 86) also allow cost-free regulatory support for certain disease indications endorsed by WHO. Support to socially desirable research can be provided by giving firm assurances that innovative products emerging from this work will be purchased at public expense. In this regard recent developments such as the Global Fund to Fight AIDS, TB and Malaria and UNITAID are firm examples of how guaranteed purchase of goods has stimulated a private sector manufacturing response. The Advanced Marketing Commitment Schemes and International Financing Facility for immunisation (IFFim) are other schemes that may lead to more sustained investment in innovation.

6 While pharmaceutical companies have often sought research collaboration with academic and state institutes, opportunities for joint effort are still missed. Institutes must be encouraged to complement their basic research with pragmatically directed research collaborations to develop new tools. Increased opportunities for this now exist in the field of neglected infectious diseases through PPP's, contributions from philanthropic organizations, an increased interest in translation research by some science funding agencies (e.g. Wellcome Trust) and the establishment of specific pharmaceu -tical centres for work on drugs for neglected diseases (e.g. GSK in Madrid, Astra Zeneca in Bangalore and Novartis in Singapore). Firms should also be encouraged to participate in open source drug and diagnostic lead discovery networks and partnerships such as are being developed by WHO/TDR. A reservation expressed by the participants to the Conference is that, while appreciating the role of PPP's, it is feared that input to these schemes from philanthropic sources may not be sustainable over a long period. Where a long term approach appears essential, other means of financing R&D should be identified, for example within the scope of a Research and Development Treaty.

New sources of financing for innovation

While many ambitious projects will probably continue to be financed from ordinary sales at commercial prices to individuals, insurance funds or health systems, some novel means of funding are now being devised and they deserve to be exploited in order to undertake or reward work of public health interest. Those proposed or already introduced are in effect capable of generating an international public sector market for public goods. They include:

- The UNITAID fund based on a levy imposed on airline tickets to purchase selected medicines for HIV, TB and Malaria, in order to increase access to medicines in poorer countries,

- The Tobin tax, as employed in Brazil, on cross-border currency; this can be specifically earmarked to finance health services,

- Advance Market Commitment (AMC), as developed by the World Bank and GAVI. Pneumococcal disease has already been recommended as the most suitable candidate for an AMC approach to vaccine development, perhaps to be followed by the development of a malaria vaccine. The mechanism would also allow for limited competition so that an incrementally improved vaccine could replace the first vaccine to reach the market if the data justified this.

- An International Financing Facility for immunisation, such as is now being managed through GAVI

- Innovative forms of global agreement to support Research and Development. Each country may for example be required under such an agreement to devote a fixed proportion of its Gross National Income to R&D in these fields; the funds provided may be used within the country allocating them or in another participating country where eligible research is being conducted.

ADVANCE MARKET COMMITMENTS FOR NEW VACCINES

"Vaccines... are routinely introduced into industrial countries at $50-100 per dose. Introducing new vaccines into developing countries at tiered prices of $4-8 per dose...would still allow industry to recoup incremental investment costs. However, these prices would be unaffordable to the poorest developing countries... An Advance Market Commitment (AMC) for vaccines is a financial commitment to subsidize the future purchase of a vaccine not yet available, if an appropriate vaccine is developed and if it is demanded by developing countries. By creating markets for vaccines for developing countries, AMC's are a bold step towards erasing inequitable access to health products between rich and poor..."

- From a paper prepared for the Conference by the World bank and GAVI

Approaches:

1. The Conference stressed the need to implement such alternative forms of financing both to boost access to existing products and to stimulate innovative research and development. In particular, governments should realize the grave economic repercussions for the world as a whole of neglected diseases and countries at any level of development should be prepared to contribute according to their capacity to the funding of certain types of research of importance to poorer countries and populations. Investment in research and innovation capabilities in developing countries should also be promoted both internationally and from within developing countries

2. Once new sources of finance have been identified, the new funding can be disbursed in those directions, public or private, where it is most likely to accelerate research work in the interests of health and where there is a both documented need for it and assurances that it will be used in a transparent manner.

The issue of Intellectual Property

National systems of patents, designed to protect and encourage inventors, have in some form existed for centuries. In the field of public health there is little or no opposition to patents as such, but there must be a balance between the innovator's interests and those of the public who need to have access to the invention, e.g. a new drug, at all times and at a fair price. Concern expressed about drug and technology patents in recent years have related largely to the TRIPS agreement of 1995 that in effect sought to create a global system of patent protection, thereby reducing piracy but at the same time creating problems for those poorer countries that had come to depend heavily on low-cost generic versions of expensive patented pharmaceuticals. Criticism advanced by public health interests has also been directed towards:

The practice of "greening" drug patents, i.e. extending their lives artificially by taking out supplementary patents on product modifications even where these do not provide any genuine new benefit.

The influence of some Free Trade Agreements considered to have been imposed by some countries on other trade partners, clauses in which may prohibit the latter from making use of those exceptions provided for in the TRIPS agreement which were intended to provide relief, when for example compulsory licensing of a drug might address a health emergency. Many countries lack the experience to use these special exceptions or to recognize the extent to which their freedom of action may be impaired by certain clauses in Free Trade Agreements.

The fact that, within developing countries, health ministries may find themselves in disagreement with ministries of trade or foreign affairs in the interpretation and use of the TRIPS exceptions.

At the same time, the Conference recognized that this is a controversial field and that patent holders themselves argue that their own interests are unduly threatened, notably by the excessive use made in some countries of the flexibilities allowed for in TRIPS, especially as regards the issuing of compulsory licenses and the subsequent possibilities of parallel exports / imports.

THE HEALTH CHALLENGE OF WIDESPEAD POVERTY

"Humanity cannot allow people to die just bacause they are poor, and yet every day - no, every - second - this happens in all corners of the world. We have to struggle with the concepts of free trade, which respects intellectual properties, and yet have to be responsible in bringing affordable therapy to the people."

- Yongyuth Yuthavong, Thai Minister of Science and Technology, addressing the Conference

Approaches:

1. The Conference stressed the need for balance between the valid interests of the innovator and those of public health but also the fact that, given a degree of goodwill, such a balance is attainable.

2. Where a country finds that a patent on a drug or other technique or instrument impedes its ability to deal with a serious public health problem, reasonable attempts to reach an agreement with the patent holder (e.g. on price reduction, or voluntary provision of a license) should precede the issuing of a compulsory license. Whether there is an actual obligation to engage in need for such prior discussion and negotiation depends on the relevant national Law. Efforts to this end should not however be so prolonged as to delay introduction of a much needed product.

3. Particularly in developing countries there is a need to strengthen capacity in the management of Intellectual property. One element must be a broader understanding of the principles of intellectual property protection and the use of the TRIPS exceptions.

Tackling non-communicable diseases

While the world has understandably tended to give priority to the development and provision of means of treating infectious diseases, it faces a growing problem in dealing with non-communicable illnesses, such as cardiovascular diseases, high blood pressure, cancer and diabetes. Once primarily seen as a problem of the industrialized world, these conditions are becoming much more common in developing countries, where there is an increasing move of populations into the cities and exposure to unhealthy marketed foods, stress, and a sedentary lifestyle, as well as a longer life expectancy.

Obesity is becoming a global pandemic, with child obesity as a matter of special concern. We know essentially how to deal with many of these conditions, especially by encouraging healthy living. Some striking successes have been booked here, e.g. by countering the use of tobacco, promoting healthy eating and physical activity, school meals, dietary education of the young and provision of screening programmes to identify these illnesses at an early stage. However, there have also been failures, and much more effort is needed by governments and in the community as a whole to tackle these conditions, especially in motivating people to take part in an active part in dealing with them in ways that are known to be effective.

"THE FIRST RUMBLES OF THE STORM"

In the U.S. there are 116 deaths per 100,000 men aged 35-59 from heart disease and stroke each year. In Russia the corresponding figure is no less than 576. India and China each have three million deaths a year from these causes. Developing economies are seeing devastation that the US and other western countries experienced 50 years ago but have since escaped. Troubling as these patterns are in developing countries, they are but the first rumbles of the storm. The worldwide shift of working people from rural to city living parallels rising levels of prosperity, but also brings pressures to consume more food. City food is cheap and carries a heavy freight of fats, salt and sugars. The car supplants the bicycle and the foot. A worldwide epidemic of overweight and obesity, even where under-nutrition persists in poorer quarters, presages high levels of diabetes, heart disease and stroke ahead. Meanwhile tobacco consumption is increasing in the developing world. These are no pro-Ebola or pro-SARS lobbies, but a tidal wave of commercial greed pushes tobacco consumption forward, causing five million deaths each year.

- *Professor Stephen Leeder, Sydney, addressing the Conference*

Approaches:

1. There is a need to dispel the myth that non-communicable diseases constitute a "developed country" issue and are solely a problem of the rich.

2. Where non-communicable diseases are concerned, the problems lie not so much in the development of new products as in the area of primary prevention through the adoption of healthy lifestyles; governments need to be considerably more aware of the burden posed by these diseases and the need to recruit entire populations to engage in preventive efforts (healthy diet, physical activity and active lifestyle, avoidance of stress etc.). Successful approaches to reducing chronic diseases involve issues of health policy, education systems, and measures at the community, family and individual levels; all these approaches complement one another.

3. It is encouraging to note the extent to which successes in large scale clinical studies, capable of influencing policy on pharmaceutical issues, indeed have exerted an effect, for example in the case of breast cancer.

4. On some fronts there is a need to rethink old dogma. The fact that many useless or illogical drug combinations have been introduced in the past should not blind one to the possibility that innovative combinations can be of value, for example where they simplify treatment and thereby promote compliance. The concept of such a "polypill" for reduction in risk of cardiovascular disease was highlighted as an area requiring further investigation, policy analysis and discussion.

5. While extensive mechanisms for control on promotional activity by the pharmaceutical and tobacco industries have been developed over several decades, particularly in western countries, these governments have been relatively hesitant to control the food and catering industries in a similar manner; as a result, persuasive pressure on populations to consume high-fat and high-sugar foods and drinks has heavily outweighed the provision of impartial advice on healthy living. There is an urgent need to correct this imbalance.

6. In many other countries, health policies with regard to tobacco have remained very weak, and the tobacco industry has transferred much of its marketing activity to these countries. This commercial influence far overshadows the effect of the much weaker health promotional activity developed in these same countries. The resulting potential for tobacco related disorders, including cardiovascular disease, lung cancer and chronic lung diseases, is immense and involves both active smokers and "passive smokers". Quite apart from considerations of health and wellbeing, the resultant economic damage is vast. Without very firm efforts to put an end to this trend, (efforts that need to be developed both in the countries where these firms are based and those where their products are sold), the consequences for public health will be disastrous. There is a need for broad mobilization to adopt cost effective policy measures as demonstrated in tobacco reduction and changes in diet and exercise. These activities must also be complemented by measures to promote alternative agriculture to replace the growing of tobacco, and alternative employment opportunities for those currently engaged in the tobacco industry and trade.

Infectious diseases and epidemic conditions

...more substantive government / public sector support appears warranted given the public sector interest in this area.

Malaria and Tuberculosis are the primary example of infectious diseases which, having long been the target of effective and safe remedies, now urgently require further innovation because of the emergence of resistance. In these major fields public/private partnerships, whether national or international, appear likely to provide an effective new approach. To date much of the benefit from public private partnerships has understandably arisen from adapting technologies and products from other fields (e.g. veterinary use) to public health use e.g. as in the case of ivermectin. The potential offered by such partnerships is however far greater. There is now a great deal of evidence that, in order to tackle malaria, tuberculosis and a range of even more seriously neglected tropical diseases, long term investment in purpose-driven innovation is required and can in this way be attained. Several impressive portfolios of discovery and development projects are being developed through a number of different public private partnerships. If such progress continues it is anticipated that several new products will emerge over the next few years. However, all such partnerships recognize that they still need to demonstrate that they can be successful and sustainable in the long term. Financial support to these partnerships relies heavily on philanthropic funds and "in kind" pharmaceutical industry support and money from these sources will only continue to flow if results are obtained. Various governments are supportive, but more substantive government / public sector support appears warranted given the public sector interest in this area.

There needs to be a recognition that engagement of developing country institutions in priority setting, planning, innovation and delivery of products is essential for sustainable solutions.

A greater emphasis on capability strengthening and capacity utilization within developing countries to contribute to such innovation is also required. Within this context the concept of "equitable partnerships" was highlighted. There needs to be a recognition that engagement of developing country institutions in priority setting, planning, innovation and delivery of products is essential for sustainable solutions.

PREVENTING CERVICAL CANCER - A WAY FORWARD?

A vaccine against HPV infection - the usual cause of cancer of the cervix - is available; ideally it should be given early in adolescence, but few developing countries have the possibility to administer it widely to such subjects and maintain the programme over many years. Much may be learnt from the methods that achieved widespread immunization against hepatitis B. One will need partnership between the programmes handling sexual and reproductive health, immunization, adolescent health and cancer registries developed and cultural acceptance assured; one must assure adequate vaccine supplies of good quality from multiple sources at fair prices. Government agencies, manufacturers and donors must all work together and the financial basis for the effort must be sound.

- From a presentation to the Conference by P. Zuber and J.M. Okwo-Bele (WHO)

Approaches:

1. While development of curative drugs continues to be of importance, the range of infectious conditions for which preventive vaccination is known or believed to be feasible continues to grow. Diseases such as malaria, HIV/AIDS and tuberculosis represent major areas in which this approach seems vital, but the world will demand long term investment, since the technical hurdles likely to be encountered in developing vaccines against these diseases are immense. Various other diseases such as pneumococcal, rotavirus and Human Papilloma Virus infections, which kill several million people annually, are all potential fields for the development of improved or entirely novel vaccines.

2. It must however be realized that the problems in tackling many of these diseases through vaccination are not merely technical. Obstacles presented by price and the limited ability of many health systems to purchase such products and then to deliver them effectively remain major barriers which, alongside the technical difficulties in innovation, will need to be overcome if this approach is to be effective and is remain sustainable over a long period. As a rule, health systems have given a high priority to vaccination programmes in the areas in which these already exist, but extension to cover additional diseases may all too ready outrun the capacity of these systems to meet the costs.

3. The Conference noted with approval the fact that Advance Market Commitment as a means of funding vaccine development is now to be tested for pneumococcal vaccines and it expressed appreciation of the establishment of the International Financing Facility for immunization under the auspices of GAVI.

Government agencies, manufacturers and donors must all work together and the financial basis for the effort must be sound.

Neglected diseases and neglected populations

In the search for cures, many very widespread diseases have been neglected, especially where they affect mostly weak or remote populations and they still represent a serious burden, preventing countries from developing adequately as well as giving rise to much suffering. In the world as a whole, the number of people afflicted with these neglected diseases has in recent years risen. The populations concerned are most commonly the rural poor, with a low level of literacy and little political influence, and their problems tend to be "invisible" at the global level. Some conditions, such as schistosomiasis, are accorded a low priority in investigational work because, despite their frequency and the misery they cause, they carry a low mortality. In many cases new drugs are needed, but a commercially based drug industry has little motivation to invest in devising drugs for populations so poor that patients will be unable to pay for them. In some cases, pharmaceutical companies with rich earnings from other sources have provided free drugs on a large scale to meet such third world needs, but there is obviously a limit to such initiatives and this is not a sustainable means of meeting most of the needs of these populations. Too often, governments in the countries where such diseases are endemic have failed to improve their management of water supplies, sanitation and the environment in order to reduce population exposure to risks.

A VAST AREA OF NEGLECT

Let us first look at what neglected tropical diseases mean - where they occur, why they occur, the damage they cause, and why we should care. Throughout the developing world, socioeconomic progress is impeded by these ancient and entrenched diseases. They maim, debilitate, blind, disfigure, and kill. They permanently diminish human potential, and do so in large populations. If emerging, like SARS or pandemic influenza, are at the high end of the health and security agenda, the neclected tropical diseases are at the other end. These are not new and frightening diseases. They are ancient. They do not flare up in outbreaks with high mortality. They do not grap the headlines. They do not travel abroad or threaten international security. These are largely invisible diseases, occurring as they do in impoverished rural areas and shantytowns. They are rarely seen today in populations that enjoy good access to health services and a resonable standard of living. And these are silent diseases, affecting as they do populations with low literacy and little political voice.

- *From the paper presented to the Conference by Dr Magaret Chan, Director-General of WHO*

The Big Three on neglected diseases - HIV/AIDS, malaria, and tuberculosis - primarily affect people in poor countries but secondarily affect in industrialized countries (e.g. people who contract malaria while travelling). Therefore, a amall market exists, as do some R&D efforts. The most neglected diseases include human African trypanosomiasis (also know as sleeping sickness), South American trypanosomiasis (also know as Chagas disease), Buruli ulcer, dengue fever, leishmaniasis, leprosy, lymphatic filariasis, and schistosomiasis.....

- *From the paper presented to the Conference by Dr Bernard Pecoul, Drugs for Neglected Diseases Initiative*

Approaches:

1. New solutions here must include more effective collaboration between parties. This must extend to partnerships between governments and the industry to fund and carry out research, public and private research partnerships, and more international networking between researchers. In particular, the industrialized world needs to realize the global burden, in terms both of health and the economy that is imposed by diseases prevalent in developing countries.

2. Alongside the other measures listed at various points in this report, some form of global subsidy should be considered as a means of funding the supply of necessary medicinal products to the world's poorest populations.

3. Especially in this field, there is a need for more research to be carried out in developing countries; the more advanced developing countries can make a major contribution, but some types of innovative research can today be carried out by relatively small organizations, e.g. working in the area of biotechnology; basic discoveries made in such small units can then be further developed elsewhere. This has been demonstrated in western countries, where even large pharmaceutical companies are increasingly relying on basic innovation from such independent sources. Increasingly also many western companies are accessing skills cost-effectively from within developing countries. The potential exists to further develop innovation activities in developing countries. Bilateral donor agreements could well play a role in promoting such initiatives.

4. It is likely to be helpful to examine critically the many traditional remedies that are still in use; many developing countries have a rich herbal tradition of their own that merits careful observation and study. Not all the remedies in use prove to have novel components or effects, but some can form the basis for sustainable local use and, with further development, provide a starting point for creating new and scientifically based remedies for more widespread use.

FROM TRADITION TO SCIENCE : THE CASE OF ARTEMESIN

There are many examples from the past of traditional remedies being assimilated successfully into scientific medicine (atropine, reserpine, quinine, senna etc.) In some classic instances that has been due to clinical vigilance followed by specific investigation, such as when Dr. William Withering identified and developed digitalis after examining the traditional use of the foxglove leaf in cardiac oedema (Withering, 1785). A modern parallel concerns the manner in which North Vietnam set out to find a treatment for malaria; an appeal by Ho Chi Minh to Chinese medical researchers led to their identifying artemesinin as the active element in the traditional plant remedy *qinghaosu,* and thence to the availability of modern artemesin preparations in widespread use against malaria today.

...there is no justification in giving way to political, corporate or other forms of pressure - products introduced as a result of attempt to compromise have often had to be withdrawn after doing more harm than good.

Tackling Development

The basic discovery of a new drug or other possible method of preventing or treating disease is no more than an initial step, after which the effectiveness, safety and feasibility of the approach has to be tested systematically. A number of obstacles to development can still arise at this stage as a result of which a potentially valuable substance or method remains unused.

Firstly, while many basic discoveries are developed rapidly into usable products, it does happen that its possible value may have been overlooked or it may be of no interest to the originator. Various non-profit or other organizations now exist that are capable of obtaining and further testing such products from firms and institutions and when appropriate developing them further, and a number of neglected products have already been rendered usable in this way.

Regulatory barriers, while created in the public interest, may themselves cause problems. There is a need for balance here; issues of safety, practical use, mass production and cost all have to be solved. The industry in particular has often pointed to instances in which drug regulation has raised excessive demands, thereby increasing costs and causing delays Hesitation to accept an entirely new product is in part understandable, especially because society has been rendered cautious and even suspicious by some dramatic drug accidents. On the other hand, these issues must always be dealt with dispassionately and scientifically; there is no justification in giving way to political, corporate or other forms of pressure - products introduced as a result of attempt to compromise have often had to be withdrawn after doing more harm than good. In principle:

a Risk/benefit considerations will and should always remain basic to drug approval but decisions sometimes have to be taken in marginal situations and may be vigorously challenged. There must always be a fair opportunity to appeal on scientific grounds against a restrictive or negative decision.

b Standards set for quality must be high but at the same time realistic in terms of cost, attainability and public health needs.

c The information on a drug provided to professionals and users must be fully in accordance with the approved data on its properties and appropriate use.

One cause of delay and error can be uncertainty and lack of experience within national agencies in dealing with manufacturers and suppliers so as to ensure that products of sufficient quality will be supplied dependably and at a fair price.

The World Health Organization's Prequalification process is of value here, being voluntary, well-recognized, transparent and technically sound. Currently some 160 products have been pre-qualified, including antiretroviral agents, tuberculosis and anti-malarial. There is a need however to further support this activity.

Approaches:

1. Where a promise of a new treatment or technique arises, priorities need to be set for the management and financing of its further assessment and development, having regard to the degree of need and urgency in public health terms. An apparently true breakthrough or some other advance of evident public health significance may warrant regulatory priority and even public financing for its further development so long as the promise is maintained; a "me too" product that is no more than an insignificant commercial variant on what is already available will merit no such support.

In this respect, the TRIPS Agreement may prove helpful in that patents are to be granted only for genuine innovations and proven innovative steps; "me too" products are therefore not to be considered as discoveries. Much will however depend on manner in which this text is interpreted in practice.

2. While it is necessary to set proper quality standards in manufacturing, these must be realistic; some simple and safe drugs can be made and used safely and effectively without any urgent need to impose ideal international standards of "Good Manufacturing Practice"

3. The rapid development of the WHO prequalification scheme is laudable and should continue to expand as a means of accelerating the supply of drugs of sufficient quality and overcoming delays due to understaffing or lack of experience in regulatory systems. The scheme also provides a valuable means of upgrading the standards of inspectorates, regulatory agencies and quality control laboratories.

TRIPS Agreement may prove helpful in that patents are to be granted only for genuine innovations and proven innovative steps.

4. The trend to international and regional collaboration in drug licensing, drug information systems and adverse reaction monitoring should be accelerated as a means of avoiding unjustified decisions or unnecessary delays and optimizing the use of scarce manpower. This will however not obviate the need to build up and strengthen capacity among developing country's national regulatory authority so as to ensure effective management and facilitate the licensing of products.

5. It is noted that some useful drugs are no longer produced because demand is too limited to justify the cost of production. Here too the prequalification of small low-cost suppliers, where these can be identified, can restore the availability of these products.

Distribution, Access and Implementation

Too often in the past, a potentially valuable health innovation has been overlooked or even actively opposed by the medical establishment or society as a whole. The eighteenth century discovery that intake of fruit could prevent scurvy remained unused in some countries for many decades. Even at the present day, the means available to counter such conditions as premature cardiac disease, diabetes or obesity are much under-used, largely because of poor acceptance in the community. Much effort and time was needed before the use of zinc in the management of diarrhea became widely accepted. Even in an industrialized country there may be widespread apathy towards health-promoting measures relating to lifestyle or disease screening, while the authorities may regard the treatment of illness primarily as a "soft" humanitarian issue that may have low priority when priorities are being set.

A severe and widespread problem, especially in developing countries but also in some industrialized societies, is that of drug pricing, which can place much needed products out of reach of those who need them.

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Approaches:

1. Many governments underestimate seriously the social and economic costs of disease and hence the major benefits to their countries that would accrue from better prophylaxis, diagnosis and treatment. Global efforts are needed to provide evidence and convince society of the need for change.

2. Within countries Ministries of Health tend to find themselves in a relatively weak position as compared with other sectors of government, especially where proposed measures to promote health might appear to impair immediate prospects for export or employment. Closer inter-ministerial contact is vital if progress is to be made and the economic importance of health is to be reflected in overall policies. It is to be hoped that Ministries of Finance will be represented at future Conferences of this type.

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There is a need for developing country governments to build up their capacity in national drug regulatory as well as the management of intellectual property.

The responsibility of parties

While the Conference laid much emphasis on the need for broad collaboration between parties having complementary interests, it also examined the responsibilities of some of these parties, responsibilities that are not always fully recognized or shouldered.

1. Governments : Governments need to set priorities in their policies regarding drugs. The emphasis needs to be on proactive encouragement to develop drugs and interventions of potential health benefit as well as limiting the use of inappropriate treatment and removing of inferior preparations from the market. In some cases, combinations of drugs may provide a simple approach to certain illnesses or to prophylactic programmes. In other instances, however the opposite applies; if, as in some countries, a thiazide diuretic is no longer available as a single product but only in combination with a patented antihypertensive agent, the public will be deprived of one of the simplest and most valuable tools to treat circulatory disorders at low cost. In such matters, governments must take an active role in delineating the market.

Viewed more broadly, Governments can and must play a crucial role in dealing with and removing financial barriers to access; negotiation of fair prices with a primary manufacturer will solve some problems, and will be greatly aided where such a supplier agrees to a considerable degree of transparency on financial matters or is prepared to issue a voluntary license; in other cases there may be a need in the public interest to use methods such as compulsory licensing. Where products still remain out of the reach of major population groups, various forms of public subsidy will be called for. These mechanisms must also be balanced against the need to encourage and promote continued innovation. There is a need for developing country governments to build up their capacity in national drug regulatory as well as the management of intellectual property.

Many countries have adopted "national drug policies" but as a rule these are only in part institutionalized (primarily with respect to drug approval and price controls).

CHINA : PROGRESS TOWARDS AN IDEAL BALANCE

Over a period of half a century, the People's Republic of China has adopted varying approaches to health needs. During an initial period of centrailzed policies an institutional basis for medicine, science and technology was created, and the Chinese Centre for Disease Control and Prevention was established. A period of political isolation stimulated successful research, e.g. into new vaccines, The move to a socialist market economy led health care to be regarded as a service industry, and goverment spending declined. Subsequent realization that health is also a social welfare issue, affecting economic growth and social stability has led to renewed goverment leadership in scientific and technological innovation, including heavy investment in drug development and the elimination of major infections.

- *From the presentation to the Conference by Prof Yiming Shao*

Approaches:

1. A fully institutionalized "national drug policy" is needed in every country if there is to be a balanced approach to public needs. This should encompass clear procedures for ensuring ongoing development of new drugs and therapies, approval systems for products to promote efficacy, safety, quality and the provision of information, financial systems designed to bring drugs and treatments within reach of the entire population and measures to promote their general acceptance and appropriate use. In all these matters, governments need to play an active and not merely a reactive role if the public interest is to be served.

2. Drug policy is only a component of overall health policy, and here very much the same need for active and not merely passive involvement applies, for example in ensuring community-wide adoption of healthy lifestyles with respect to diet and physical activity.

...governments need to play an active and not merely a reactive role if the public interest is to be served.

...it is also essential that there be a more open exchange of ideas and information between industries and governments if sufficient trust is to be created and a fair financial balance achieved.

2. The Health Products Industry : It is recognized that this industry, with the pharmaceutical industry as its largest component, cannot always be expected to invest heavily in innovation in those areas in which little return on investment is to be expected, either because the health problem concerned is not widespread or because the population concerned does not have the means to pay for it. While various solutions advanced elsewhere in this report (including public-private partnerships) may relieve this problem, it is also essential that there be a more open exchange of ideas and information between industries and governments if sufficient trust is to be created and a fair financial balance achieved. By virtue of its technical dominance of the field, the industry has unavoidably assumed a responsibility for its acts to society as a whole, and in particular to the developing world, that has not frequently featured in its priorities and plans but that could with due effort come to offer a rewarding field of operation for the industry later in this century. To attain that, the industry will need to play an active and also a sympathetic role in these countries, providing stimuli and opportunities for their growth. Pricing policies will need to be restrained, opportunities for technical collaboration sought, and technological transfer actively practiced.

THE PHARMACEUTICAL INDUSTRY - FOR BETTER OF WORSE

The pharmaceutical industry earned itself an enviable reputation for creating new and valuable drugs over a period of decades. Critics point however to the extent to which the industry's sense of social responsibility can now be questioned; contested issued relate to excessive profits, pricingand publicity, lack of transparency, frequent indifference to the needs of the developing world and to serious cases of concealment or distortion of un-favourable scientific data. Firms need to meet this critcism by behavioral change rather than by image-building.

- From contribuitons to the debate at the Conference

3. International Governmental Organizations :

International organizations can do a great deal to promote the sharing of responsibility between richer and poorer countries, with the latter assuming a relatively greater part of the global public health burden. All such organizations experience pressure from many sides and find themselves tempted to accede to the demands of their most powerful and influential members. In a world where the imbalance between countries is so extreme however an international body must seek to accord more weight than hitherto to the views and needs of its many weaker members, who together will shape the global future.

Where two international bodies both deal with a particular area, it is vital that each represent individually the particular responsibilities accorded to it; in the area of patented health technology, for example, it is reasonable to expect that while the World Trade Organization represents the reasonable interests of the patent holders, the World Health Organization will remain committed to the health interest of populations. Effective but competitive advocacy by two such bodies is more likely to lead to balance than an attempt by either to reach a compromise.

International organizations can do a great deal to promote the sharing of responsibility between richer and poorer countries.

Effective but competitive advocacy by two such bodies is more likely to lead to balance than an attempt by either to reach a compromise.

There is no doubt that altruistic bodies of this type are now playing and must continue to play a significant role in guiding society towards an effective implementation of health care.

4. Non-Governmental Organizations : Over a period of little more than two decades a series of influential public interest bodies have emerged in the health field, some purely national and others operating globally. Often originating as lobbying groups or consumer associations, these bodies have at their best become vital champions of public health causes, possessing much expert knowledge and experience and commonly providing technical services of their own. Organisations such as *Médécins sans Frontières* have gained respect and influence because of their proven idealism, independence and transparent honesty. In this respect they can prove more influential than either professional or industrial bodies that have their own interests and agendas. There is no doubt that altruistic bodies of this type are now playing and must continue to play a significant role in guiding society towards an effective implementation of health care, either by their well-founded influence alone or by their active involvement, frequently either complementing or strengthening the role of government.

HEARTFILE : A SMALL BUT VALUABLE N.G.O.

Heartfile in Pakistan is characterised as a modest nationally-based non-government organization, independent but under-resourced. It has sought to ensure that issues of cardiovascular health receive sufficient attention in national policy, establishing as one of its earliest activities a demonstration project. Using authoritative global statistics it created a wide realization of the prominence of cardiovascular disease among the documented risks to health, often translating figures into readily understood and persuasive text for policy makers. Heartfile has developed memoranda of understanding with municipal and national bodies and built it plays a role in developing policies and in planing and ensuring effective implementation.

- From a presentation to the Conference by Dr. Sania Nishtar, Pakistan

General Conclusions

While the problems examined by the Conference were numerous and serious in degree, it found that there were grounds for optimism and evidence of commitment from many sides.

"COMMITMENTS BY ALL KEY PARTNERS..."

"...discussions during the two days indicate strong commitments by all key partners... This includes national governments, scientific communities, non-government organizations, private sector (especially the pharmaceutical industry), private foundations and philanthropic agencies in shaping the Discovery, Development and Delivery of essential health technologies...

...In the context of the report by the Commission on Intellectual Property, Innovation and Public Health, much work needs to be done in the bridging of Discovery to Development and Development to effective Delivery. We do need more fora for the constructive dialogue among all stakeholders and this Prince Mahidol Award Conference can be one of them."

- *From the closing address by the Minister of Public Health of Thailand, Dr. Mongkol Na Songkhla*

In most or all of the areas discussed, examples are to be found of successes, especially where there is a willingness to think laterally in searching for new solutions, to plan globally, to engage in broad collaboration between parties, and to compromise where necessary without at any point abandoning the primary interest of promoting and maintaining public health. In all these matters, however, it will be necessary to create and maintain efficient and robust health systems, capable of translating scientific progress into practical and accessible measures to advance public health.

We do need more fora for the constructive dialogue among all stakeholders and this Prince Mahidol Award Conference can be one of them.


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Reaching Neglected
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Annex

Annex I

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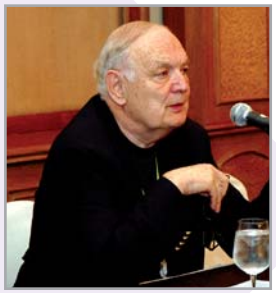
Annex II

Session	Chair person	Speaker	Rapporteur
Keynote speech: Access to essential health technologies: global perspective		Dr. Margaret Chan Dr. Dilip Mahalanabis Prof. Stanley G. Schultz	
Panel 1: From Discovery to Development to Delivery of health technology-challenges and lessons learned	Dr. Omi Shigeru	Sir Richard Peto Prof. P. Roy Vagelos Prof. Nicholas White	Mr. Tom Blair Dr. Rosalia Sciortino Dr. Piya Hanvoravongchai
Session 1.1 : From Discovery to Development: the cases of neglected diseases	Dr. Howard Zucker	Dr. Olivier Fontaine Prof. Paul Herrling Prof. Joanne Webster	Mr. James Arkinstall Ms. Chutima Akaleephan Dr. Nithima Sumpradit Dr. Chanwit Tribuddharat
Session 1.2 : The emerging roles of scientifically and technologically advanced developing countries in Discovery and Development of essential health technologies and the role of productions of generic products	Dr. Richard Nesbit	Prof. N.K. Ganguly Dr. Hans Hogerzeil Dr. Navaratnam Visveswaran Prof. Shao Yiming	Dr. Eamonn Murphy Dr. Petcharat Pongcharoensuk Dr. Pathom Sawanpanyalert
Session 1.3 : Product development partnership (public-private, North-South, South-South collaborations) on Discovery and Development of health technologies	Dr. Lincoln Chen	Dr. Javier Guzman Dr. Bernard Pecoul Dr. P. V. Venugopal	Dr. John Bryant Dr. Churnrurtai Kanchanachitra Dr. Sirinmas Katchamart Dr. Myat Htoo Razak
Session 2.1 : From Discovery to Development and to Delivery of essential health technologies: the role of Innovative Financing Mechanisms	Dr. Ellen T. Hoen	Ms. Amie Batson Prof. Sulamis Dain Dr. Tim Hubbard Prof. Michel Kazatchkine	Mr. James Arkinstall Dr. Jutamas Arunanondchai Dr. Siriwan Pitayarangsarit Ms.Waranya Teokul
Session 2.2 : TRIPS flexibility and access to medicine, the case of new ARV medicines	Dr. Fadia M. Saadah	Dr. Harvey Bale Prof. Carlos Correa Dr. Martin Khor	Ms.Chutima Akaleephan Ms. Cecilia Oh Dr. Jiraporn Limpananont
Session 3.1 : From Development to Delivery: the case of access to HPV vaccine for prevention of cervical cancer	Prof. Dr. Pornchai Matangkasombut	Dr. Hugues Bogaerts Dr. Julian Lob Levyt Prof. Khunying Kobchitt Limpaphayom Dr. Jean-Marie Okwo-Bele	Ms. Tara Acharya Dr. Han Hogerzeil Dr. Supon Limwattananon Dr.Yot Teerawattananon
Session 3.2 : From Development to Delivery: access to prevention, screening, diagnostics and treatments for non-communicable diseases	Dr. Myint Htwe	Dr. Gauden Galea Prof. Stephen Leeder Dr. Sania Nishtar Prof. K. Srinath Reddy	Dr. Katherine Bond Dr. Weerasak Putthasri Dr. Pornchai O-charoenrat
Panel 2 : The way forward: Immediate actions to stimulate Discovery, Development and improved access to essential health technology	Prof. Dr. Vicharn Panich	Dr. David Nabarro Dr. A.E.O. Ogwell Prof. Pakdee Pothisiri	Dr. Robert Oelrichs Ms. Daisy Mafubelu

Leading Rapporteur



Dr. Graham Dukes

Dr. Viroj Tangcharoensathien

Dr. Robert G. Ridley

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