Making Today's Drugs Affordable for All While Boosting Breakthrough Research:

A Few Lessons from the Arguments over Importing Drugs from Canada

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I'm happy to acknowledge that the ideas presented here have been developed in collaboration with my colleague, Deborah Socolar.

Let's begin by seeing if we can agree on a few things—16 things, actually.

1. High U.S. prices spur importing.

2. Drugs could be imported from Canada with reasonable confidence in their safety. Savings on price would greatly exceed costs of assuring safety. If any safety problems result from importing today, they result from the apparent illegality of importing, just as prohibition led to unsafe liquor. If importing is legalized, unsafe suppliers will disappear. Allegations of safety problems

can't be seen as a pretext for intransigence. The reality of unaffordable medications must be addressed.

3. If Americans could pay Canadian prices for brand name drugs, other things equal, we would save a great deal of money. I estimate this saving at close to $60 billion in 2004. The emphasis here should be on winning Canadian prices for U.S. drugs, not on physically bringing drugs from Canada. We should recognize that one of the main lessons from Canada, communicated to all Americans—by bus, by fax, or by web—is that high U.S. drug prices are not a natural or immutable phenomenon.

4. Physically, a nation of 30 million can't supply all or even most of the needed volume of prescription drugs for a nation of 300 million. Importing is a retail solution that helps a vigorous and mobilized minority obtain the meds they need. Shutting off this safety valve would be explosive politically, as the FDA undoubtedly knows well. Importing is not a comprehensive solution. In this, it resembles the arguments over generics, patent length, pill-splitting, and the rest. If importing were expanded, it could certainly provide additional short-term relief by making medications more affordable for more people. Still, importing is a palliative, not a cure, to the problem of financing affordable meds for all Americans and breakthrough research. It's a secondary discussion, helpful but somewhat removed from the heart of the matter.

5. Importing drugs would not, essentially, be an act of market competition or free trade. That's because lower prices elsewhere are achieved through price controls and other government actions. At the same time, high U.S. prices are not, mainly, a result of free market forces. That's because patent-generated monopolies, mergers and oligopolies, administered pricing, substantial information inadequacies and distortions, supplier-induced demand, insurance coverage, and other forces all tend to inflate prices here above the levels that would be found in a free market.

6. Financially, Americans don't need to wash our pills in Canadian laundromats to get them clean.

7. Logistically, drug makers can and do work to hold down inventories in Canadian warehouses, as I predicted in Senate testimony early in September of 2001.[1]

8. Importers can and do then go to Ireland, the U.K., the E.U., Israel, Chile, and elsewhere. Drug makers can try to wall off the rest of the world. They can proselytize about the importance of high drug prices and demand that other nations raise theirs, but that's pushing on a string. They can even try to sustain the current federal government efforts to negotiate free trade agreements that prohibit free trade in drugs. But, in the end, it's hard to build a Grand Coulee dam high enough or strong enough to keep the level of U.S. prices so artificially far above those of the rest of the wealthy world. And this becomes a bigger problem each year, as the gap between U.S. prices and those in other wealthy nations continues to grow. The U.S. average price excess, over prices of drugs in Canada and six European nations, rose from 60 percent higher in 2000 to 81 percent higher in 2003—a rise of one-third in three years.[2]

9. Total U.S. prescription drug spending in 2004 is about $250 billion, about one-half of the world-wide total, and up from one-third in 1996.[3] (This, appropriately, includes spending on drugs in hospitals and nursing homes in addition to retail spending.)

10. Drug spending has been doubling every five years since 1994—from about $60 billion in 1994 to about $120 billion in 1999 to about $250 billion this year.

11. Some 75 million Americans, one-quarter of us, have no prescription drug coverage, and many additional millions are under-insured. The new Medicare Part D drug benefit will leave seniors under-insured.

12. The inevitable choice, in the prescription drug field, is among continued suffering and premature death from lack of needed medications, continued increases in spending, and reform. Put that way, reform is inevitable. What, then, holds it back? Reform is retarded by two main things:

    - The first is pessimism, lack of imagination, and lack of appreciation that the job of winning affordable prescription drugs for all Americans is the easiest problem to fix in the United States. Reasons for optimism include today's very high spending on medications in this nation—already enough to finance all the drugs that all Americans need—and the low marginal cost of making more pills once the research is done and the factories are built.

    - The second is failure to distinguish between two very different questions: making today's medications affordable for all and incentivizing more breakthrough research tomorrow. Drug makers insist that high prices today are essential to breakthrough research tomorrow. They are dramatically wrong—wrong in ways that are dangerous to the public and to the drug makers' own well-being. High prices today have blocked provision of needed meds to all Americans today, and they do not incentivize breakthrough research tomorrow. In this talk, I therefore separate these two very distinct jobs.

13. There are two ways to limit spending on drugs—cutting price or cutting use. If prices are deemed untouchable, limiting use is all that remains. But that makes little sense—financially, politically, or clinically.

- Limiting use is financially inappropriate, since the marginal cost of making more pills is tiny, once the research is done and the factory is built.

- Limiting use is politically inappropriate, since teasing people with valuable meds but then denying them access is infuriating.

- Limiting use is clinically inappropriate. Drugs are very important to health today. Many people already use less than they need. They offer many opportunities for more effective health care in the future, and possibly some opportunities for reducing spending on health care.

14. These opportunities won't materialize without substantially more breakthrough research. That probably requires devoting less of the research dollar to me-too or copy-cat drugs.[4]

15. This research won't materialize without adequate investment—either public financing through NIH and other vehicles; or private financing by today's large drug makers, tomorrow's innovators, venture capitalists, and the like; or both public and private investment.

    That investment won't materialize without adequate incentives, perceived rewards. But that's only part of the picture.

16. Today, investment in breakthrough research is depressed, apparently by a combination of a) perceived or real scientific barriers to developing valuable new drugs and the costs of overcoming them, and b) a well-justified fear of U.S. price controls.

Now a few things—16 again—on which some of us might not agree.

1. Drug makers bluster that price controls will lead them to cut breakthrough research further, and that we will all suffer or die prematurely as a result. This is bluster for at least two reasons. First, drug makers already invest far too little in breakthrough research. Second, U.S. price controls are inevitable. The questions concern when and how, not whether. So, it is the drug makers' continued refusal to engage with public and private payers to negotiate a soft landing for drug prices that would help lead to the very worst case that the drug makers rage about publicly—harsh, sudden limits on price. Sustained drug maker intransigence will help to elect the angriest Congress in the history of the world in about 2006 or 2008, a Congress that will slash drug prices. While drug makers are primarily accountable for this problem, they are not uniquely responsible. Advocates of durably affordable medications for all Americans could do more to engage with drug makers.

2. The fear of price controls—the threat of price controls—is real, not imaginary. A Reuters report asserts that both Kerry and Bush, if elected, are seen as "pressed to curb drug prices."[5]

3. What makes the threat real? Not political jockeying or fabricated problems. The threat of price controls is real only because of the drug makers' own decades of success in harvesting ever-higher revenues from American patients and payers, a success that finally frightens patients, employers, state Medicaid programs, HMOs, many elected U.S. legislators, and even—perhaps—some CMS actuaries.

4. Drug makers are understandably nervous, the most nervous very-well-dressed people in the United States. Said one big-PhRMA CEO, "We know we are defying gravity." After all, nothing can keep doubling forever. And blockbuster drugs are going off patent. Relatively little is in pipeline.

5. How, then, have the drug makers worked to sustain rapid revenue growth? The drug makers have come to rely excessively on the very conservative strategy of what I call the 3Ms—me-too's, mergers to cut competition, and marketing and advertising. About one-half of PhRMA members' research goes to me-too or copy-cat drugs. Also important to bolstering revenue growth have been increases in price on existing drugs.

6. Underpinning much of this conservative strategy has been the undermining of objective science—from the conduct of research to the reporting of research (and the non-reporting of some research findings) to the subsidization of journal publication and all the rest. Evidence-based prescribing must rest on objective evidence—evidence that's too often lacking today.

7. Rationalizing much of this conservative, cautious strategy has been the public talk of the drug makers themselves, often supported by hijacked free market enthusiasts. To the degree that my analysis is correct, the drug makers are not vigorous and unrestrained free market competitors but rather high-price, low-volume members of restrictive medieval guilds.

8. Drug makers and their friends like to assert that the political threat of price controls undermines breakthrough research. They talk publicly that incentives do count and that they won't conduct risky breakthrough research without the reward of enormous profits, so the threat should be withdrawn.

   I'd like to suggest that drug makers have it only half right publicly. Yes, rewards induce risk-taking. But no, the threat of price controls is not political whimsy or opportunism. Rather price controls are an inevitable result of drug makers' own financial success in the U.S. market. Did they really expect that they could quadruple their U.S. revenues from 1994 to 2004 without facing serious consequences? I believe that drug makers have already privately recognized that price controls are inevitable and have already begun relying

heavily on the conservative and protective strategies for boosting revenue that were described a few minutes ago. (Happily, the U.S. can institute price controls in ways that spark, reward, and reinvigorate breakthrough research.)

9. Further, since incentives do count, our nation has been erring badly by allowing drug makers to harvest extraordinarily high profits in recent years while offering little in the way of breakthrough research. In a sense, we have been throwing money at the drug makers without demanding specific performance. (More accurately, they have been extracting money without delivering the breakthrough research they promised in exchange.) They have asserted that high profits will be the incentive to perform breakthrough research. They have not, however, demonstrated that connection through their own behavior. The drug makers employ camouflage when they assert that high profits are the incentive for breakthrough research, albeit a camouflage twisted out of recognition.

   One of the things about camouflage is that it's hard to see that it's been twisted out of recognition. It's vital to pay for results, not to throw money at any industry, no matter how vigorously it engages in self-sanctification. We need to learn how much profit/reward is needed to elicit the investments in breakthrough research that the nation desires. And we need mechanisms that clearly link profit to risky and expansive investments and the breakthroughs they produce, not to the constrictive and protective conservatism of the 3M's or price boosts on existing products.

10. First, please consider that, even if the U.S. pharmaceutical industry (itself a thing whose boundaries are hard to survey and mark in a globalize industry) has been more innovative than other nations' (a very debatable proposition), high U.S. drug prices can't be responsible. That's because all of the main drug makers of the wealthy world harvest a disproportionate of their profits in

the U.S. market. It's equal opportunity pillaging and plundering of the American patient and payer.

11. Next, please consider the evidence that, if 45 percent or more of the drugs imported from Canada are new prescriptions (as opposed to replacements for existing prescriptions), drug makers' profits (revenues less costs) will actually rise when more drugs are imported from Canada.[6]

12. This suggests the possibility that volume increases could offset price cuts.

13. I call this a ***prescription drug peace treaty***. It might work like this:

    a. cut U.S. prices for brand name drugs to Canadian levels

    b. drug makers' revenues fall by $60 billion, other things equal

    c. but other things aren't equal: lower prices mean higher private market demand

    d. how much higher? considerably higher than the 0.3 price-elasticity of demand estimated by the RAND researchers from data collected in the mid-1970s

    e. why higher than 0.3? Because meds have changed enormously toward higher-cost chronic-use drugs over the past 30 years, because the RAND study excluded Medicare patients, typically among the highest users of the high-cost drugs—those most sensitive to price, and because of the influence on demand of drug makers' marketing and advertising. (But please note that the success of this proposed peace treaty does not rest on how high or how low the price-elasticity of demand turns out to be in practice. That's because the peace treaty would specifically calibrate the

sum of the private payments and the public payments to replace all revenue lost owing to the price cut.)

f. further, lower prices would allow Medicare and Medicaid to expand eligibility and benefits

g. together, public program expansions and public prices to drug makers could be calibrated to both replace
   - that share of the $60 billion not replaced by the rise in private demand, plus
   - the tiny added cost of manufacturing additional pills and dispensing them.

14. I see this as an interim measure, to allow the drug makers a transition from today's constricted, sheltered, and manipulative corporate welfare system to one that actually rewards wholehearted, expansive investment in successful breakthrough research. Today, many drug makers—though certainly not all—can make very good money without investing adequately in breakthrough research. And they can point to the fear of looming price controls as a justification or pretext for refusing to invest adequately. Tomorrow, we can cut prices while sustaining revenues and profits, thereby removing the pretext. We can build a solid financial and political foundation for vitally needed breakthrough research.

    You might wonder why, if the job of winning affordable meds for all is so easy, drug makers don't just lower prices and recoup the lost revenue through private market volume increases. There are several reasons: a) Change is difficult, particularly for very large and, until now, very successful corporations.
    b) Abandoning control over one's prices is exceptionally difficult.

c) Drug makers have succeeded in digging themselves into a hole with their high U.S. prices, but this has—after all—worked for many years.
d) Drug makers are so far down that hole that it's hard for them to see out of it: They've been captivated by their own propaganda that high U.S. prices are essential to innovation.
e) Further, which CEO will cheerfully abandon what has worked until now? Better, as Louis XV said, to try to bring in a few rich harvests and hope that the flood hits after you retire.
f) Finally, and perhaps most important, the revenue replacement in the proposed peace treaty depends on a reasonably high and sustained level of trust between payers (both private and public) and the drug makers, backed by both physicians and the public (the patients and ultimate payers). That's because higher private market volume alone is very likely to be adequate to replace all of the revenue lost to a price cut by drug makers. In other words, revenue replacement isn't under drug makers' sole control. This makes public participation is essential. Building the foundation for trust among payers, drug makers, physicians, and the public must begin soon. That's why payers and drug makers need urgently to converse about a durably affordable and sustainable future of affordable medications for all Americans combined with strong and targeted incentives for conducting breakthrough research.

(In these remarks, I am happy to acknowledge the apparently substantial differences among drug makers. Some have remained committed to conducting breakthrough research despite the threat or, I believe, the inevitability of price controls. These generally tend to be smaller and mid-size companies without established product lines. Public policy should document, acknowledge, and respect the important differences among drug makers in these regards.)

15. After the transition period, we need to reward breakthrough drugs very generously. Indeed, we should pay for all new drugs in proportion to their demonstrated value.

16. The main point is that incentives count. If we want drug innovation, we have to reward that behavior, and stop rewarding the conservative and cautious—yet expensive—alternatives of the 3 M's plus price rises on existing drugs. The Australians, for example, have gotten fairly good at pricing new drugs in proportion to value.

In conclusion, what can we derive from this dispassionate look at prescription drugs?

First, both individually and as a nation, we don't always get what we pay for. We have been paying enough to buy all the prescription drugs that all Americans need, while financing heavy investments in breakthrough research, but we have gotten too little coverage and too few breakthroughs. What we get depends not only how much we pay, but also on how we pay. We have been paying for prescription drugs in ways that allow drug makers to, all too often, print money in the basement.

Second, that has to stop. We have to incentivize and reward only the behaviors we want.

Third, that means very generous rewards for breakthrough research.

Fourth, the research is meaningless if more and more people can't afford the product—the product of the research.

Fifth, that's one reason why we need a prescription drug peace treaty now. The other reason is to protect and expand the research to develop the cures our citizens and those of the entire world both need and deserve.

Sixth, I'd like to urge and encourage each of us to regard the job of winning affordable medications for all Americans while enhancing and rewarding investments in breakthrough research as the most exciting opportunity and the easiest problem to fix in the U.S.A. Not an easy problem, just easier than all of the others. We spend enough--$250 billion is enough—and the marginal cost of manufacturing is tiny, making equity affordable. To grasp this opportunity, we all need to abandon the comfortable slogans and abstractions of the past.

In particular, I hope that drug makers move forward quickly but carefully by beginning privately to discuss practical ways to make all of today's medications affordable to all U.S. patients who need them, and to appropriately incentivize tomorrow's breakthrough research. The time to compromise is when you are still strong. Despite recent problems, drug makers still retain substantial public credibility, respect, and gratitude. These will wane if the public grows steadily more angry. Drug makers' political support will fall as public anger rises. The next few years may offer drug makers their best chance both to negotiate a soft financial landing that resolves today's problems and to build a platform for launching future breakthroughs.

Someone, probably Oscar Wilde, described fox hunting as the unspeakable in pursuit of the inedible. We should cease apologizing for drug makers' current behavior, the inequitable in pursuit of the unsustainable.

Notes

[1] Alan Sager, *Americans Would Save $38 Billion in 2001 If We Paid Canadian Prices for Brand Name Prescription Drugs: How to Win Those Savings and Use Them to Protect All Americans against High Drug Costs without Hurting Drug Makers or Drug Research,* Invited testimony before the U.S. Senate Commerce Committee, Subcommittee on Consumer Affairs, 5 September 2001, www.healthreformprogram.org, published in United Sates Senate Committee on Commerce, Science, and Transportation, Subcommittee on Consumer Affairs, Foreign Commerce, and Tourism, *Comparative Pricing of Prescription Drugs Sold in the United States and Canada, and the Effects on U.S. Consumers,* Washington: U.S. Government Printing Office, 2003, pp. 71-86.

[2] Alan Sager and Deborah Socolar, "2003 U.S. Prescription Drug Prices 81 Percent Higher than in Other Wealthy Nations," Data Brief No. 7, Boston: Health Reform Program, Boston University School of Public Health, 28 October 2004, www.healthreformprogram.org.

[3] 1997: IMS Health, World Review, 15 Largest Pharmaceutical Markets in the World, 1997, www.ims-global.com/insight/world_in_brief/new_yearly/largest.htm, accessed 5 May 1999. 2002: IMS Health, "IMS Reports 8 Percent Constant Dollar Growth in 2002 Audited Global Pharmaceutical Sales to $400.6 Billion," www.imshealth.com, accessed 26 February 2003.

[4] In 2000, Merrill Goozner asserted that 40 percent of drug makers' research goes to developing me-too drugs. See "The Price Isn't Right," *American Prospect,* 11 September 2000. Joseph DiMasi of the Tufts University Center for the Study of Drug Development concurred in this estimate.

[5] Lisa Richwine, "Bush, Kerry Both Seen Pressed to Curb Drug Prices," Reuters, 26 October 2004, http://www.reuters.co.uk/newsArticle.jhtml?type=healthNews&storyID=6614468&src=rss/uk/healthNews&section=news, accessed 26 October 2004.

[6] Alan Sager and Deborah Socolar, *Do Drug Makers Lose Money on Canadian Imports,* Boston: Health Reform Program, Boston University School of Public Health, 15 April 2004, www.healthreformprogram.org. This estimate rests on the 2002 gap between U.S. and Canadian prices for brand name drugs, not the somewhat higher gap reported by the Canadian government for 2003. See Alan Sager and Deborah Socolar, *2003 U.S. Prescription Drug Prices 81 Percent Higher Than in Other Wealthy Nations,* Data Brief No. 7, Boston: Health Reform Program, 28 October 2004, www.healthreformprogram.org.