

Drug Importation: Would the Price Be Right?

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Testimony

Good morning Chairman Enzi, and the Members of the Committee. My name is Kevin Outterson, and I will testify today about the Commerce Department Study on Pharmaceutical Price Controls in OECD Countries.

The Study is a flawed discussion of the issues regarding global pharmaceutical pricing, including the strategy of the Department of Commerce and the USTR to utilize trade agreements and trade leverage to increase foreign drug prices. I will discuss 2 issues: (1) free riding by foreign countries; and (2) the linkage between pharmaceutical innovation and drug prices. In my written testimony I also discuss related issues in the HHS Task Force Report on Prescription Drug Importation, and conclude that importation would be safe and save several billion dollars, with no net effect on pharmaceutical innovation.

I offer 3 conclusions on the Department of Commerce Report:

— The strategy to raise foreign drug prices through free trade agreements is not only unnecessary, but dangerous. It will not succeed in rich OECD countries, but will offend our best trading partners. In low income countries it may succeed in raising prices, but with a minimal impact on innovation and a devastating impact on global public health. The strategy will also open important US domestic programs to criticism.

The Department of Commerce Report grossly—overstates the likely impact of free riding by rich OECD countries, probably by a factor of 8 to 16 times or more. The strategy may yield only \$355 million per year after years of effort, enough R&D to buy just one innovative drug every decade. The cost to global health will be 10 to 100 times greater. A 1% change in the NIH budget would have a larger effect on drug innovation.

Pub—lic data is not available to properly answer these questions. Congress needs transparent access to verifiable data. Any studies interpreting such data must be independent. The National Academies of Science, the Institute of Medicine or the GAO are possible sponsors.

1. Free riding

First, let's discuss the charge that other OECD countries are 'free riding' on American innovation.

Undersecretary Aldonas, CMS Administrator McClellan, former USTR Zoellick, and

several Members of Congress have publicly articulated the strategy of using free trade agreements to address free riding.

The strategy depends upon raising patented drug prices abroad, but it will succeed only in poor countries which will suffer under higher prices and will fail in rich countries where it is needed most. According to the Report, the greatest free riders are the UK (\$1.0 to 1.6 billion), France (\$1.0 to 1.5 billion), Japan (\$200 million to 1.4 billion), Germany (\$700 million to 1.2 billion), Canada (\$600 million to 700 million), Switzerland (\$400 million), and Australia (\$400 to 700 million).

In each of these countries, what PhRMA calls ‘price controls’ is actually a limit on what the government will pay for drugs under national health plans. The US employs very similar rules in the VA federal supply schedule (FSS), the Public Health Service’s 340B program, and mandatory and supplemental rebates under Medicaid. Data clearly demonstrate that our government’s prices for these programs are lower than Canadian and European prices. If Patricia Danzon’s pricing studies used FSS, 340B and Medicaid prices as the US price, most or all of the international price differentials would disappear.

Consider the negotiations between USTR and the EU: we demand that they modify an important social policy, universal access to care, and raise their drug prices to match our own. If they respond at all, it will be to call us hypocrites, and to demand that we sacrifice our veterans, public health clinic patients, and Medicaid recipients in the bargain.

Powerful OECD countries are likely to resist an American attempt to increase domestic drug prices. Even Australia stood up to most of the US drug price demands during the free trade negotiations. While the USTR and some Members of Congress suggest that the AUSFTA will raise prices in Australia, the actual language of the Agreement is quite modest. The Australian government insists that the AUSFTA won’t raise Australian prices at all. In fact, just as the AUSFTA became effective, Australia announced a plan to cut drug reimbursement prices by an additional 12.5% when the first generic in a therapeutic group is approved. The net price reductions are estimated to exceed AU\$830 million over four years. A strategy which relies upon attacking a core domestic policy of our most important trading partners seems an unlikely path to success.

It is far more likely that the US will ‘succeed’ in raising drug prices in smaller and more vulnerable countries. In the face of the humanitarian crisis of access to drugs in low and medium income countries, do we really want to raise drug prices in Central America and the Dominican Republic through DR-CAFTA? In Morocco or Jordan? In sub-Saharan Africa? Can anyone imagine a worse idea for global drug pricing?

When it comes to the world’s poorest countries, the free rider label is especially inapposite. Low income countries cannot contribute much global drug R&D cost recovery in any case, and should be considered fair followers rather than free riders. The economist F.M. Scherer described this policy in a recent article, giving economic language to the human rights appeals by essential medicines advocates like Médecins

Sans Frontières. Scherer's point is that any pharmaceutical patent rent extraction from low income countries is likely to be very damaging to people and not very helpful to R&D.

In the wake of the Indian Ocean tsunami, we've seen the WTO and rich countries suggest trade concessions and debt forgiveness to help this region rebuild. While the tsunami was a terrible tragedy, the ravages of AIDS and other diseases inflict a larger toll every month in much poorer countries. The US and the WTO should offer new flexibilities to these countries, permitting them to be fair followers in pharmaceutical innovation. Millions of people would benefit from enhanced access to patented medicines, without harming innovation.

2. Revenues, R&D and Innovation

My second topic is the relationship between drug company revenues, R&D and innovation. To the extent the HHS Task Force Report is concerned about R&D, then these comments apply to that study as well.

The Commerce Report relies on a series of highly contestable estimates, primarily relying on the work of a pharmaceutical economist, John Vernon. It begins with the calculation that foreign prices should be raised by \$17.6 to \$26.7 billion per year.

The report then calculates, based upon industry-provided data, that an increase of \$17.6 to \$26.7 billion in sales will result in \$5.3 to \$8 billion in additional R&D.

Finally, it concludes that \$5.3 to \$8 billion in additional R&D will translate into 3-4 new drugs per year. In short, that free riding by rich OECD countries destroys 3-4 innovative new drugs per year.

Let's take these points one at a time. I will perform a sensitivity analysis to some of the assumptions.

First, as I stated moments ago, it will be impossible to raise drug prices abroad by billions of dollars, except in the poorest of countries where it will do the greatest damage. When we tried in Australia, drug prices look like they will actually decline. The strategy is counterproductive. Rather than assuming that the global increase will be \$17.6 to \$26.7 billion per year, it would be much more realistic, given the experience with Australia, to assume that the price increases will come largely in low and medium income countries. The total prescription drug market size of these countries is approximately \$25 billion. A 20% price rise in all non-OECD countries might yield approximately \$5 billion per year in additional revenues.

Second, why assume that drug companies will use the additional sales to increase R&D in the US? In recent tax court filings, GlaxoSmithKline claims that most of its R&D profits are in Ireland, not the US. (GSK is trying to avoid a multibillion dollar IRS assessment.) Vernon assumes that about a third of the additional revenues will be spent

on R&D, but this is based on data provided by the companies themselves, and is highly suspect. PhRMA self-reports that about 15.6% of its revenues are currently spent on global R&D. If we use PhRMA's number, the estimates in the Department of Commerce Report must be cut in half.

But there is every reason to assume that even PhRMA's R&D figures are inflated. Some funds which are characterized as R&D are actually marketing tools. The revelations of rampant consulting arrangements at NIH and off-label marketing which relied on sponsored studies are other possible examples. While the NSF has estimated that PhRMA's 'real' R&D figures are much lower, around 7.1% we have no way of knowing what the truth is. If 7.1% is the correct number, the Department of Commerce report is inflated by 465%. Raising drug prices by \$5 billion per year might result in a net gain of \$355 million in global R&D. The terrible human cost of a 20% price rise in patented drugs in non-OECD countries would be many billions of dollars, relying on PhRMA-supported studies on the value of medicines and consumer sensitivity to price increases.

The third and final step in the calculation assumes that \$5.3 to \$8 billion in additional R&D will yield 3-4 new molecular entities. (The actual R&D increment is likely to be only \$355 million, with offsetting costs in poor countries in the tens of billions). The translation of R&D money into actual drugs is based on DiMasi, Hansen and Grabowski's analysis of confidential data provided by PhRMA companies. It cannot be verified for accuracy and has many critics. Even if one accepts these numbers, it represents an average cost. We should expect that the project PhRMA companies trimmed from the R&D budget were less likely to succeed, that they were being intelligent in managing the R&D budget. If so, the effective yield from this incremental R&D will be less, perhaps much less. Nor does this mean that the supposed new drugs will be actually a major improvement. Most new drugs are modestly incremental, or actually no better than existing drugs in class. If one estimates 75% of new FDA approvals to be in this category, then the Department of Commerce estimates must be reduced by another factor of 4.

My cumulative analysis suggests that \$355 million per year will buy one innovative drug every 12 or 13 years, which is hardly a price worth paying for the likely impact on the world's population of a 20% increase in non-OECD drug prices. A 1% change in the NIH budget would have a larger effect on R&D.

3. Transparency

I am not suggesting that my rough estimates be relied upon as the last word on these subjects. What is needed is transparency. The US Congress is making major public policy decisions without the necessary facts. Every time someone proposes to improve drug access, PhRMA retorts with "protect innovation," but never discusses questions of financial access to drugs or the optimal level of R&D. It is shocking that Congress does not have access to reliable data with independent analysis on pharmaceutical innovation and pricing.

APPENDIX A: What is the optimal level of pharmaceutical innovation?

For the pharmaceutical industry, the optimal level of appropriation through rents must be sufficient to fund the socially optimal level of R&D. Optimization must balance concerns of cost, quality, and access, looking for the greatest net gain to global public welfare. Excessive rents harm human health without advancing socially optimal R&D. Society adjusts incentives such as patent law, grants, and tax incentives to achieve the best level of appropriation.

Maximizing R&D at all costs should not be our objective. Resources devoted to R&D are not available for other uses. Uwe Reinhardt puts it this way: “Year after year, the last dollar spent on drug research and development (R&D) should yield society as much benefit as it would have yielded if it had been spent to produce other goods or services.”

We should also avoid the assumption that all R&D targets are equally valuable. Some innovations are more valuable than others. Companies allocate research funds in response to price signals from commercial pharmaceutical markets. As a result, Americans now have a third drug for erectile dysfunction, and funds for neglected disease innovation are literally going to the dogs, but malaria and AIDS vaccines are not available.

You get the sense that ships are passing in the night on this issue. James Love estimates the static global deadweight loss on pharmaceutical patents at over \$400 billion per year, and Larry Lessig implores us not to allow IP law to be perverted while a holocaust devastates millions in the developing world. Meanwhile Joseph DiMasi and Henry Grabowski suggest that the “dynamic benefits created by patents on pharmaceuticals can, and almost surely do, swamp in significance their short-run inefficiencies.” Yet, in a major study, the Congressional Budget Office conceded that no one knows whether current levels of pharmaceutical R&D are optimal. This is the pressing question.

Some empirical evidence suggests that PhRMA companies earn well above market rates of return, one possible indicator of supra-optimal pharmaceutical rents. Until recently, the industry’s long-term profits were four times the rate of the Fortune 500. IRS data from 1990 to 1996 demonstrate that the drug industry’s after-tax profits are more than triple the rate for all industries. The industry is not doing as well in the recent past.

Calculating optimal pharmaceutical rents must account for other sources of public funding for R&D, such as government grants, direct government expenditures, foundation donors, and tax incentives. The industry receives substantial tax incentives, resulting in an effective U.S. federal income tax rate in the late 1990s of 16.2%, compared with 27.3% generally. Again, this tax rate advantage has recently moderated, but other tax advantages remain which are not captured by rate comparisons.

The ways in which PhRMA companies currently opt to expend their cash flows may also indicate supra-optimality. The pharmaceutical industry currently spends more on sales

and marketing than on R&D. Large marketing expenses are not proof that pharmaceutical rents are supra-optimal, but merely indicate that the industry believes the return on investment in marketing is greater than alternative investments such as R&D. If the industry holds a relatively low view of the value of an additional dollar of R&D investment, then perhaps society would be better served with that additional dollar being used to provide life-saving access to medicines.

Some scholars, including proponents of the anti-commons movement, suggest that the neo-classical link between patents and innovation is overstated, particularly for industries marked by cumulative innovation such as genetics. If so, optimal rents may be lower than previously expected.

The most important data required to resolve this question are in the hands of the pharmaceutical industry and are not available in a reliable form to independent researchers. This fact alone is a compelling reason to demand transparency. It certainly seems plausible to presume that supra-optimal rents are currently being collected. The burden of coming forward with contrary evidence should be placed on the parties controlling the relevant information: the PhRMA companies.

Appendix B: A Brief Note On the HHS Study

1. Safety

While in the abstract, safety is a possible issue with drug importation proposals, in the real world any supervised importation program is preferable to today's unregulated Internet importation markets. Programs like I-SaveRx (Illinois and other States) or the Dorgan-Snowe Bill (S.334) are much safer than anything that is happening today, and more closely supervised than present domestic mail order pharmacies serving millions of Americans.

2. Impact on US Sales

As for the likely volume of drugs which would be imported from abroad, some highly speculative estimates can be made. Current volume of Internet purchases from Canada are on the order of \$600 million per year. Opening the US market to drugs from Canada and Europe will have an appreciable impact on US prices, but not perhaps as much as some claim. Recently created importation programs (such as Illinois and Minnesota) have seen modest growth, demonstrating the effectiveness of the FDA campaign as well as drug company practices to restrict importation.

Recently, two competing studies on the European experience with parallel trade have been issued, one for the name brand companies, and another for the parallel importers. As is common, these studies come to opposite conclusions, favorable to the firms which funded the study. But they do agree that within Europe, parallel trade comprises about 10 to 20% of the market share by value in higher priced European markets.

If we make similar assumptions in the US, adjusting for the existing price discrimination within the US market, one could expect parallel trade to stabilize after a few years at \$12 to 24 billion per year.

Savings to US health plans are more difficult to estimate. The drug industry funded study reported meager savings. But this is primarily because the industry has made life so difficult for parallel traders. Today, the savings from Canada are less than a year ago because the drug companies are choking off the supply to Internet pharmacies. If one assumes a more transparent market, and forbids companies from manipulating downstream markets (as in S.334), then one could expect significant savings after expenses, in the range of 20% to 30% of the sales. Net savings to US health plans and consumers can thus be estimated in the range of \$2.4 billion to \$7.2 billion per year. It is a modest sum compared to total US health expenditures, and yet the savings are significant for the individuals who resort to Internet purchases. Most importantly, PhRMA supported researchers (such as Frank Lichtenberg) suggest that increased access to drugs will save lives. We must assume that \$2.4 billion to \$7.2 billion per year in lowered consumer prices will save hundreds or thousands of American lives, based on these PhRMA estimates.

3. Impact on R&D

Assume reduced sales on the order of \$2.4 to \$7.2 billion per year. To calculate the amount of R&D affected, and then the number of drugs affected, requires us to face the same issues described in the Department of Commerce report above. If the R&D response is 33%, the range is \$800 million to \$2.4 billion per year. If the percentage is 7.1%, the range is \$170 million to \$511 million per year. With savings of \$7.2 billion, the upper-end R&D deficit of \$511 million could be addressed with increased NIH grants, leaving taxpayers with a dynamic gain of \$6.689 billion dollars due to importation, together with the associated health impacts of enhanced financial access.