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Differentiated Pricing of Patented Products

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DIFFERENTIATED PRICING OF PATENTED PRODUCTS

The development of pharmaceutical products requires enormous expenditures for research and clinical trials. On a per-unit basis, these costs are generally quite large compared to the actual marginal production cost of producing the product. Unless these expenditures are absorbed by taxpayers through subsidies to research, they must be absorbed by patients, either directly or through intermediary health care organizations (which may themselves be taxpayer-supported). Typically, the patent system is used to permit a higher-than-marginal-cost price for the first generation of patients (and the relevant intermediaries), who absorb this development cost. After the product goes off patent, the price normally falls, so that future patients face a cost closer to the marginal cost of production and distribution.[1]

It is equitable that wealthier patients pay a relatively larger share of the research and development costs. This equitable allocation of costs can be achieved by "tiered pricing" also called "equitable pricing," under which patients in developed, high-income nations pay higher prices than patients in developing, low-income nations.[2] To maintain

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[1] Note that there are actually two kinds of "fixed costs:" those associated with research and development, and those associated with the construction of particular manufacturing plants. The "excess capacity" of a particular plant can be marketed at near marginal cost; larger amounts can be marketed only at a cost which permits recovery of incremental manufacturing capability, but need not permit recovery of research and development costs.

[2] The feasibility of such tiered pricing has recently received substantial attention. The leading current materials are those associated with the workshop organized by the World Health Organization and the World Trade Organization Secretariats, and those being discussed within Europe. See *Report of the Workshop on Differential Pricing and Financing of Essential Drugs*, 8-11 April 2001, Høsbjør, Norway, [hereinafter *Høsbjør Report*], available at http://www.wto.org/english/tratop_e/trips_e/tn_hosbjor_e.htm#news; the European Commission Issue Paper, *Tiered Pricing*, available at http://europa.eu.int/comm/trade/csc/med.htm; and the UK

this price difference, there must, of course, be barriers to the reverse (or arbitrage) flow of products from low-income nations to high-income nations.

Such a price differentiation appears unambiguously good, since it makes the product available to those in the developing world who would not otherwise be able to afford it, and allocates the cost of research in an equitable way, without harming patients in the developed world.[3] But a caveat should be noted – this is a sound approach to distributing the costs of products whose development is justified by the developed world market, but it leaves little or no incentive to develop products oriented primarily to the developing world market. For these products, there must be a return from the developing world patient or, more likely, from an international subsidy.

This paper reviews the current evidence on actual price differences between developed and developing nations, as well as what is known (or can be surmised) about the parallel trade market of reverse flows, and ways those flows can be affected. It then examines alternative ways to achieve equity in price discrimination. It finally makes recommendations on appropriate international law polices, and appropriate policies in developed and developing nations.

Performance and Innovation Unit, Cabinet Office, paper, *Tackling the Diseases of Poverty*, 8 May 2001, available at http://www.cabinet-office.gov.uk/innovation/.

[3] It is wise to note the precise relationship between the interests of the high-paying and the low-paying patient. If the pharmaceutical firm sets its price for a particular product in a profit-optimizing manner in the higher-price nation, that price would not be affected by the presence or absence of sales in other nations. Any receipts above marginal cost in the lower-income nations would contribute to overall profits, and would not lower costs to high-income patients. See *Høsbjør Report* at pp. 11-12. Note also, however, that any increase in overall profits would make drug development more appealing economically and would therefore increase the total availability of new pharmaceutical products to the world as a whole.

I. THE CURRENT REALITY OF PRICE DIFFERENTIATION

It is wise to begin by exploring the economics of a profit-maximizing pharmaceutical firm, on the assumption that the firm's markets can be separated. Such a firm will attempt to maximize its profits in each of its markets. In estimating whether to enter a particular market, the firm must compare the possible return from that market with the costs of entering the market. The possible return depends on the availability of exclusivity and on the character of the demand curve in the market. And, if this return is outweighed by fixed costs in entering a particular market (such as obtaining regulatory approval or creating a local distribution system), the firm may choose not to serve the market.

Exclusivity is especially important in determining price. Although it is usually viewed as deriving from patent protection is available, it may be available in many other ways, as through a trade-secret based monopoly on production capability, economies of scale of a type that make multiple entrance economically infeasible, or through exclusivity based on having the sole product approval. If exclusivity is available, one would, of course, expect a higher price. If exclusivity is not available, the price should normally fall toward marginal cost.

Where exclusivity is available, the firm will optimize against the available demand curve — and the firm's optimum price will be higher if the demand curve is

more inelastic. This is important in pharmaceuticals, where demand curves are likely to be relatively inelastic, because the purchaser is strongly interested in obtaining the product, subject to his or her ability to pay. This certainly implies that prices will generally be lower in nations with lower incomes. It also implies that the price may not be lower in nations with unbalanced income distributions — the pharmaceutical firm may find it much more rewarding to offer a product at a high price to the wealthy portion of the nation than to offer one at a low price to the much larger poor community.

And it is particularly important to take into account the differing patterns of purchases -- not only do some nations have price controls, but some have monopsonistic health service buyers, who are, of course, able to negotiate much better prices than individual patients.

But, there are important factors beyond price optimization that affect the real availability of pharmaceutical products in developing nations. In some cases, the market may be so small that firms may find they can serve it only at a high price or not at all. Or firms may fear that any products they offer will be smuggled into other nations. Other factors that may affect price include protectionism and corruption.[4] Moreover, even if the pharmaceuticals are available, the services to make them useable may not be available. Some products, for example, require regular diagnostic evaluations to be effectively used; if the diagnostic systems are not available, the price of the products is essentially irrelevant. And, in some cases, firms may fear that, without an adequate

[4] See the list in H. Bale, (International Federation of Pharmaceutical Manufacturers Associations), TRIPS, Pharmaceuticals and Developing Countries: Implications for Drug Access and Drug Development, WHO Workshop on the TRIPS Agreement and Its Impact on Pharmaceuticals, Jakarta, 2 May 2000.

medical infrastructure, drugs may be misused and may contribute to the emergence of disease resistance.

This very brief economic review suggests significant caution in assuming that prices will automatically be correlated with national income levels. There is almost certainly such an effect, but the actual prices are likely to reflect a number of other factors as well. This caution is reflected by the relatively limited empirical data that is available. A recent careful analysis, a United States International Trade Commission Study,[5] carefully begged off from producing a price comparison across different nations. And it also noted serious methodological issues, deriving from index issues associated with different mixes of pharmaceutical sales in different nations and from structural issues of comparing prices in systems whose market structures vary.

This study did, however, review a number of previous studies that compared prices in various developed nations. The most complete studies compare the various developed nations. They tell the important story that the prices within the developed and middle-income world rarely differ by more than a factor of three. It is useful to review the three most recent reports cited that actually produced indexes, and were discussed in the International Trade Commission study. One, a 1998 U.S. House of Representatives Minority Staff International Report,[6] calculated an index based on a small and equally-weighted sample of drugs. It found US prices to be 72 % higher than those in Canada and 102 % higher than those in Mexico. A 1998 study by Danzon &

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[5] United States International Trade Commission, Pricing of Prescription Drugs, Investigation No. 332-419, Publication 3333. December, 2000.

[6] Minority Staff International Report, "Prescription Drug Prices in the 1st Congressional District in Maine: An International Price Comparison."

Kim,[7] compared the prices of a number of cardiovascular products across nine developed nations. Although the precise numbers depended on the precise product definitions and weighting principles used, the extreme indexes (taking the United States as 1.00) were 3.728 for Japan and .398 for France. Most of the indexes were much closer to 1.00. A further study by Danzon and Chao[8] found indexes as low as .331 for Italy and as high as 1.282 for Japan.

In the overall scheme of things, these are not large differences, certainly not as large as the factor of 100 that differentiates UNICEF prices for purchases of vaccines from the developed-world prices for the same vaccines. (There are reasons why vaccine prices might differ more than those for other medicines. The product liability issues are especially important in the United States and must be reflected in the price. And the distribution system in the developing world is almost entirely in the public sector, and benefits from a uniquely favorable procurement structure managed by the international development community.)

Although data is much less available for comparing developing world pharmaceutical prices with those in the developed world, these comparisons sometimes show very substantial differences. One data set available, is that of Médecins sans Frontières' Campaign for Access to Essential Medicines, which has assembled price data

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[7] P. Danzon & J. Kim, "International Price Comparisons for Pharmaceuticals: Measurement and Policy Issues," Pharmacoeconomics **14** Suppl.1 (1998) p. 15.

[8] P. Danzon & L. Chao, "Cross-National Price Differences for Pharmaceuticals: How Large and Why?"

for certain HIV drugs.[9] Comparisons of developing nation prices with U.S. prices show factors as great 1 to 68, and a very approximate calculation of indexes (based on equal weighting of the available numbers) suggests overall prices on the order of 1/5th the U.S. price. Clearly then, significant price differences are, at least sometimes a reality. But the link to per capita income is still weak. The lowest prices (on average) were in India and Brazil — the first a low-income and the second a middle-income country. And the highest were in Columbia and Uganda, the first a middle-income and the last a very-low-income country. Income matters, but is far from the only factor.

This sense is strongly reflected in the more recent study by Scherer and Watal,[10] who perform a multiple regression of a data set on HIV drug prices in developing nations. They find, with high confidence, a slight income effect. But they also find that the effect is increasing over time, i.e., that the international pharmaceutical industry has been, over the last five years, reducing its prices in developing nations. And, using a demand curve analysis, they suggest that prices are particularly likely to be high in nations in which incomes are particularly maldistributed.

II. ENCOURAGING TIERED PRICING: KEEPING DEVELOPING-NATION PRICES LOW AND PREVENTING REVERSE FLOWS

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9 C. Pérez-Casas, HIV/AIDS Medicines Pricing Report, Setting objectives: is there a political will? Update: December 2000, available at www.accessmed-msf.org.

10 F.M. Scherer and J. Watal, Post-Trips Options for Access to Patented Medicines in Developing Countries, January 2000, prepared for Working Group 4 of the Commission for Macroeconomics and Health.

Based on the data just presented, there is already a substantial – but highly imperfect – tiered pricing system already in existence. There are two important issues in strengthening the system: ensuring that the price really will be low in the developing nation, and avoiding reverse flows that might undercut the price differentiation.

II.1 Keeping the price low in developing nations

The low price/income correlations that were just discussed leave doubt that prices will be kept low in developing nations simply by preventing reverse flows. One group of barriers are those imposed by the developing nations themselves, such as taxes and tariffs. Clearly, these need to be eliminated to make tier pricing possible. Another group of barriers are those imposed by the pricing policies of the pharmaceutical firms. Again, as just suggested (and as will be confirmed below in the discussion of alternatives to tier pricing), these policies may well be evolving toward greater voluntary price differentiation and tier pricing. This may in particular be the implication of the international controversy over imports of HIV products into South Africa during the late 1990s, when that nation passed a law to permit parallel imports (expected to be from India).[11] The dispute was resolved in April 2001 by settlement of a South African court

[11] The law was Section 15C of the Medicines and Related Substances Control Act 1965, added by the Medicines and Medical Devices Regulatory Authority Act of 1997. The U.S. pressure effort is documented in a letter from Barbara Larkin, Assistant Secretary, Legislative Affairs, U.S. Department of State, June 5, 1999, and the attached Report on U.S. Government Efforts to Negotiate the Repeal, Termination, or Withdrawal of Article 15(C) of the South African Medicine and Related Substances Act of 1965, published by an activist group at www.cptech.org. The issue was settled by a Joint Understanding Between the Governments of South Africa and the United States of America on 17 September 1999. For general background see, e.g., F. Abbott, The TRIPS-Legality of Measures Taken to Address Public Health Crises: Responding to USTR-State-Industry Positions that Undermine the WTO, forthcoming in Festschrift in honor of Robert Hudec; P. Bond, Globalization, Pharmaceutical Pricing and South African Health Policy, Int'l J. of Health Services **29** (1999).

action. The settlement, taking place in the midst of strong political forces, suggests that industry is broadly willing to accept tiered pricing, even beyond the poorest nations.

But, in at least some cases, it may be necessary to push the industry (and this may be especially true in nations with highly skewed income distributions). There are several options. Products (at least for public markets) may be purchased by groups that are sophisticated in the pricing issues, as is now done for vaccines. Or there may be long-term, large-scale arrangements such as those emerging under UNAIDS, that will be discussed in the next session. There can be price controls, and, if necessary, there can be compulsory license procedures.[12] And it is possible that some form of international expert group can assist in estimating marginal costs, and thus facilitate negotiations favorable to the developing nations.

Industry may find it difficult to discuss and negotiate over this issue, simply because cooperative industry discussions of price issues are competition law violations in

[12] Note, however, that the pattern of the South African case of 2001 may not be repeatable. In that case, South Africa was seeking to ensure the achievement of low prices by relying on imports from India. There was dispute in the case over whether South Africa was correctly using the compulsory license procedure authorized by the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), Article 31, but it is certainly possible for a nation to authorize imports under Article 31. However, it is not clear that TRIPS authorizes manufacture for export to such a market. This issue was moot in the particular case, since India did not yet apply patents to pharmaceutical products, but the issue will be serious in the future when essentially all nations apply such patents. Unless a mechanism to authorize manufacture in such circumstances is developed (or is in fact consistent with TRIPS, perhaps by an interpretation of Article 30 on exceptions to rights), the compulsory license process is feasible only for nations whose market is big enough to support manufacture, a highly inefficient response! The legal issue is quite unclear – as stated by a recent European Commission study, "Arguments by smaller developing countries that their right to issue compulsory licenses would be meaningless if they could not grant a license to a foreign manufacturer should be taken seriously, but TRIPs does not seem to give any legal certainty on this issues." See European Commission, Issue Group on Access to Medicines, Legal issues related to compulsory licensing under the TRIPS Agreement, (2001), available at http://europa.eu.int/comm/trade/pdf/med_lic.pdf.

many nations.[13] There are many ways to avoid this problem. One is by treating the issue on a company by company basis — and that is quite often adequate because different companies' products may not be directly competitive. Another is by ensuring that the key negotiations be in the public sector, e.g., under the auspices of national governments or international organizations. Almost certainly, this last approach is essential if there is to be any form of group that is, in effect, suggesting prices. Industry's legitimate competition law concerns must be recognized.

II.2 Reverse flows

Among the key issues in preserving or strengthening a tiered pricing system is the possibility of reverse flows, i.e. sales of products from lower-price markets to higher-price markets – such flows are a major concern to industry, which wishes to protect its higher price markets against price erosion. Even if the industry continues to make products available in the face of such arbitrage, the arbitrage might also raise the price of products to consumers in the low price nations. Hence, the avoidance of reverse flows is an extremely important issue in designing global tiered pricing system.

There is little empirical data on the actual flows. Much that is available is on transborder sales within the European Union, where there is a strong intellectual property/trade policy that products placed on the market within any member nation may

[13] See, Workshop on Differential Pricing and Financing of Essential Drugs, Background Note prepared by Jayashree Watal, Consultant to the WTO Secretariat, p. 21, available at http://www.wto.org/english/tratop_e/trips_e/tn_hosbjor_e.htm#news.

be marketed in other member nations as well.[14] One recent study shows a major growth in the number of licenses granted by the UK for such import.[15] Surprisingly, however, in spite of the legal possibility of trade here, there remain price differences.[16] But no matter what the actual numbers, one can anticipate that, as a global matter, this issue will be more serious in the future. Arbitrage is a natural reaction to price differences. And transborder sales of pharmaceuticals are almost certain to become easier with the internet, and with the magnitude of international travel. (Internet-based sales have already become a public heath concern at the domestic level.[17])

II.3 The law of reverse flows

There has been substantial discussion of the law governing these sales, and particularly of the precise scope and implications of the World Trade Organization's TRIPS Agreement.[18] In WTO parlance, the issue is one of "exhaustion," i.e., whether the right to use intellectual property law to prohibit marketing of a product is exhausted once

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[14] See generally, M. Farquharson & V. Smith, Special Report; Parallel Trade in Europe (Sweet & Maxwell, 1998); J. Ammann, Intellectual Property Rights and Parallel Imports, 26 Legal Issues of Euro. Integration 91 (1999).

[15] MPA Report on Parallel Import Licenses and Licensees, October 2000, described on the website of the British Association of European Pharmaceutical Distributors, http://www.api.org.uk/news_baepd_mpa1000.htm.

[16] Memorandum submitted by the Association of Pharmaceutical Importers, House of Commons Select Committee on Trade and Industry, Tuesday 11 May 1998.

[17] Statement by W. Hubbard, Senior Associate Commissioner for Policy, Planning and Legislation, Food and Drug Administration, before the Subcommittee on Oversight and Investigations, Committee on Commerce, U.S. House of Representatives, May 25, 2000, available at http://www.fda.gov/2000/internetsales.html.

[18] Agreement on Trade-Related Aspects of Intellectual Property Rights.

the product is marketed in one nation (in which case intellectual-property based restrictions on reverse flow would be impossible) or whether alternatively intellectual property rights are not exhausted and can be used again to prevent marketing in a new nation (in which case intellectual-property rights would be useable to prevent reverse flow).

Actually, it is quite clear that the TRIPS agreement is an agreement to disagree on the issue. Article 6 states:

> For the purpose of dispute settlement under this Agreement, subject to the provisions of Articles 3 [national treatment] and 4 [most-favored nation] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

The result is that nations may, subject to the national treatment and most-favored nation obligations, define their own law of parallel imports.[19] They may, as did South Africa,

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[19] There are industry arguments that another section of TRIPS, article 28, bans such imports, and that article 6 prohibits only dispute settlement in this context. See F. Abbott, supra. Article 28 provides:

A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing [footnote call] for these purposes that product;

The footnote reads

This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

This argument must certainly take into account the presence of this footnote. Given the goals of the international medical community with respect to tiered pricing, this is, in any event, a situation in which the needs of that community and of the pharmaceutical industry are closely aligned.

permit products properly marketed in third nations to be imported without regarding these products as infringing local intellectual property rights, or they may, as do many nations, permit intellectual property rights to be used to bar such parallel imports.

This means, of course, that national policies (set independently or in parallel) or a full international agreement, could, as a legal matter, easily be devised to make reverse flows illegal and thus to facilitate tiered pricing. There is a WTO non-discrimination issue if a nation or an agreement were to set up tiers of nations and authorize restrictions against imports from lower-price tiers, while permitting imports from other nations, but this problem can probably be solved by the private sector. Assuming the agreement permits — but does not require — use of local patent rights to bar imports of legitimately marketed products, a rational pharmaceutical firm would use its right to bar parallel imports that upset its intended tier prices, but would not assert its patent rights against itself if it chooses to make a product available in a number of different nations from a centralized production facility.

Intellectual property law is not the only law that can be used to help separate markets. In some cases, product approval procedures may be used. Thus, a product approval may authorize sales in a nation to be only of product produced in a particular production facility. Moreover, languages and packing labels can be used to help separate markets. These arrangements should, of course, be evaluated realistically. It is impractical to use any form of law to bar small international sales, perhaps made over the

internet. But regulatory or intellectual property law can be used to bar large scale sales, especially those intermediate in the distribution process or those to public health agencies.

II.4 Issues in developed nations

The key barrier here may not be what is possible under international law, but what is politically feasible in shaping the national law in the developed nation. Nowhere is this shown more clearly than in the United States, which passed a law in late 2000 to permit the import into the United States of certain pharmaceutical products from abroad.[20] The law derived from pressure from legislators from border states, whose constituents were complaining about the lower prices of pharmaceuticals in Canada. In doing so, it followed a long tradition of U.S. consumer protest against higher U.S. prices, a tradition that has led U.S. firms to be less willing to undertake tier pricing in even the vaccine world.[21] The 2000 law was strongly opposed by the U.S. pharmaceutical industry; and it was badly drafted, dealing solely with product approval issues and not explicitly considering intellectual property issues at all. It applied only to certain imports from a statutory list of nations with relatively sophisticated pharmaceutical approval capabilities,

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[20] This was the Medicine Equity and Drug Safety Act of 2000, Appropriations Bill for Food and Drug Adminstration, P.L. 106-387, section 745, Oct 28, 2000. The Bill included a separate provision, section 746, the Prescription Drug Import Fairness Act of 2000. The provision, which was not suspended by the Secretary, restricted the extent to which the FDA can send warning notices to individual importing FDA-approved drugs from abroad.

[21] This dates back to 1982 congressional hearings objecting to differences between U.S. and international prices,. See U.S. Institute of Medicine, The Children's Vaccine Initiative: Achieving the Vision, p. 72 (1993).

a list that included mainly OECD nations but did also include South Africa. Its operation was suspended by Secretary of Health and Human Services Shalala in late December 2000, under a provision of the act which required a determination, that she concluded she could not make, that the reimportation would pose no additional risk to the public's health and safety.[22]

Whether or not this kind of legislation is reconsidered,[23] it reflects a concern in the United States (and perhaps in other developed nations as well) that domestic consumers should have the benefit of foreign low prices. And the issue goes well beyond the United States – many developed nations have "reference pricing systems" designed to ensure that their consumers (or national medical authorities) pay no more than other nations.[24] This network and the underlying political concerns must be dealt with in any international plan for tier pricing.

III. APPROACHES OTHER THAN TIER PRICING

The use of tiered pricing is not the only approach that may help in making important pharmaceuticals available to patients in developing nations. Other examples include gifts and special agreements.

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[22] Letter to President Clinton, Dec. 26, 2000.

[23] The Congressional Research Service has prepared a legal memorandum stating that future Secretaries of Health and Human Service could reverse Secretary Shalala's determination and bring the legislation back into force. Memorandum from Morton Rosenberg to Hon. James Jeffords, Effect of the Secretary of Health and Human Services' Failure to Make the Demonstration Required by the Medicine and Drug Safety Act of 2000 On Any Possible Future Implementation of the Act, January 9, 2001

[24] Høsbjør Report at page 23.

The pharmaceutical industry has provided substantial quantities of pharmaceuticals as gifts to developing nations. For example, Boehringer Ingelheim announced on July 7, 2000 that it would provide nevirapine free for five years for preventing mother-to-child transmission of HIV, and Merck has long provided ivermectin for treatment of river blindness.[25] This is wonderful and can be extremely helpful under some circumstances. It poses, of course, an obvious question as to sustainability, as compared to a commitment to (and a structure to facilitate) making products available on a long-term basis at a price that covers marginal cost.[26]

What is more sustainable is the approach organized by UNAIDS, under which four major pharmaceutical firms provide concessionary prices on a contract basis. The firms are Boehinger Ingelheim, Bristol-Myers Squibb, Glaxo Wellcome, and Merck Sharp and Dohme, and they have, so far, entered arrangements with Rwanda, Senegal, and Uganda.[27] Similarly, Bayer provided ciprofloxacin to Médicins Sans Frontières at a concessionary price in 1997. [28] These arrangmenst are basically commitments to tier pricing in a specific situation. They offer the benefit that the products will certainly be priced reasonably — the commitments are for up to 90 % price reduction. (This deals

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[25] H. Binswanger, How to make advanced HIV treatment affordable for millions in poor countries, Dec 26, 2000 (manuscript).

[26] See A. Guilloux & S. Moon, Hidden Price Tags: Disease-Specific Drug Donations: Costs and Alternatives, Access to Essential Medicines Campaign, Médicins Sans Frontières, October 2000.

[27] See UNAIDS, Accelerating Access to HIV Care, Support and Treatment, News Bulletin No. 2, 20 February 2001, available at http://www.unaids.org/acc_access/acc_care_support/news_bulletin2.html; International Federation of Pharmaceutical Manufacturers' Associations, Major Industry Developing Country Programs, available at http://www.ifpma.org/UpdatesAIDS.htm.

[28] B. Pécoul et al, Access to Essential Drugs in Poor Countries, A Lost Battle?, Jour. of the American Medical Assoc., **384**: 361 (1999).

with one of the points implicit in the above analysis, that the economic incentives facing industry do not necessarily favor prices in the developing world as low as marginal cost.) Moreover, this type of arrangement can include specific provisions to ensure that the medicines are complemented by relevant health care capabilities and to provide forms of accounting that decrease the risks of re-export.[29] Should such arrangements become the ractical mechanism for tiered pricing, it is important that the arrangements be negotiated in a way that is transparent and that avoids competition law problems — there is a major responsibility here on the public sector partners.

IV. IMPLICATIONS AND RECOMMENDATIONS

The above analysis provides a basis for defining and proposing specific approaches. These approaches should be designed to maintain price differentials benefitting low-income nations, and, at the same time, to maintain incentives for adequate levels of production and of research and development.[30] It is useful to break the final analysis and recommendations into four areas: that oriented toward international and trade law, that oriented toward high-income nations, that oriented toward low-income nations, and that oriented toward procedures of achieving the other recommendations.

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[29] See UNAIDS, Report of the Meeting on the Evaluation of the UNAIDS HIV Drug Access Initiative, Geneva, 30-31 May 2000; WHO-IFPMA Action Paper, Improving Access to Essential Drugs Through Innovative Partnerships; An Opportunity for Action: Antimalarials for Sub Saharan Africa (Nov 2000).

[30] As noted above, this is not an issue for products whose research costs are already being recovered in high-income markets. That is the case for essentially all present products and will probably be true for most future products as well. But products whose major markets are in the developing world will have to be treated differently; for these products, research costs must be covered either from research donors or from the developing-nation markets themselves (which may, in turn, receive portions of their funding from the international donors).

International analysis and recommendations. It is clearly wise to slow reverse flow, which is probably, but not necessarily, most readily achieved by use of intellectual property rights. In the most dramatic form, this would be an agreement to amend Article 6 of TRIPS to require that patent rights on pharmaceutical products be defined in such a way as to prohibit import of products lawfully marketed in another nation (subject of course to the ability of the patent holder to choose not to exercise its rights, so that it could serve regions of several nations, and possibly several prices, from a small number of production centers). Such an agreement may not be easy to achieve, for the wisdom of applying similar market division principles in other contexts is both unclear and controversial. Moreover, legal change is not necessarily needed here, for TRIPS permits nations to bar imports -- the only real question is whether this is a strong enough right to give the pharmaceutical industry confidence in tiered pricing. Hence, the anti-reverse flow issue may be better resolved through a health-specific agreement or a parallel statement of nations that, in the particular sector, they will write and apply their law to permit restrictions on reverse flow of pharmaceuticals. And, it must be recognized that permitting firms to separate markets does not necessarily imply that they will set prices to match tiered-pricing objectives. The market price in the developing nation depends in substantial part on the market conditions in that nation; depending on these

market structures, some form of industry commitment to keep prices low may be an essential part of the package.[31]

High-income nation analysis and recommendations. The key issue here, exemplified by the U.S. debate, is to find a way to gain long-term political support for the concept of paying higher prices for pharmaceuticals than are paid in developing nations. Preaching about the global benefits and equity of such pricing is unlikely to be very helpful. It may be helpful, however, to ensure equity among developed nations so that prices in those nations are not too different – this might be achieved through some form of formal agreement or it might be achieved through each of the high-income nations ensuring that its own price controls and national purchase rates are not used in a way that creates substantial differentials. And what is likely to be most helpful is to design medical systems in such a way that costs of pharmaceuticals do not fall inequitably on any single group in the high-income nations – certainly the concern of the elderly who lack insurance coverage for pharmaceuticals is the prime mover of opposition to pharmaceutical prices in the United States.

Low-income nation analysis and recommendations. The developing nations face three issues here. *First*, global encouragement of tiered pricing will not necessarily lower prices in these nations — there are many other factors in the nation's control that affect

[31] If compulsory licensing is to be relied upon to ensure that developing-world prices are low, it is necessary to face the issue discussed above of whether TRIPS authorizes a compulsory license to satisfy a small market by imports from a nation in which the product involved is patented. The issue may be resolvable by an interpretation; if not it would have to be faced as a TRIPS amendment. Such an amendment might be more negotiable if cast as specifically a way to create tiered pricing for pharmaceuticals over a patent holder's opposition, with a process, possibly at the international level, designed to make such a decision fairly.

prices, e.g. protectionism and poor or corrupt distribution systems. It is essential to face these issues as part of keeping prices low — the issues are not only those of patent law. And it may be very useful to minimize the costs of product approval, as through use of regional product approval agencies. These issues may be best faced on their own; alternatively, they may be best faced in the context of agreements like those of UNAIDS, in which the pharmaceutical firms promise to lower prices, as part of an overall procurement and distribution reform. And it is possible also that developing nations can facilitate tiered pricing by entering into licensing arrangements with major pharmaceutical firms for developing-world production -- this provides a political cover for the firms against developed-world consumer price concerns. *Second*, developed-world import restrictions are not necessarily adequate to support price differentiation — there may need to be efforts within the developing-world public and private distribution systems to contribute to preventing the outflow of products. *Third*, the developing nation recipients should commit themselves to developing the medical infrastructure necessary to use the pharmaceuticals effectively; this may require support from donors. *Fourth*, the issue for developing nations is quite different with respect to products developed for the developing world itself (e.g. anti-malarials etc.) For these products, very little of the research and development costs can be absorbed by developed world users; these costs must be paid either by international donors as research sponsors or by international donors and the developing world supporting the users. Hence, it may be inappropriate to seek (at least initially) to bring the prices of these products down to marginal cost in other than extremely poor nations.

Procedural and packaging issues. How the final recommendations of Working Group 4 or of the Commission should be presented is a matter deserving substantial discussion. Moreover, the way that the pharmaceutical industry fits into and is consulted in the development of specific proposals is important, and must take into account the antitrust concerns of its members. But, for the sake of discussion, two extremes and an intermediate might be suggested:

The minimal: A statement that intellectual property law can, consistent with TRIPS, be used to obtain tier pricing, and a group of recommendations to both high and low income nations as to the ways to make tiered pricing work.

The maximal: A proposal for a new international treaty (The International Drug Equity and Orphan Drug Development Treaty?) that would seek some combination of the following goals (a) to clarify the law of import restrictions under TRIPS and make it mandatory for members to allow use of intellectual property rights to obtain tiered pricing of pharmaceuticals, (b) to ensure that national price controls in the developed world are not used to avoid appropriate shares of research and development costs, (c) to define a commitment for the pharmaceutical industry to enter into arrangements like those of UNAIDS at least for a limited range of products for the poorest nations, (d) to reduce product distribution costs in the developing world, as by lowering tariff barriers and creating regional product approval procedures, and (e) to include procedures (that will be discussed in WG 2) for encouraging and supporting pharmaceutical

industry research for developing-world disease. Commitment (c), for the industry to enter into appropriate arrangements, is, of course, very unusual for an international agreement, which normally binds only nations. There are several ways to achieve it. One is through a form of social compact, such as that in which the international pharmaceutical industry promised to maintain research facilities within Canada as part of its lobbying for the 1993 termination of compulsory licensing in that nation.[32] Another is through carrots or sticks. Carrots might involve conditioning tax or other orphan drug benefits on participation in such arrangement. Sticks might involve the use of a national compulsory licensing procedure or a global arrangement that creates the equivalent of such a procedure for a number of poorer nations.

The intermediate: Although there are many possible intermediates, a reasonable one example is a new arrangement specifically on drug pricing. Its provisions might (a) require high income markets to use intellectual property or other parallel import restrictions to prevent the reverse flow of tiered price pharmaceuticals, (b) require developing nations to provide complementary medical services and appropriate assistance in preventing reverse flow, and (c) create an international fund, secretariat, decision-making process that would, in some combination, subsidize prices in the poorest nations, negotiate agreements such as those

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[32] See Government of Canada, Review of The Patent Act Amendment Act 1992 (Bill C-91), February 1997, available at http://strategis.ic.gc.ca/pics/ph/billc91.pdf.

currently negotiated by UNAIDS, and/or assist in estimating an actual level of marginal cost for use in setting prices in the poorest nations.