Importation of Prescription Drugs
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Testimony

Mr. Chairman and Members of the Committee, I wish to thank you for the opportunity to testify today on the issue of pharmaceutical reimportation. My name is John Vernon and I am a professor in the Department of Finance and in the Center for Healthcare and Insurance Studies in the School of Business at the University of Connecticut. I have a Ph.D. in economics from City University, London and a Ph.D. in Health Policy and Management from the Wharton School of Business at the University of Pennsylvania. I also hold bachelors and masters degrees in economics from Duke University and North Carolina State University, respectively.

My testimony today will be quite narrow in focus. I will not discuss whether drugs imported from Canada or elsewhere are safe, nor will I discuss the potential economic benefits that importing drugs from price-regulated markets (such as Canada and the EU) may produce through expanded access to existing medicines. While both of these issues deserve careful analysis and attention, they lie outside the domain of my research and expertise. Instead, this morning, I will limit my testimony to the potential long-run economic costs of legalizing reimportation, which can be viewed as importing foreign price controls to the U.S. pharmaceutical market.

Because informed policy debate must always weight the benefits of a proposed policy against its costs, and because the costs associated with regulated drug prices in the U.S. will occur many years into the future (through reduced levels of pharmaceutical innovation), my colleagues, Carmelo Giaccotto, Joseph Golec, and Rexford Santerre, and I have undertaken several research studies that attempt to estimate these long-run costs. We calculate them to be quite substantial, and in the trillions of dollars.

I would like to begin by clarifying an important point: reimporting patented pharmaceuticals from outside the United States is not a free trade issue. This is a common misunderstanding. The rationale for free trade is based on the doctrine of comparative advantage: where countries specialize in the production of goods and services for which they are, comparatively speaking, low-cost producers, and then trade freely with other countries doing the same thing. Free trade is good for the economy and good for society. But pharmaceutical prices in Canada and elsewhere are lower because drug prices are regulated in those markets, and not because those countries have a comparative advantage in the production of pharmaceuticals (in the absence of price regulation, it is likely that prices would still be lower outside the U.S. because of lower real income levels). It is imperative to understand that the real issue at hand is intellectual property

rights. If patented pharmaceuticals are imported from abroad, the U.S. patent system is circumvented, and price controls will be indirectly imposed on pharmaceuticals in the U.S. Please allow me to clarify this point.

Once a new pharmaceutical or molecular entity has been discovered, researched and then developed (which typically takes 12-15 years), and all the safety, efficacy, and other clinical data are collected and analyzed, the marginal manufacturing cost of a single pill is quite small. This is because the final product of all the R&D is essentially just new information and knowledge: information that has taken many years and hundreds of millions of dollars to obtain. In the absence of intellectual property rights, and the ability of pharmaceutical firms to price their products significantly above marginal manufacturing costs, no investor or firm would spend the time and money to discover and develop this information. Thus, there must be a sizable reward to induce these R&D activities. As is, only 3 out of 10 new products generate returns in excess of average R&D costs (Grabowski and Vernon, 2000).

This being said, however, once a product has been brought to market, pricing above marginal cost results in an underutilization of the new product (from a social welfare perspective). Clearly, then, a tradeoff exists between providing incentives for research and development (R&D), and thus innovation, and consumer access to today's medicines: this is the balance the U.S. patent system tries to strike.

While there is nothing sacrosanct about the current structure of the U.S. patent system for pharmaceuticals, or indeed the existing rate (and stock) of R&D investment, what is immediately apparent is that allowing importation of prescription drugs from price-regulated markets, while possibly expanding access to medicines already developed, effectively circumvents the U.S. patent system and allows foreign governments to set the price of pharmaceuticals in the U.S. If successful, the result will be to significantly diminish the incentives to invest in R&D, which in turn will reduce the future supply of new drugs.

The research I will summarize today represents an attempt to measure the long-run costs associated with imposing foreign drug prices on the U.S. market. While economic theory predicts it is unlikely this would occur through legalized reimportation alone, because this is the implicit intent of the policy, our analyses are based on this scenario.

Measuring the costs associated with forgone future innovation is indeed a difficult task: there are many variables that can affect the outcome. However, because there is an overwhelming tendency for public policy debate to focus on the short-run benefits of lower (regulated) drug prices, it is critical that efforts be untaken to estimate what the corresponding costs would be in terms of lower levels of innovation. Only then can the benefits be weighted against the costs to determine if the policy is a good one. Obviously, our research focuses on only one component of the economics of importation and price regulation: the long-run costs. As such, our analyses must not be viewed as a complete cost-benefit analysis.

It is well known that the allocation of resources to investment activities depends on the expected costs and future returns of those investment activities. Pharmaceutical R&D is no exception. The effect of a policy permitting the large-scale reimportation of price-regulated pharmaceuticals from abroad, if successful, or if accompanied by direct price controls, will be to significantly reduce the expected returns associated with pharmaceutical R&D. Rational firm managers, acting on behalf of their shareholders, will divert resources away from pharmaceutical R&D and into other, now relatively more attractive, investment activities. Pharmaceutical R&D will decline. What is uncertain, however, is by how much R&D will decline. This will depend on two things: (1) the "success" and scale of the reimportation policy, or price control scheme, and (2) the sensitivity of R&D investment to expected pharmaceutical profitability. For the purposes of our research we assumed that the policy would achieve its objective, and the result would be pharmaceutical prices (profit margins) in the U.S. that are comparable to those found outside the U.S.

To quantify the sensitivity of R&D to pharmaceutical prices and profitability in our research, we employed a variety of methodological techniques, including standard retrospective statistical analyses of industry and firm-level data and prospective simulation analyses (Vernon, 2003, 2004; Giaccotto, Santerre and Vernon, 2004). Interestingly enough, our findings were strikingly consistent across methods and studies, and suggest that such a policy, if successful, would reduce R&D by approximately 25 to 30 percent. For our base case analyses we used the low-end figure of 25 percent (Golec and Vernon, 2004). Depending on the study and method, this figure may reflect either a one-time drop in R&D, with no impact on the future growth rate of R&D investment, or a decline in the growth rate of R&D by between 1-2 percentage points only, with no one-time effect. The two effects generate the same estimate. It seems likely, however, that both effects would occur, at least to some degree, but in estimating the long-run costs of forgone innovation, we adopted a conservative approach, and assumed a single effect (Golec & Vernon, 2004).

Then, using results from recent studies on the growth rate of industry R&D (Scherer, 2001) and the cost of capital for pharmaceutical R&D (DiMasi, Hansen, and Grabowski, 2003; Myers and Shyam-Sunder, 1996) we calculated the present value of forgone R&D using standard methods. Finally, we combined this measure with estimates of the productivity of pharmaceutical R&D (Lichtenberg, 2002, 2003) to translate this policy-induced decline in R&D into human life years and lives lost, and then into dollars using standard estimates of the value of a human life year (Cutler and McClellan, 2001). Our findings predict that a policy successfully reducing pharmaceutical prices (and profit margins) to the levels observed in markets where governments regulate drug prices will impose a cost of approximately 79 million life years, one million lives, or about $8 trillion (Golec and Vernon, 2004).

To place the later figure into context, consider that the 2003 GDP for the U.S. economy was roughly $11 trillion. This cost estimate seems reasonable when compared to the recent findings by University of Chicago economists, Kevin Murphy and Robert Topel, that a permanent 10% reduction in mortality from cancer and heart disease would have a

value of $10 trillion dollars to Americans.

In conclusion, I wish to emphasize that the research I have summarized looks at only one aspect of the policy issue: the long run costs of forgone innovation. Informed policy debate must consider all aspects and consequences of legalizing importation, or of regulating drug prices in the U.S. This being said, however, the present value costs of such a policy to future generations appear to be quite significant.

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