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Written testimony

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In Public Hearings on

International Pharmaceutical Prices

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I wish to thank the Joint Committee on International Trade and Health for inviting me to testify today in today's hearings on international pharmaceutical prices. I am a Resident Scholar at the American Enterprise Institute for Public Policy Research, where I have conducted research on pharmaceutical markets and other topics. The views I present today are my own and do not necessarily represent those of the American Enterprise Institute.

My testimony focuses on five points.

1. Economically advanced nations other than the United States control the prices of innovative pharmaceuticals at below-market levels

All advanced economies but the United States control the prices of innovative drugs.[1] Price control regimes take on a variety of forms including profit limits, cost-effectiveness-based ceilings, reference pricing (where prices or reimbursement for all drugs in a therapeutic class are set equal to that for the cheapest drug within the class), adopting price ceilings in other nations, and directly negotiated ceilings.

A natural question is the extent to which foreign controls hold prices below market levels. By "market" levels, I refer to prices at which drugs would be sold to non-government buyers in the absence of controls. What would those prices be? A starting point is prices at which drugs are sold in the U.S. to buyers other than government. The American non-government prescription drug market amounts to about $126 billion annually (excluding drugs covered by Medicaid, the Veterans Administration, Medicare's limited Part B program, and other much smaller programs). That is far larger than the

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[1] A convenient source comparing drug prices in wealthy nations is Canada's Patented Medicine Prices Review Board (PMPRB), which regularly publishes an index that invariably shows American prices to be substantially higher than those in Canada and other nations. This is available at www.pmprb.com/CMFiles/ar2002e21LEF-6252003-6142.pdf. Danzon and Furukawa 2003 described the many difficulties in constructing accurate and unbiased international drug price comparisons (because of differences in generic status, dosage, therapeutic category, currency fluctuations, and other factors), thus casting doubt on the precision of the PMPRB's indices. But the basic points -- that Canada and western European prices are substantially higher than American prices, and that this is very much by design -- remain largely true. In addition to the article cited above, Danzon and her coauthors have written a series of papers on foreign price controls and their effects, while emphasizing the difficulty of constructing simple measures of the effects of price controls. See Danzon 1997, Danzon and Chao 2000, Danzon and Ketcham 2003, and Danzon, Wang, and Wang 2002. An indispensable source on the variety of foreign price control regimes is a series of papers written or organized by Panos Kanavos at the London School of Economics. These are available at http://pharmacos.eudra.org/F3/g10/p6.htm.

entire pharmaceutical market in any single European nation (Germany's being the largest at $20 billion) or the entire Japanese market, the second largest in the world at $53 billion.[2] In the huge non-government American market, prices are determined primarily through competitive forces. These forces do not yield a single "market price," as transaction prices depend partly on negotiations between pharmaceutical manufacturers and large buyers (especially the pharmaceutical benefit managers, or PBMs).[3]

Foreign prices would probably be lower than American prices even if they were not controlled by governments. Economists have often noted that it is in the financial interest of pharmaceutical manufacturers to charge lower prices to less wealthy nations (Danzon 2001; Danzon and Furukawa 2003; Danzon and Towse 2003; Wagner and McCarthy 2004). In the past decade or so, per capita incomes in the U.S. have come to exceed those in Canada, Western Europe, and Australasia by some 25 to 40 percent (OECD data). Such disparities would be expected to generate lower pharmaceutical prices abroad even in the absence of controls. The same logic can apply to other products. For example, a controversy arose in 1999 over the fact that Canadian automobile prices were some 16 percent lower than U.S. prices (Graham 2003)

Foreign price controls are explicitly designed to reduce prices below the levels that would arise from natural economic forces. This is clear from the statements of price control boards such as Canada's Patented Medicine Prices Review Board (PMPRB). However, the extent to which controlled prices fall below free-market levels is not easily assessed. Danzon and Furukawa (2003) calculated that in 1999, average price disparities between U.S. and Western Europe for branded drugs were roughly in line with relative per capita GDP, while U.S.-Canada price disparities were roughly twice the disparity in per capita GDP. Price disparities are larger for some individual drugs, of course, and

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[2] U.S. data are from CMS National Health Accounts. German and Japanese data are from the *IMS World Review*.

[3] A useful review of the economics of differential pricing in U.S. markets is Frank 2001.

they may have increased on average since 1999 despite the recent weakness of the U.S. dollar. Germany and other nations often resort to ad hoc price reductions in addition to whatever ceilings would normally prevail.[4] There seems little doubt that for many of the most important patented drugs, international price disparities are often substantially larger than can be accounted for purely in terms of income differences.

The situation is quite different for off-patent drugs, i.e., generics. Danzon and Furukawa (2003) found that generic drug prices in the U.S. tended to be lower—and often much lower—than those in Western Europe. As will be noted below, this raises the possibility that European nations have available to them a tool for providing more reasonable rewards for innovative drugs while reducing costs in the generic sector.

A relatively little noticed fact in the debate over pharmaceutical prices is that within the U.S., spot checks and informal surveys reveal substantial disparities in retail prices, apparently due to large differences in retailer cost structures, competitive conditions, and markups. For example, thirty tablets of the antibiotic Amoxicillin can cost as little as $4 and as much as $27.95 in the same metropolitan area.[5] In a recent presentation at a Canadian conference of cross-border pharmaceutical trade, Palmer (2004) presented data indicating large differences in retail prices within both the U.S. and Canada.

2. In nations with price controls, patients have faced delays in the introduction and uptake of innovative new drugs

Nations with pharmaceutical price controls usually employ a two-part approval process: first, medical approval (roughly equivalent to FDA approval of new drugs in the U.S.), followed by "registration" of negotiated prices and reimbursement. A substantial and growing body of evidence documents delays in both the approval of innovative drugs and the registration of reimbursement or wholesale prices in nations with the most

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[4] See Kanavos ___, and ___

[5] Graham 2003; *Consumer Checkbook*.

stringent price controls. In some cases, the delay can involve several years or even the failure to introduce certain pharmaceuticals at all. In their analysis of the fate of 85 new chemical entities in 25 countries, Danzon, Wang, and Wang (2002) found (p.18), "The three countries that do not require price approval before launch had the most launches: the US led with 73 launches, followed by Germany (n=66) and the UK (n=64). At the other extreme, only 13 NCEs were launched in Japan, followed by Portugal (n=26) and New Zealand (n=28)." They concluded (p. 3), "Our results suggest that countries with lower expected prices or smaller expected market size experience longer delays in access to new drugs, even after controlling for per capita income and other country and firm characteristics."

A December 2002 report from Cambridge Pharma Consultancy provides more detail. The European Union has established a goal of registering prices for new drugs within either 90 or 180 days after medical approval, depending on the nature of the drug. The Cambridge Pharma report found that most European countries take far longer (p.17): "Patients in Belgium on average wait 2 years longer to receive new medicines than patients in the UK and Germany. Although the average delays are lower in other countries, patients could still wait more than 2 years in Austria, Greece, Finland, France, Italy, and Norway. These delays are usually attributable to extended reimbursement negotiations."

European nations may also be slower to adopt innovative drugs after they have been approved. Gilbert and Rosenberg (2004, published by the Bain consultancy) noted that of patients for whom the statin class of cholesterol-reducing drugs were recommended, 56 percent of American patients have been prescribed statins versus only 26 percent of the corresponding group of German patients. The authors also noted that cardiac mortality rates had declined more rapidly in the U.S., by 13 percent compared to 8 percent in Germany between 1990 and 2000.

It is difficult to assess the reasons for these delays in approving and using innovative drugs. Clearly, price negotiations take time, but health systems usually have ample advance notice before a new drug actually gets approved. Many drugs are approved in the U.S. before they are approved in Europe, and in any case, most new

drugs are widely discussed in the medical literature and the medical community well before regulatory approval. One reason for delay may simply be a reluctance of the European and Canadian health care systems to take on the burden of paying for new drugs. Because direct-to-consumer advertising is prohibited in these nations, pharmaceutical manufacturers cannot appeal directly to patients while approved drugs await the outcome of pricing negotiations, nor can they use advertising to accelerate uptake among under-treated populations.

3. Pharmaceutical price controls discourage the development of innovative new drugs

The linkage between prices, profits, and pharmaceutical R&D is nearly universally recognized by economists.[6] They typically emphasize that price controls are bound to blunt R&D incentives. For example, (p.5) "If the manufacturer or investors, anticipating [regulated prices], expect that the prices the various jurisdictions will ultimately set will not in the aggregate cover the cost of development plus a return to capital, the manufacturer will not develop the drug, even though the willingness to pay for the drug in the world might greatly exceed the drug's development costs."[7] An essential problem is that pharmaceutical development involves large sunk costs, lengthy development times, and great financial risk. When the product is finally ready for marketing, its benefits can apply to populations of all nations including those that set price ceilings. Thus price regulators have an incentive to impose relatively low ceilings, confident in the knowledge that manufacturers will still want to sell the product as long as ceilings are well above the costs of manufacture and distribution. Drug developers must take these incentives into account when raising and allocating R&D funds. The

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[6] Useful sources include cf. Scherer 2001; Grabowski and Vernon 2000 as cited in Vernon 2004; Lichtenberg 2001? H.A. 2001; Newhouse 2004; Frank 2001; Danzon 2000 and 2001; and citations therein.

[7] Newhouse 2004.

clear implication is that the prospect of price controls can substantially undermine incentives to develop new drugs.

Because the benefits of pharmaceutical innovation are essentially global, the progress of R&D depends on the global contribution to pharmaceutical profits, which are the primary source of new drug development (cf. Scherer 2001). To the extent that foreign price controls reduce the overall payoffs from innovation, we can expect an adverse impact on total worldwide pharmaceutical R&D regardless of where that research takes place. Although it is difficult to quantify these effects, several studies indicate that they are significant. Danzon observed in 1997 (p. 63), "There seems to be a rough negative correlation between the stringency of a country's price controls and the innovative success of its domestic pharmaceutical industry." Her 2001 survey of pharmaceutical economics reviews the extant literature as of 1999, which has been extended by her work with several colleagues. These show that price controls tend to reduce the returns to innovative drugs in a variety of sometimes subtle ways. An econometric study by Vernon (2004) finds that for a sample of large pharmaceutical firms, R&D investment was determined partly by the share of the firms' drugs that were sold in nations with relatively stringent price controls. Although the U.S. has been largely free of pharmaceutical price controls, an analysis of the 1993 Clinton Administration health plan, which would have capped the prices of innovative drugs, found that stock prices in the pharmaceutical industry declined when the prospects of passage of the Clinton plan were greatest (Ellison and Mullin 2001). These results are consistent with the fact that the rate of increase in R&D expenditures dropped substantially during 1993 and 1994 (Calfee 2000).

Also relevant is the decisive shift of pharmaceutical R&D activity in the past decade and a half toward the United States as European price controls took effect. In 1990, European pharmaceutical firms outspent American firms in research and development by 8 billion Euros to 5 billion Euros. In 2000, U.S. firms outspent European firms by 24 billion Euros to 17 billion Euros (EFPIA, p. 4). European pharmaceutical firms have also been shifting the locus of their R&D to the U.S. The British firm Glaxo Smith-Kline moved its operational headquarters to the U.S. in 2000.

Novartis, a Swiss firm, moved its research headquarters to Cambridge, Massachusetts. The German firm Schering AG moved its therapeutics division to the U.S. Organon, formerly the only established pharmaceutical R&D firm in the Netherlands, relocated to New Jersey in 2001.

The U.S. share of successful innovation has also increased dramatically. In 1988, American manufacturers developed only 19 of the 50 best-selling drugs worldwide. By 1998, American manufacturers sold 33 of the top 50 drugs.
By 2001, American firms were selling 8 of the top 10 drugs worldwide, and one of the remaining two was from a joint venture between Takeda (Japan) and Abbott (U.S.). The pattern for biotechnology drugs is most striking, as U.S. manufacturers account for 14 of the top 15 biotechnology drugs.[8]

These patterns reflect the fact that no objective basis for "fair" or "reasonable" drug prices or profits exists (cf. Calfee 2001). Regulators of pharmaceutical prices cannot base prices on the value of drugs, because that would tend to mimic the very market prices that controls are supposed to correct. Controllers cannot set prices to encourage the "right" research because they lack the necessary information, such as the ultimate value of a particular drug or the likelihood of success of a specific line of research. Finally, basing prices on the actual development costs of individual drugs is neither practical nor appropriate. This is partly because research and administrative expenses are shared among numerous drugs and, sometimes, among several firms, some of whom may have failed to create a marketable drug at all. Regulators also have no objective and consistent way to assess the degree of financial risk that was overcome in the drug development process, including the research failures and bankruptcies that may have preceded the creation of a financially successful new drug. Thus there is simply no way to construct price controls in a manner that assures reasonably efficient incentives for R&D. The lack of a simple, straightforward approach is one reason why international price controls are quite diverse, with several nations simply borrowing price ceilings from other nations.

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[8] ___ Redwood presentation in the Dec. 2003 GMF conference.

European authorities, especially in Germany, have undoubtedly noticed that their automobile industry, which like pharmaceuticals is also research-intensive and rebounded strongly after its total destruction in World War II, has continued to thrive, while its pharmaceutical industry, which once dominated world markets, has fallen behind. Recent European Commission reports have concluded that price controls have harmed the European pharmaceutical industry, and perhaps should be rethought (Echikson 2003). A recent report from Bain Consulting argued that on the whole, the financial costs of the decline in the European pharmaceutical industry may outweigh the financial savings from price controls (Bain 2004).

4. Economically advanced nations are starting to use price controls to free-ride on pharmaceutical R&D paid for by American consumers

As a general rule, the clinical trials that lead to a new drug approval demonstrate the value of that drug not just in the nations where the drug was developed or the trials were conducted, but in almost any comparable population in the world. In other words, research conducted with the American market in mind demonstrates that Australians could benefit from the same drug. This commonality is recognized in the drug approval procedures in Australia and virtually all other advanced nations, where great weight is placed upon the FDA-approved clinical trials used for drug approval in the United States.

These circumstances, combined with the fact that most pharmaceuticals can be manufactured and distributed for a fraction of what they cost to develop, create a temptation for nations to free-ride on research by cutting drug prices. There is some evidence that free-riding has begun to occur. In a September 25, 2003 in Cancun, Mexico, former FDA Commissioner McClellan noted:

> "In many ways, the economic consequences of overly strict price controls on drugs are no different than violating the patent directly through compulsory licensing to make copies of the drug. Either way, there isn't likely to be a fair payment based on the value of the new patented product. This year, Americans, who account for a fraction of prescription drug use worldwide, will pay for about half of all pharmaceutical spending worldwide. By contrast, citizens in the world's third largest economy,

> Germany, paid less than five percent. The same kind of drug payment disparity is true for many other developed nations who have about as much ability to pay as Americans do."

The data support McClellan's observation. In 1990, U.S. revenues accounted for 31 percent of the worldwide market. Canada plus the five largest European nations were almost equal to that, at 30 percent. By 2001, the share for Canada plus the European nations was only 20 percent, while the U.S. share was 46 percent. In biotechnology, the most innovative pharmaceutical sector, the disparity is even greater. In 2002, biotechnology revenues in the United States were approximately $16.5 billion, compared to about $5 billion for the five largest European nations combined (Jones and Bate 2003). In particular, U.S. sales were about 25 times those in the U.K.

The primary source of R&D investment, however, is not revenues but profits (Scherer 2001). Because revenues must cover marginal costs of manufacturing, distribution, and overhead, which tend to be of roughly comparable levels across nations, we would expect that the American share of profits would be greater. The facts seem to bear this out. A recent analysis concluded that in 1992, Europe accounted for 33 percent of the global pharmaceutical profit pool, but by 2002, its share had fallen to only 18 percent. In 1992, the U.S. enjoyed 47 percent of global profits from pharmaceuticals. In 2002, it accounted for 62 percent of profits.[9]

5. Relative simple changes could substantially reduce actual and potential free-riding by wealth nations

Like most economists, I think that price controls are almost always a very bad idea, invariably leading to pernicious long-run consequences. Pharmaceuticals are an especially unfortunate target for price controls. In most markets, price controls generate shortages and other obvious distortions, which may inspire measures to relax or even bring an end to controls. An example of ameliorating measures are the annual

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[9] Data from *Medical and Healthcare Marketplace Guide*, as cited by Gilbert and Rosenberg 2004.

adjustments to Medicare reimbursement levels made by CMS and Congress in the face of threats of exit by physician specialties and health care organizations. Such correctives can certainly lessen the harms from controls even if they cannot reverse them altogether. Unfortunately, the pharmaceutical R&D market does not offer this essential check on price controls. Once controls are in place, no one will be able to identify the useful pharmaceutical R&D projects that have been curtailed or prevented. Because R&D takes so long, and involves such high financial risk, there is no substitute for the market incentives of handsome profits from success and financial setback, even bankruptcy, in the face of failure. This is not an industry in which price controllers would be able to pick winners among the hundreds of potential research lines.

There is no avoiding the fact, however, that governments put themselves into a difficult position whey they decide to pay for prescription drugs. If they simply pay what manufacturers demand, there is no natural limit to such demands. Hence some constraints on payments are inevitable. As we have seen, however, many of our wealthiest national competitors are constraining prices via direct controls rather than relying upon market mechanisms. The result is to reduce worldwide pharmaceutical R&D funding and to move toward free-riding on American-funded research. The best solution would be to dispense with price controls and adopt market-based cost control methods similar to those employed by large health care organizations in the U.S. The prospect for such a change seems remote, however.

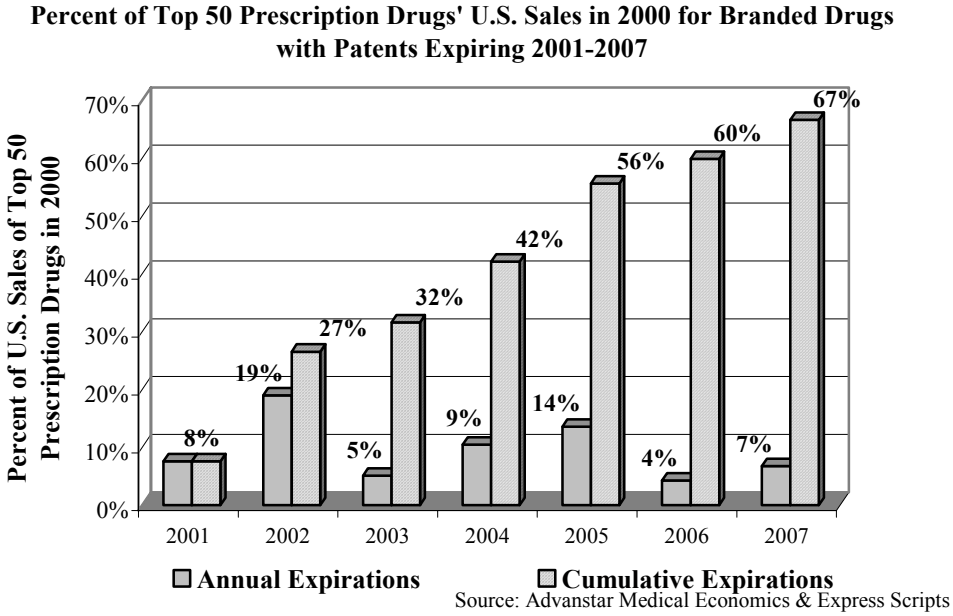
Nonetheless, at least a few measures are available to wealthy nations which, if implemented, could at least reduce the current drag on innovation and the growing tendency toward free-riding.

Make greater use of generics:

One tool, emphasized by former FDA Commissioner Mark McClellan, is wider use of generic drugs (McClellan, September 25, 2003). The ability of generics to reduce health care costs is almost startling. Since passage of the Hatch-Waxman Act in 1984, the generic share of all prescription has increased from 19 percent to more than 50 percent. In many respects, however, the generic revolution is just reaching maturity. The

U.S. pharmaceutical market is now in the middle of a remarkable and unprecedented surge in patent expirations of blockbuster drugs, followed by generic entry and dramatic price reductions. The overall pattern can be seen in Figure 1, which shows the proportion of total prescription drug spending in the year 2000 that has gone generic or soon will. As the chart indicates, this has been happening very roughly at about 10 percent annually, so that well over 50 percent of the year 2000 market will be generic or eligible for generic entry by the end of 2006. It is true that litigation has sometimes delayed generic entry, but it is unlikely to do so for more than a year or so in the future, and many important patent expirations are quickly followed by generic entry. This has already happened with several blockbuster drugs including Prozac (the pioneer among the dominant antidepressant category of SSRIs), Prilosec (which was the best-selling drug in the world as recently as 2000), Claritin, and such essential but less well-known drugs as Glucophage and Zestril.

Figure 1



Source: Advanstar Medical Economics & Express Scripts

The U.S. has been the world leader in generic competition since passage of the Hatch-Waxman Act in 1984. Some nations, notably Canada and the U.K., have nearly

caught up. Several other economically advanced nations, however, impose substantial barriers to generic competition. In fact, stringent price controls tend to work to the disadvantage of generics. In their study of the competitive effects of price controls and other regulations, Danzon and Chao (2000, p. 311) concluded, "We find that price competition between generic competitors is significant in unregulated or less regulated markets (United States, United Kingdom, Canada, and Germany) but that regulation undermines generic competition in strict regulatory systems (France, Italy, and Japan)." In their recent analysis of international pharmaceutical prices, Danzon and Furukawa (2003, p. 525) noted, "…total generic share of unit volume is low in the price-regulated markets of France (28 percent), Italy (34 percent), and Japan (40 percent), and higher in countries with freer pricing such as the United States (58 percent), Germany (61 percent), and the United Kingdom (49 percent)." They also noted that price controls and other regulations in some nations, notably France and Italy, have traditionally discriminated against generic entry by foreign manufacturers while favoring domestic manufacturers. The result is that generics are often priced at levels comparable to those for branded drugs.

This mix of lower prices for innovative drugs and higher prices for old generics amounts to a bias against rewarding R&D. The prospect for a better trade-off, one that encourages rather than penalize pathbreaking research, is enticing. Former FDA Commissioner McClellan (Sept. 25, 2003) pointed out that these and other nations could relax some controls in order to curtail the tendency toward international free-riding while also saving money on generics.

Permit a more efficient pharmacy retailing sector:

Some nations impose regulations that limit competition or otherwise raise retail pharmacy prices. Danzon and Chao (2000, p. 311) note, "Regulation of retail pharmacy further constrains competition in France, Germany, and Italy." Kanavos (2004) has estimated that anti-competitive regulations in European nations often increase retail prices on the order of 15 percent or more. Germany is an example of this phenomenon. German fixes pharmacy retail margins and prohibit discounts while also restricting entry.

This arrangement leaves pharmacies with little incentive to obtain lowest-cost pharmaceuticals including generics. This arrangement has been noted by many observers, including the German Department of Health, which has undertaken measures to encourage pharmacies to obtain supplies from lower-cost sources. Anti-competitive retail pricing extends beyond the European mainland. Australian authorities recently refused to reconsider regulations that restrict competition so as to increase price pharmacy prices by 15 percent.

Eliminate heavy-handed disincentives for the use of innovative drugs:

In the French price controls system, the government reimburses nearly the full price, with minimal patient copays, if the manufacturer agrees to the government's price ceiling. If the manufacturer charges more than the ceiling price, the patient must pay the entire price (rather than a higher copay, as is the practice with American managed care systems). The effect is that even if the patient and his or her physician believes a newer drug has a decisive advantage, worth more than the difference in price between the two drugs, the patient is forced to pay far more than the difference in price. This kind of disincentive to using innovative drugs could be dismantled. That would probably raise prices somewhat as manufacturers would be in a better position to resist sub-market price controls. However, it would end what is presently a very unwise trade-off in which health care costs are moderately suppressed at the cost of rewarding competition within a therapeutic category. As recent developments in the market for the statin class of cholesterol-reducing drugs have demonstrated, post-approval research within a therapeutic category can yield extremely valuable medical advances (Topol 2004). Denying rewards for such progress makes little sense.

Permit direct-to-consumer advertising of prescription drugs:

Direct communication to patients is an escape valve around harmful price controls. The experience of two nations, the United States and New Zealand, has demonstrated that direct-to-consumer advertising of prescription drugs yields substantial benefits with little harm. Among the benefits are information about newly approved

drugs, improved treatment regimens, and better compliance with prescribed therapies (Calfee 2003). The blanket prohibition on DTC advertising in Canada, Europe, and Australia appears to have little basis beyond a desire to curtail a tool that may increase health care costs even as it improve patient health.

Provide for greater medical and patient input in setting prices:

The FDA has greatly improved the new drug approval process by systematically drawing on the experience and expertise of academic, medical practitioners, and patient groups. A comparable arrangement may improve the registration component in the price controls systems of Europe, Australia, and others. The opportunity for public scrutiny and comment by those with both expertise and a direct stake in the benefits of innovative drugs might reduce the probability of opportunistic price-setting policies that threaten to increase the size and scope of free-riding pharmaceutical R&D supported by revenues in the U.S. market.

Explore PBM-like arrangements for negotiating drug prices:

In the United States, pharmaceutical benefit managers provide a potent free-market tool for reducing pharmaceutical costs with little sacrifice in medical benefits from innovation. This process could offer valuable experience, and perhaps a model, for price negotiations elsewhere. Among the potential benefits could be far more aggressive use of generics.

Abjure the threat of compulsory licensing when negotiating prices:

Although wealthy nations have avoided invoking the threat of compulsory licensing since the early 1980s, some people believe the threat remains in place. Except in short-run emergencies when supply problems arise unexpectedly, there is little reason even to hold compulsory licensing in reserve. As long as nations avoid shipping lower-priced drugs to the U.S. market, firms will feel reasonably confident in selling at lower prices where per capita incomes are less than in the U.S. The possibility that manufacturers of patented drugs will simply refuse to work their patents (legal term)

despite price ceilings that bear a reasonable relationship to per capita incomes, appears to be remote. On the other hand, the threat of compulsory licensing, which amounts to abrogation of fundamental patent rights, creates downward pressure on the expected rewards to innovation and therefore at least marginally reduces R&D incentives.

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