Workshop on Differential Pricing and Financing of Essential Drugs
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Session I: Access to Essential Drugs in Poor Countries -- Key Issues The Industry Perspective

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Summary of Presentation

The program calls for this session to provide an overview of the obstacles to access to essential medicines in poor countries – and examine the relative importance of various factors affecting access (e.g., financing, pricing) *and* to address the significance of patent protection. This is an ambitious agenda.

The title and the *chapeau* introduction to the session differ in their reference to countries – "poor" versus (in the *chapeau*) "developing." Many of the latter countries can and do undertake to provide for most of their public health obligations, whereas most of the HIPC's do not have the resources to meet public health needs -- although even here there is sometimes a question of the relatively low level priority given to health care in national spending priorities. Further, many "developing" countries – and even some "poor" ones -- have a significant, relatively prosperous, class of people possessing public or private insurance schemes or exercising an ability to pay for medicines. These countries however have a larger "underclass" of people who lack access even to basic health care. As discussed below, we need to take these differences into account in designing and distinguishing targeted programs to improve access to health care including medicines.

This presentation is divided into three parts covering discussions of: (A) the role of industry in providing health care; (B) a discussion of barriers to access: and, (C) providing views on the issues of financing and differential pricing.

Part A. The primary role of the research-based pharmaceutical industry is to discover and to develop innovative medicines and vaccines, and to manufacture them under quality conditions. The four key policy elements in promoting innovation are: (1) a high standard of enforceable intellectual property protection (IPP, for patents, trademarks, etc.); (2) a system of quality, efficacy and safety regulations for medicines approvals, (3) macro- and micro-economic policies that foster innovation at the national level; and (4) mechanisms for informing and promoting new medicines to medical professionals (and, possibly, patients -- with

the INTERNET becoming an increasingly important mechanism for patients to address their particular conditions).

The pharmaceutical industry, relative to other industrial sectors, is very heavily dependent on IPP protection – especially patent protection – in order to develop and introduce new pharmaceutical products (see table below).

Relative Reliance of Biopharmaceutical Industry on IPP

Industry	*%Developed*	*%Introduced*
Pharmaceuticals	**65%**	**60%**
Chemicals	30	38
Petroleum	18	25
Machinery	15	17
Fabricated Metal Products	12	12
Primary Metals	8	1
Electrical Equipment	4	11
Instruments	1	1
Office Equipment	0	0
Motor Vehicles	0	0
Rubber	0	0
Textiles	0	0

* Two numerical columns showing the percentage of products that, according to survey, would not have been developed and introduced, respectively, ranged by industry.
Source: E. Mansfield, Management Science (February 1986)

The "Human Genome Project" is multiplying the scope of application of chemical applications to treat currently intractable disease targets. However, drugs and vaccines are expensive to develop; but they are often very cheap to copy, intellectual property protection is a necessary incentive for the discovery and development of new medicines. The evidence suggests that the pharmaceutical industry (and its cousin the health-related biotechnology industry) is the most reliant of manufacturing sectors on IPP to justify substantial investments, comparable in terms of dependency of other selected sectors such as software, books, films and recordings (these being copyright-dependent). Because of strong IPP protection and strengthened global rules under TRIPS, the industry is conducting research and development into more than 100 new drugs and vaccines for HIV/AIDS and related conditions, more than 130 new drugs and vaccines for various other infectious diseases, etc.

Patent and other forms of IPP may not be sufficient to develop drugs and vaccines in all areas of need as determined by public health authorities. Science obstacles can be a critical barrier to developing cures or vaccines in certain areas (e.g., AIDS cures and vaccines). In addition, there must be a market created for the critical role of the private sector to be performed. To do this, some countries have enacted "orphan-drug" legislation to provide additional incentives to industry to develop medicines for diseases affecting very small populations.

But IPP has, as Abraham Lincoln stated over 140 years ago, been a system that has provided the "fuel of interest to the fire of genius" and without it the

private sector will not invest the hundreds of millions of dollars needed to develop new vaccines for AIDS and other infectious and non-infectious diseases.

Access is the main issue of the conference, but indirect negative effects on access will occur if attempts to weaken the level of IPP succeeded in discouraging specially targeted R&D (e.g., HIV/AIDS) and in discouraging a number of developing countries (e.g., China, India, Korea) from progressing their emerging R&D pharmaceutical and biotech industry. It must be kept in mind that the small company model of investment in biotechnology research is not limited to the USA or Europe, but is adaptable to many developing countries. However, these countries sometimes lack the intellectual property and other policy actions needed to develop local expertise, which could reduce the economically and socially debilitating "brain drain" flow. Increasing research capacity in developing countries is at least partially equated to increasing IPP, and if mistaken efforts to weaken IPP are avoided, TRIPS will be seen naturally over time as a contribution, not an impediment, to improved access. And conversely, weakened IPP translates to reduced incentives by the current R&D industry and potential new entrants in a number of developing countries to find accessible new technologies now lacking for diseases prevalent primarily in these countries.

Part B. The serious matter of access to essential medicines in developing countries risks being misconstrued -- unless attention is paid to the problem of access to medicines that have been on the market for decades and have lost their patent protection. Some groups derive, from the WHO Director-General's statement of fact that a third of the world's population lacks access to quality essential medicines, the wrong conclusion that patents are the problem. This ignores the reality that nearly all of these medicines are off-patent -- and have been so for a number of years. We cannot possibly address the problem of access to *newer* medicines unless we learn the lessons of why *older* medicines (for TB, ARI's, etc.) are not being delivered to patients who need them. For example, we see in the recent UN-industry Accelerating Access Initiative for AIDS drugs, that while prices have been greatly reduced (in some cases to below-cost or to zero) the uptake in utilization is seriously limited, pointing to some of the same problems that prevent *older* medicines from getting to patients – lack of health prioritization, winting to12.75 roa des- 47u Tccen05 Tcs317lilp Tf rtiae1 4ieD D /F048 Tc -0.D (e.g.2175 Tw

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> "Unexpectedly, the private sector…is in many cases more generous than governments. One company (Bristol Myers Squibb) has committed $37 million of grants since mid-1999 which is more than that of some DAC governments."…"Despite nevirapine…being available for free…without wealthy governments offering aid to distribute the drug, only a few developing countries can implement control of mother-to-child-transmission" of HIV/AIDS (Lancet 6 January 2001)

We need to be realistic -- not ideological – in recognition that the private sector role is constrained by what public authorities are prepared to undertake.

Part C. Finally, what are the respective roles of the much-discussed differential pricing and financial issues? This is the final question we are asked to address.

Frankly, it is impossible to deny that, at this point in time and in the context of efforts to expand access to essential medicines for HIV/AIDS and other infectious diseases, the *financial issues* are predominant. To repeat, we have seen that reduced prices for HIV/AIDS drugs are having little current effect on treatment levels so far. From an industry perspective, there is an imbalance seen in the actions necessary by all stakeholders, inasmuch as while a number of companies have reduced their prices on ARV's and OI medicines for HIV/AIDS, the problem of financing of infrastructure and medicine acquisition is seriously lacking and is imposing the critical barrier to increased access to these therapies. Meanwhile therapeutic and vaccine research within industry goes on trying to find new cures and preventions for this affliction.

It is unfortunate – with ultimate costs to be borne by current and future patients -- that some OECD governments are prepared to allow IPP be seen as a barrier to access, suggesting that the industry should "do more", and also suggesting that industry avoid or withdraw from any purely legitimate legal efforts to protect patents -- while continuing themselves to stall in efforts to increase the flow of funds to enable poor developing countries to take advantage of reduced prices. Without adequate North-South transfers, not only will efforts fail to improve access to HIV/AIDS therapies, but additionally, access to other essential medicines are certain to fall well short of what would be considered acceptable. Meanwhile efforts to re-open old debates about TRIPS could have the effect of discouraging new research and development.

If governments wish to introduce conditions to support differential pricing (and this concept is *not* the same as, but quite different from "tiered pricing" in its feasibility and consequences) the following factors are among those that need to be addressed:

(1) *Avoiding product diversion from* populations intended to receive either discounted prices or donations, which is in fact a more general proposition than merely avoiding "parallel trade", since it is both an international and a domestic diversion issue;

fortunately, though some argue erroneously that TRIPS condones parallel trade, the TRIPS agreement in fact provides the framework for addressing parallel trade in national legislation by providing, in Article 28, the right to control importation by the patent holder;

(2) *Ensuring that a "market" exists* – related to the discussion above on financing few developing countries can fund public health needs thus discouraging companies from serving poorer populations other than through donation programs (i.e., "access determines price levels" as much or more than "price determines access.");

(3) *Protecting intellectual property* -- otherwise it is fruitless to ask companies to make a long term commitment to R&D into

(10) Recognizing the importance of maintaining secure *donation programs* that have helped sustain disease-targeted programs in developing countries (e.g., river blindness, leprosy);

(11) Respecting the *legal (antitrust) and competitive conditions* that prevent companies from making any joint commitments on matters such as licensing and prices;

(12) Considering the necessity of making the provision of medicines to developing countries by companies, including generic companies, a *sustainable undertaking* meaning that a positive level of financial returns will be required;

On behalf of the members of IFPMA from developed and developing countries, we look forward to the deliberations in Oslo and thank the WHO and WTO, along with the Norwegian government and other sponsors, for inviting industry representatives to be included in this unique and important discussion.