Policy Options for European Pharmaceutical Markets

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Abstract

European consumers spend significantly less on prescription drugs than Americans. While American policymakers may wish for higher spending in Europe as a stimulus to innovation, there is little indication that the regulatory stance of Europe will move in that direction. Indeed, it is possible that new regulations in Europe will lower prices and pharmaceutical revenues further. Using a global microsimulation model of pharmaceutical policy, we analyze the impact – on Europe and the US – of both lowering pharmaceutical prices (and revenues), and raising pharmaceutical prices in the European market. We find that European policies that impose further price-tightening, by lowering manufacturer prices by 20%, would cost about $30,000 in per capita value to American near-elderly cohorts alive in 2060, and $25,000 to similarly aged Europeans in that year. There would also be very small costs to near-elderly cohorts in the nearer term. The opposite is true for increases in European prices, which benefit Americans and Europeans in the near- and long-term. These conclusions are robust to variation in the values parameterizing the underlying model.

A. Introduction

Many US policymakers have expressed frustration with the perceived disparity in pharmaceutical pricing between the US and Europe. There is some debate about how much quality-adjusted prices themselves differ, but there is little debate that Europeans spend far less per person on biopharmaceuticals, partly because of more restrictive access to newer, more expensive drugs, and partly because of differences in prices for given drugs (Danzon and Furukawa, 2006). Regardless of its source, Mark McClellan, during his tenure as the head of the Food and Drug Administration (FDA), argued that this spending gap was unsustainable (McClellan, 2003). However, rather than advocating lower US prices and spending, as some policymakers have urged, McClellan and others suggested the need for greater pharmaceutical revenue in Europe.

On the other side of the Atlantic, European policymakers have shown little willingness to raise revenues, and in fact, a significant willingness to lower them further. As an example, the UK implemented its Pharmaceutical Price Regulation Scheme (PPRS), which was intended to establish a stable 5-year pricing regime; as early as 2006, however, the government announced a previously unplanned 7% price cut to control spending. In France, consistent tightening of the health budget (ONDAM) typically leads to required "clawbacks" from pharmaceutical companies, to ensure budget balance. Examples from the rest of Europe abound.

Clearly, there is a conflict between the short-term policy goals of Americans and Europeans. However, there is relatively little quantitative analysis of these different approaches to the pharmaceutical marketplace. The debate has played out as one of

obvious American self-interest pitted against obvious European self-interest. It is reasonably well-established in both the theoretical and empirical literature in economics that higher pharmaceutical revenues and profits provide greater incentives for innovators to produce new drugs (Acemoglu and Linn, 2004; Finkelstein, 2004; Danzon, Wang, and Wang, 2005). Therefore, Americans have a clear and obvious interest in higher European pharmaceutical spending, since they bear none of the cost and derive at least some benefit in the form of an additional stimulus to innovation that benefits everyone in the world. However, given the complexities of innovation in health care, it is not clear where European self-interest actually lies. To be sure, European consumers would rather spend less than more, all else equal. However, if lower spending leads to less innovation for future Europeans, there may be downstream costs borne by Europeans themselves. The relative size of this cost is uncertain, particularly given the large fraction of global spending undertaken by American consumers, who already provide substantial incentives for firms to innovate.

In light of the uncertainty surrounding these policy choices, we provide quantitative analysis of both lowering and raising pharmaceutical revenues in Europe, and characterize the welfare effects of these policies both in Europe and in America. Our approach utilizes a microsimulation model of the US and European marketplace, using data on individuals aged 55+ in both regions. The model predicts that further tightening of European revenues would harm the welfare of Europeans and Americans, both in the current and future cohorts of near-elderly, because the value of induced innovation outweighs the cost of higher spending on pharmaceuticals. Conversely, higher European

revenues confer benefits on both Europeans and Americans. These implications are robust to wide variation in the underlying parameters of the model.

The paper is organized as follows. We begin in Section B with a brief description and justification of the policy regimes we analyze. Section C provides a very brief overview of the microsimulation model's structure. Section D provides the quantitative estimates of the welfare effects of changing European manufacturer or consumer prices. Section E analyzes the robustness of those policy evaluation results. Finally, Section F discusses the policy implications of our work.

B. Policy Regimes

There are a great many specific regulations of the pharmaceutical marketplace in both Europe and the US. For example, European governments implement global prescribing budgets, various forms of reference pricing, profit controls, economic evaluation of coverage decisions, and the list goes on. It would be somewhat impractical to attempt to model the specific implementation of a set of such policies, since there are so many possible permutations. Instead, our approach is to model the family of policy regimes that lowers the revenues paid to pharmaceutical manufacturers, and the family of regimes that raises these revenues. This simplification makes the problem more tractable, while continuing to remain relevant to actual policy choices.

Implicitly, we distinguish between prices paid to manufacturers and the prices paid by consumers, which need not be the same. The existence of pharmaceutical insurance implies that consumers face prices lower than the ones manufacturers receive. In general, European consumers already face relatively low drug prices, and there is little indication

that these consumer prices will rise. As such, we assume that consumer prices do not change, but consider changes in revenue driven by changes in the prices paid to manufacturers.

Specifically, we analyze the impact of reducing — all else equal — the prices paid to pharmaceutical manufacturers by 20%, and the impact of raising manufacturer prices by 20%. The size of the reduction or increase has virtually no qualitative impact on our findings, and is chosen for comparability with the US policy analysis undertaken in our companion paper on US pharmaceutical pricing regulation.

These regimes encompass a wide variety of possible policy choices. Direct price cuts that target manufacturer prices are an obvious example, but there are a wide variety of other policies — such as economic evaluations, reference pricing in all its forms, and global budget controls — that have the effect of depressing average pharmaceutical prices.

We deliberately exclude from consideration the range of auxiliary impacts and policies that could be associated with a price-reduction policy. For example, the money saved by reducing manufacturer prices could be put to use in a variety of different ways — increased utilization of drugs, additional investment in education, rebates to taxpayers, and so on. However, we do not need to explicitly consider what happens to money saved, as long as we can estimate the monetary value to society generated by that dollar of savings, and compare it to the monetary costs of the policy. This estimation is simple, provided that one dollar is worth exactly the same amount to society, no matter where it accrues.

Put differently, a policy that saves the government $100, and costs individuals $50, is net-beneficial, regardless of what the government does with the money. The presupposition is that the government cannot generate more value with its savings, than individuals could have generated with their foregone funds. In practice, this approach might overstate the value of programs that save government money, because the public sector tends to be a bit less efficient at generating high returns. For instance, if the public sector is less than half as efficient at generating value as the private sector, the policy above may in fact be harmful to society. This will cut against a finding that price reductions are harmful, and vice-versa.

C. Structure of the Microsimulation Model

We developed a demographic and economic model to predict costs and health status for the US and European population over the age of 55.[1] A crucial component was a model of how new innovations are discovered, and how they impact the health transitions of this population. The Global Pharmaceutical Policy Model (GPPM) is a microsimulation model that tracks a US-representative sample of 55+ year-olds, and a similar European-representative sample, over time to project their health conditions, functional status, health expenditures, and mortality experience. The European sample is based on the countries represented in the SHARE (Survey of Health, Ageing, and Retirement in Europe) database: Denmark, France, Germany, Greece, Italy, the Netherlands, Spain,

[1] We focus on the 55+ age group, because longitudinal data on health are not readily available for younger populations.

and Sweden. In the interests of simplicity, we consider pan-European policies implemented uniformly across these countries.[2]

The model takes as inputs the policy regimes in the US and Europe. It allows for the analysis of reducing (or increasing) manufacturer prices and revenues. The model then simulates the impact of these changes, for current and future generations, on: health care utilization, medical spending, the prevalence of major diseases, functional status, longevity, and the pace of innovation on the major diseases modeled. Details of the model's underlying estimated relationships are provided in an online technical appendix, and in our companion paper, "US Pharmaceutical Policy in a Global Marketplace."

Ultimately, the goal of the GPPM is to simulate the social costs and benefits associated with changes to the pharmaceutical marketplace. In practice, we calculate the benefit (or cost) associated with more (or less) longevity, net of changes in medical and drug cost. This excludes benefits associated with reductions in morbidity or improvements in lifestyle, and is thus a conservative approach to valuing the introduction of pharmaceuticals. The conservative approach is warranted by the difficulty of quantifying the value of morbidity reductions and lifestyle improvements. The downside is the possibility of undercounting the value of pharmaceutical innovation.

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[2] While the model is capable of analyzing heterogeneity across countries, it is difficult to construct a single, heterogeneous "bundle" of policies for analysis.

D. Quantitative Analysis of Policy Regimes

The GPPM is used to estimate the global impacts of regulation. We explore three kinds of policy regime changes: (1) Lowering manufacturer prices by 20% from their current levels; (2) Raising manufacturer prices by 20% from current levels; and (3) Status quo.

As discussed earlier, we model policies that lower manufacturer prices without affecting consumer prices, and thus utilization. At least in the short-run, decreases in manufacturer prices: lower current drug spending, but leave current utilization unchanged; lower revenues and the future rate of innovation; and have uncertain effects on medical spending. In the long-run, price changes can and do affect drug utilization by affecting the pace of innovation, and the drugs available.

To evaluate the welfare implications of each policy scenario, we focus on the key dimensions of health and medical spending. The model simulates gains (or losses) in life expectancy due to these policy choices; as mentioned earlier, the baseline simulations value these gains using $200,000 as the value of a statistical life-year. In addition, price restrictions are often motivated by a desire to contain costs. Therefore, we also calculate the impact on both drug spending and medical spending. The net present value of a particular policy is given by: the present value of life expectancy, less the present value of medical spending and drug spending.

A.1 *EU Price Reductions*

Our first analysis calculates the effect of further manufacturer price reductions — of 20% — in the EU. Introducing such price reductions — or, more generally, lowering manufacturer revenues by 20% while leaving consumer copayments unchanged — would

affect the pace of innovation, as well as health care spending. The savings from lower prices must be weighed against the cost of foregone innovation. Figure 1 illustrates the impact on global longevity of lowering prices in the EU. The figure shows the impact on 55-59 year-old cohorts in the EU and US, at different points in time. For example, the left-most bar shows the longevity impact for those aged 55-59 in 2010, while the right-most bar shows the impact for those aged 55-59 in 2060. Reductions in EU prices would lower life expectancy in this cohort by about one-tenth of a year. Over time, lower revenues have cumulative effects on foregone innovations. As a result, the effects on longevity accumulate in a similar fashion. For the 2050 and 2060 cohorts, the reduction in longevity has more than tripled from the initial effect, to range between 0.3 and 0.4 years of life.

The net value of a price reduction policy is equal to the cost-savings it produces, net of the cost of foregone longevity due to slower innovation. Figure 2 quantifies the impact of price reductions on the lifetime drug and health care spending of these same 55-59 year-old cohorts in the US and the EU sample countries. On a per capita basis, Europeans of this age group can expect to save between $5000 and $6000 over their remaining lifetimes. All these numbers are given in terms of present value for 2004 dollars. For the US population, there is no direct effect of EU price reductions on health care spending, because this policy does not affect US prices directly. However, to the extent that EU policies affect the pace of innovation, they do affect the demand for and spending on medical care throughout the world. Over a long horizon, therefore, US consumers face about $3000 less in lifetime health and drug spending, largely due to reductions in life expectancy.

For the latest cohorts, this savings in drug and medical costs offsets the present discounted value of 0.3 to 0.4 year reductions in longevity. As a rough guide, the absolute decline of 0.3 years of life expectancy is worth approximately half that in terms of discounted life expectancy, because the reductions in survival do not all take place immediately at age 55 to 59. Therefore, we are offsetting savings of about $6000 in present value, against reductions in discounted longevity of 0.15 to 0.2 years. Therefore, a value of $40,000 or higher for a statistical life-year implies that the policy is welfare-reducing, because the cost-savings are not justified by the size of the longevity decline.

Figure 3 quantifies this reasoning by illustrating the net per capita value of the price reduction policy, to 55-59 year-olds in the US and EU sample countries. Using our baseline value of a statistical life-year of $200K, we find that the price reduction policy only costs $100 per person for 55-59 year-old Europeans in 2010, and only slightly costly to Americans in 2010. However, the costs of the policy mount over time, so that the 2060 cohort faces costs of $25,000 per person in the EU, and $30,000 per person in the US.

To appreciate the numbers in an aggregate context, Figure 4 quantifies the total value of price reductions to the entire 55+ population at different points in time. For example, the figures in 2010 correspond to the values for all individuals alive and aged 55+ in 2010, and so on. The aggregate costs of price reductions to the 55+ population are quite small initially, but mount over time, to reach $6.1 trillion in the US, and $4.1 trillion in the EU sample countries.

A.2 *EU Price Growth*

Figure 5, Figure 6, Figure 7, and Figure 8 illustrate the impact of raising manufacturer prices in the EU by 20%. Increases in manufacturer prices stimulate innovation, but at the expense of higher drug and medical costs. On balance, the additional innovation is worth the cost.

Figure 5 illustrates the impact of EU price increases on longevity. Americans aged 55-59 in 2010 can expect to live 0.2 years longer as a result of the EU policy change, while Americans of this age group in 2060 can expect to live 0.7 years longer. The longevity increases for Europeans of the same age are roughly similar in magnitude, ranging from 0.2 to 0.7 additional years of life.

The gross costs of this policy change are shown by Figure 6. EU price increases are projected to cost 55-59 year-old Europeans between $5300 and $7500 per capita over their remaining lifetimes. Americans face similar increases in cost, but that is entirely through the channel of increased longevity and innovation, both of which raise per capita lifetime spending on drugs and medical care.

Combining the gross benefit in longevity gain with the gross cost yields the net value of the policy, on a per capita basis, as shown in Figure 7. If the EU moved manufacturer prices higher by 20%, and thus closer to US levels, both Americans and European cohorts would benefit. The benefit to the earliest American cohorts is approximately $18,000 per person, and runs as high as $57,000 per person in the latest cohort. For Europeans, the benefit ranges from $8000 to $39,000.

E. Robustness of Policy Recommendations

The baseline estimates of the model imply that EU price reductions would harm future generations in the EU and US, with little or no benefit to current generations. In contrast, EU price increases of roughly similar magnitude would provide benefits to cohorts on both sides of the Atlantic. However, these conclusions are subject to the assumptions of the baseline model. While we relied on the best available economic and medical evidence to parameterize the model, the issues are sufficiently controversial that this approach is not ironclad. Therefore, we assess which of our conclusions are robust to variation in these underlying assumptions.

While the model contains assumptions about a variety of variables, our quantitative analysis pointed to three sets of variables that have quantitatively significant impacts on our predictions. The three critical parameters are: the value of a statistical life-year; the value of new drug introductions; and the responsiveness of innovation to changes in revenue. For all other parameters, either our estimates did not vary, or there is broad consensus in the literature about the best possible value.

Figure 9 displays the sensitivity of the model to variation in the value of a statistical life-year. The Figure shows how the value of a statistical life-year affects the per capita net present value of policy regimes to EU residents aged 55-59 in 2060. The figure graphs the net per capita value of both raising and lowering EU manufacturer prices, relative to the status quo.[3] As emphasized earlier, the only benefit of innovation we consider is

[3] Results are extremely similar for the US net present value and European net present value.

mortality reduction. Changes in the value of a statistical life-year have a linear impact on the value of these benefits. Since the value of a life-year has no direct impact on costs, the overall impact of this parameter on net values is linear.

The figure illustrates that the qualitative predictions of the model – regarding which policies are beneficial and which are costly – are robust to a wide range of variation in the value of a statistical life-year. We consider values from $50,000 to $300,000, a range which encompasses all widely used values for this parameter. Of course, higher values of life imply larger benefits for policies that stimulate innovation. Therefore, the size of the costs associated with price reductions rise, and vice-versa.

The second class of parameters we investigate concerns the value of new drug introductions. We analyze variation in this value along two dimensions: the probability that a new drug will be a top-seller;[4] and the "access effect" of new drugs on the number of patients getting treatment. The third dimension of drug value, which we do not explicitly consider here, is the "clinical effect," which measures the clinical benefit of using new drugs. Owing to our extremely conservative approach to quantifying clinical effects, these were calibrated to be reasonably modest — the model presumes that new treatments in lung disease and cancer confer clinical benefits, but that other innovations do not yield any.

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[4] We make the very conservative assumption that only top-selling drugs have any positive effects on patient health. In other words, we assume that the introduction of all other drugs adds no value for patients.

The probability of a top-seller was estimated empirically, for each of our disease categories, using actual drug introductions from 1998 to 2002. The mean probability of a top-seller in each disease was used in our baseline estimates. To conduct sensitivity analyses, we vary the parameters uniformly over their respective confidence intervals. For example, we reduce all probabilities so as to place them 25% of the way between their mean and the bottom of their confidence interval, 50% of the way, 75% of the way, and at the bottom of their confidence intervals. We repeat the procedure, in reverse, to inflate the values of this parameter. Figure 10 displays the results. Not surprisingly, when the probability of a blockbuster gets smaller, so do the per capita values of price increases and the costs of price controls. At the very bottom of the confidence intervals, we see that price reductions involve a relatively small cost ($1700), while price increases involve a small benefit ($1600). However, just as with the value of a statistical life-year parameter, the qualitative predictions for policy changes are largely robust to variation.

Figure 11 varies the access effect across the width of its 95% confidence interval. On average, the launch of a new top-selling drug expands access by 26%. The confidence interval around this mean ranges from 2% to 50%. Therefore, we consider values from zero to fifty percent. Perhaps the most striking aspect of this figure is its non-monotonicity, which is generated by the interaction between two offsetting forces. Higher access effects increase consumer welfare in the baseline regime, and both alternative policy regimes. On the one hand, a higher access effect makes innovation – and policies that stimulate it – more valuable. This leads to a positive relationship between the access effect and welfare, for the repeal of price controls. On the other hand, when prices are lower, higher access effects might be more important as a means of

generating scarce innovations. The result is that the net value of EU policy changes does not change very much in response to shifts in the access effect. The benefits of price increases range from $33,000 per capita at the low end, to $61,000 at the high end. On the other hand, the cost of price cuts range from $13,000 per capita to $29,000 per capita.

The last parameter we analyze, and the one with the most important qualitative impact, is the responsiveness of innovation to revenues. Estimates in the economics literature suggest that a one percent increase in pharmaceutical revenues leads to a four percent increase in the number of new molecules (Acemoglu and Linn, 2004). However, the paucity of estimates in the literature warrant caution in interpreting this parameter. As a result, we consider values ranging from zero to 5.0. As argued earlier, several papers in the literature suggest that innovators respond, at least a little, to changes in revenues. Therefore, zero seems a strict lower bound on this parameter. Figure 12 plots the impact of changes in this parameter on the net present value of policy to cohorts of 55-59 year-olds. Depending on the value of this parameter, EU price reductions can generate $5000 of benefit per person to the 2060 cohort of 55-59 year-olds, or impose up to $64,000 of cost. At a value of 1.0, price reductions are almost exactly welfare-neutral, and below this value, they are somewhat welfare-improving. The key drawback of price reductions is not their obvious costs or benefits, but instead their substantial downside risk. On the other hand, the worst-case scenario for price increases is a welfare loss of $4000 per person, and that for the case where innovation does not respond to revenues at all – a case

that has been rejected in the empirical literature.[5] The baseline case is a $39,000 welfare gain, while the best-case is a welfare gain of over $100,000.

F. Policy Implications

Much of the analysis has focused on the normative analysis of different policy regimes. However, the results also shed light on an equally important positive question. It is easy to see why price reductions are more easily adopted than price increases.

The patterns over time in Figure 3 neatly illustrate one of the two critical issues. From the perspective of today's cohort, price-reductions are largely welfare-neutral, but they are tremendously costly from the perspective of future cohorts. Indeed, if policymakers operate using a lower value of a statistical life-year, EU price reductions are somewhat beneficial to today's cohort. For example, for a $100,000 value of statistical life-year, price reductions generate $2400 of per capita benefit to 55-59 year-old Europeans; this number rises to $3600 for a $50,000 value of statistical life-year. However, as we will see, future cohorts are hurt by price reduction policies even for these low valuations of a life-year. Since future cohorts do not vote, the result is a predilection towards price reduction policies, even though they hurt future generations.

In addition, and particularly in Europe, governments tend to bear the burden of greater medical and drug spending, while individuals enjoy the benefits of added longevity. Therefore, any tinge of self-interest in government decisionmaking will skew policy

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[5] Several papers, in different contexts, have reported a nonzero link between pharmaceutical innovator revenues and innovation (Acemoglu and Linn, 2004; Finkelstein, 2004; Danzon, Wang, and Wang, 2005).

towards choices that reduce medical spending, at the expense of greater longevity. This adds further impetus to the adoption of price reductions.

In spite of these political economy challenges, the quantitative analysis reveals the simple arithmetic of innovation policy. Taken in context, lifetime spending on medical spending and drugs is relatively small compared to the value of life-extension, even adopting very conservative values of life. In terms of expected present value, a 55 year-old European can expect about $75,000 to be spent for his medical care, during the remainder of his life. Therefore, even a 50% reduction in the cost of his care is only worth $37,500, which even by conservative estimates is worth less than one statistical life-year. Therefore, reductions in life expectancy of just one-quarter to one-half of a year must generate twenty-five or even fifty percent reductions in the lifetime value of medical spending. The model makes clear that savings of this magnitude are associated with larger reductions in longevity.

The analysis has also provided insight into the nature of policy uncertainty. The market for pharmaceuticals is quite complex, and it is unreasonable to expect that policy decisions will be made with perfect information about their consequences. However, due in large part to the arithmetic of life-saving, policies that threaten the rate of innovation are much riskier than policies that protect it. A policymaker grappling with the fundamental uncertainty surrounding these markets has to gauge the risks associated with every policy decision. The quantitative analysis reveals that price reductions are much riskier than price increases. The downside of a price increase policy is limited by the relatively small magnitude — in the context of values of life, at least — of total medical spending. This effectively reduces the risk associated with such policies.

G. Conclusions

European governments have long differentiated themselves from the US policy approach to pharmaceuticals, by aggressively negotiating prices with pharmaceutical manufacturers, and adopting regulations to contain cost in both the pharmaceutical and broader medical care sector. It is well-appreciated that policies restricting pharmaceutical prices may harm consumers overseas, but this understandably plays little role in a domestic policy debate. We have analyzed both the foreign *and* the domestic policy consequences of different approaches to pharmaceutical price regulation. The data show that price reductions for pharmaceuticals confer little to no benefit on today's consumers, but substantial costs on tomorrow's consumers, even ignoring the international effects, which only magnify the costs of price controls.

We cannot ignore or dismiss the strong incentives European governments have to contain prices, when they are the primary health care payer, and when they are elected by today's generations, not tomorrow's. Nonetheless, our analysis reveals that the benefits of price reduction policies are rather limited, particularly when taken in the broader context of the value of health. It is unclear whether these factors will overcome the political incentives for cost-containment, but the quantitative analysis of overall social welfare yields reasonably robust and clear conclusions: price reductions run the risk of harming future generations a great deal, in exchange for a rather limited upside that may be enjoyed by today's consumers, and then only in certain cases.

Figure 1: Effect of EU Price Reductions on Longevity, among 55-59 year-olds in the US and Europe.

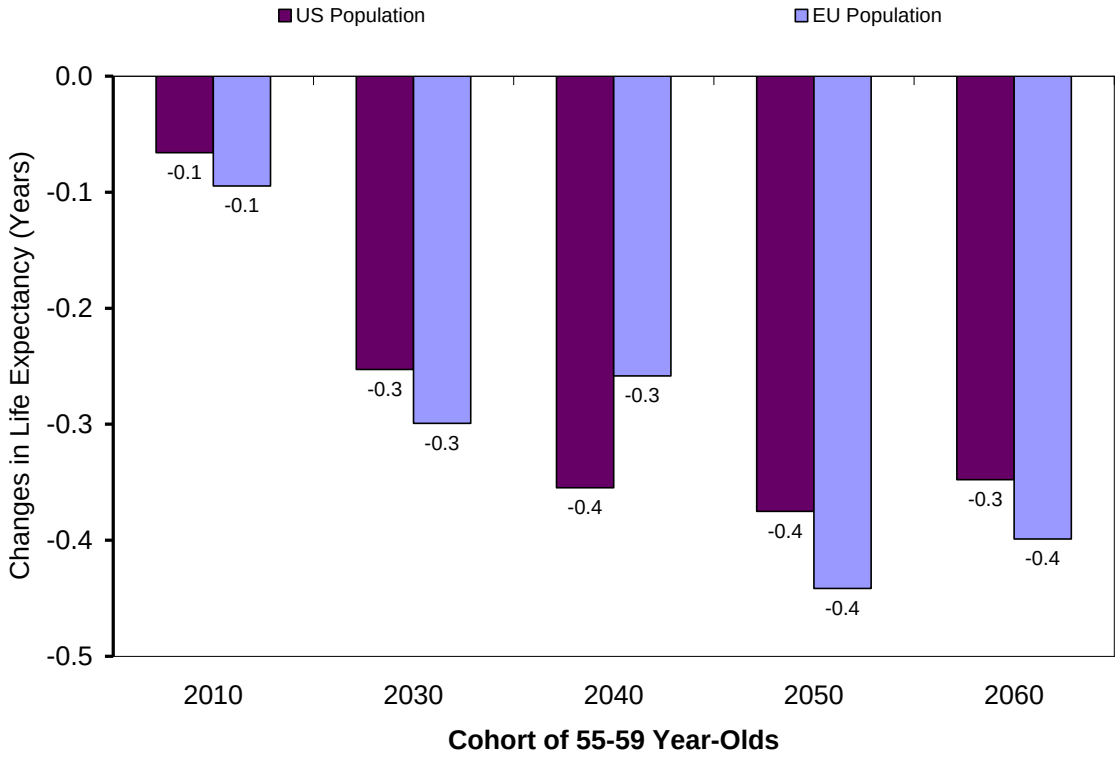


Figure 2: Effect of EU price reductions on lifetime drug and health care spending, for cohorts of 55-59 year-olds in the US and Europe.

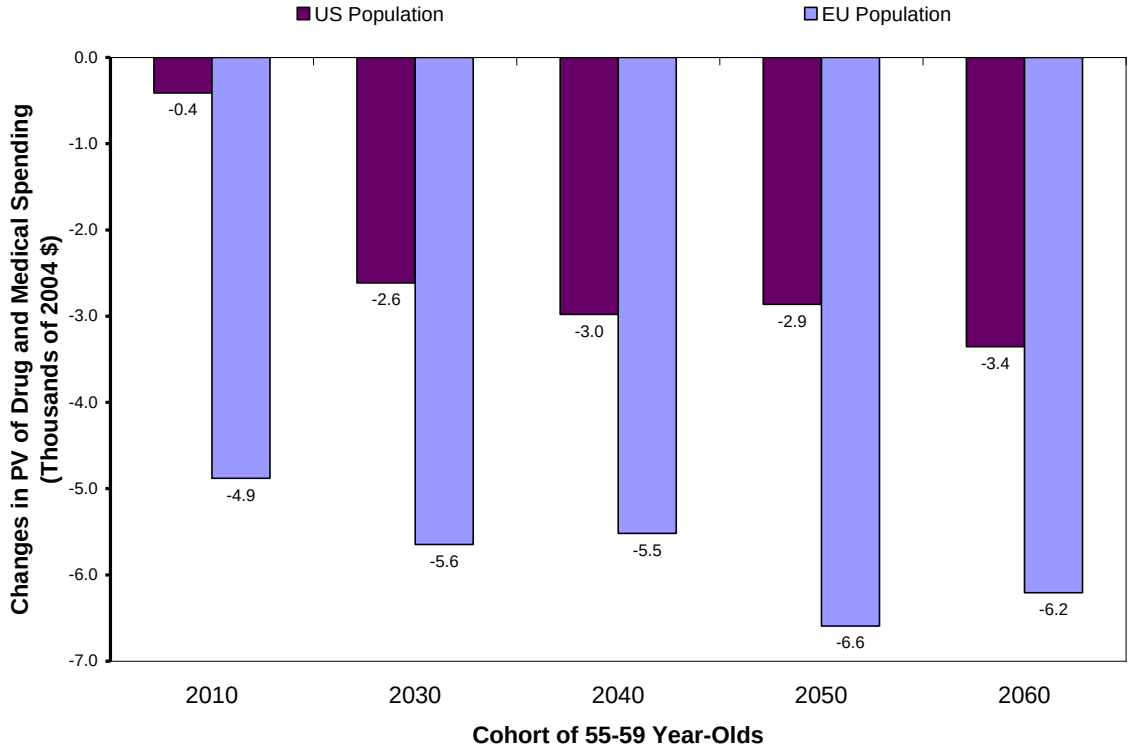


Figure 3: Net per capita value of EU price reductions to 55-59 year-olds in the US and Europe.

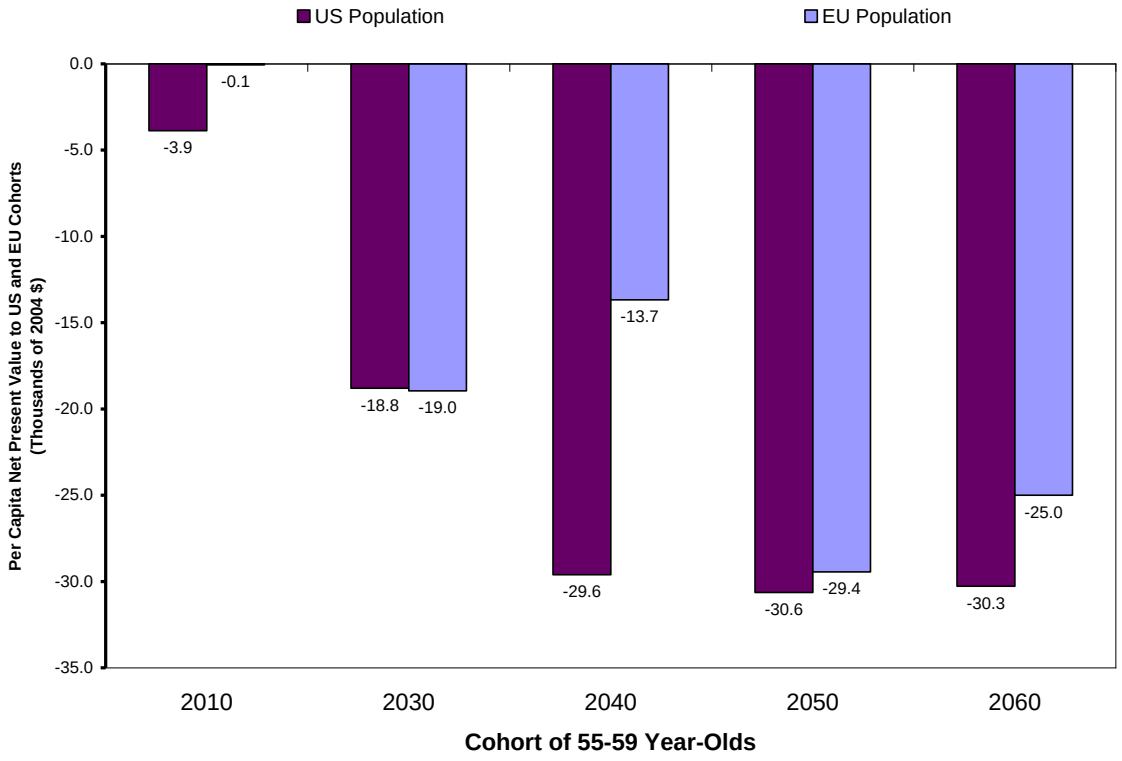


Figure 4: Aggregate net present value of EU price reductions to 55+ population in the US and Europe, by cohort.

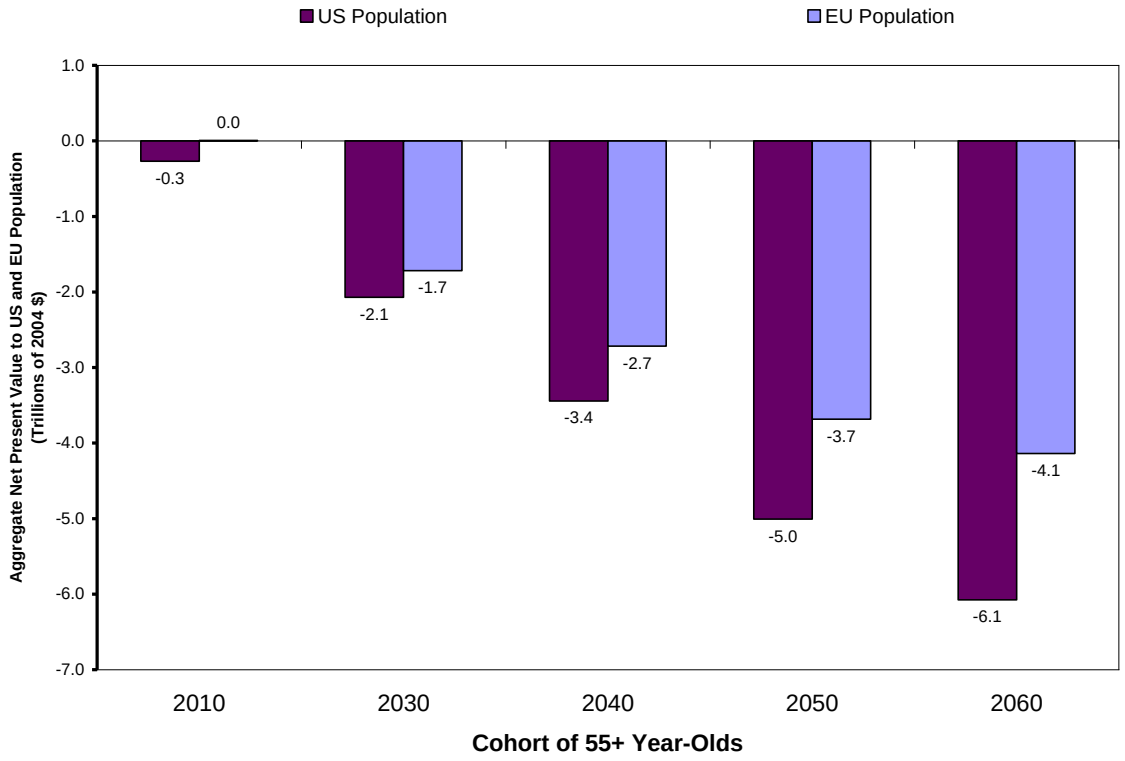


Figure 5: Effect of EU Price Increases on Longevity, among 55-59 year-olds in the US and Europe.

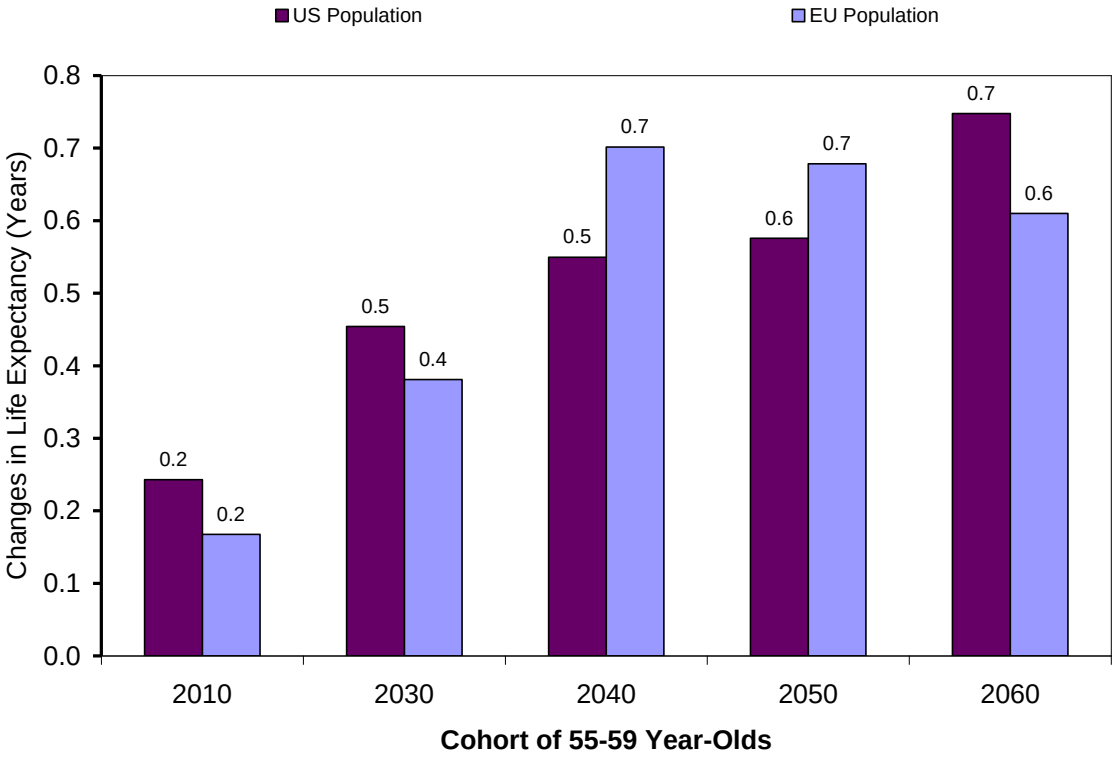


Figure 6: Effect of EU price increases on per capita medical spending for 55-59 year-old cohorts in the US and Europe.

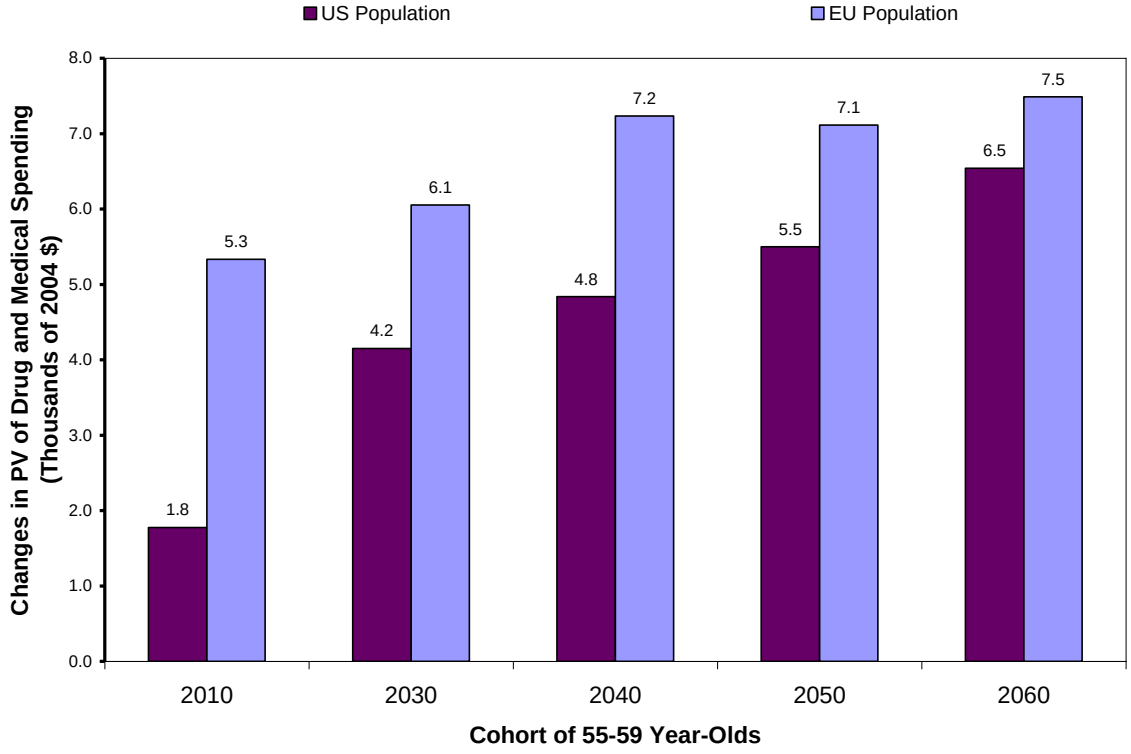


Figure 7: Net per capita value of EU price increases to 55-59 year-olds in the US and Europe.

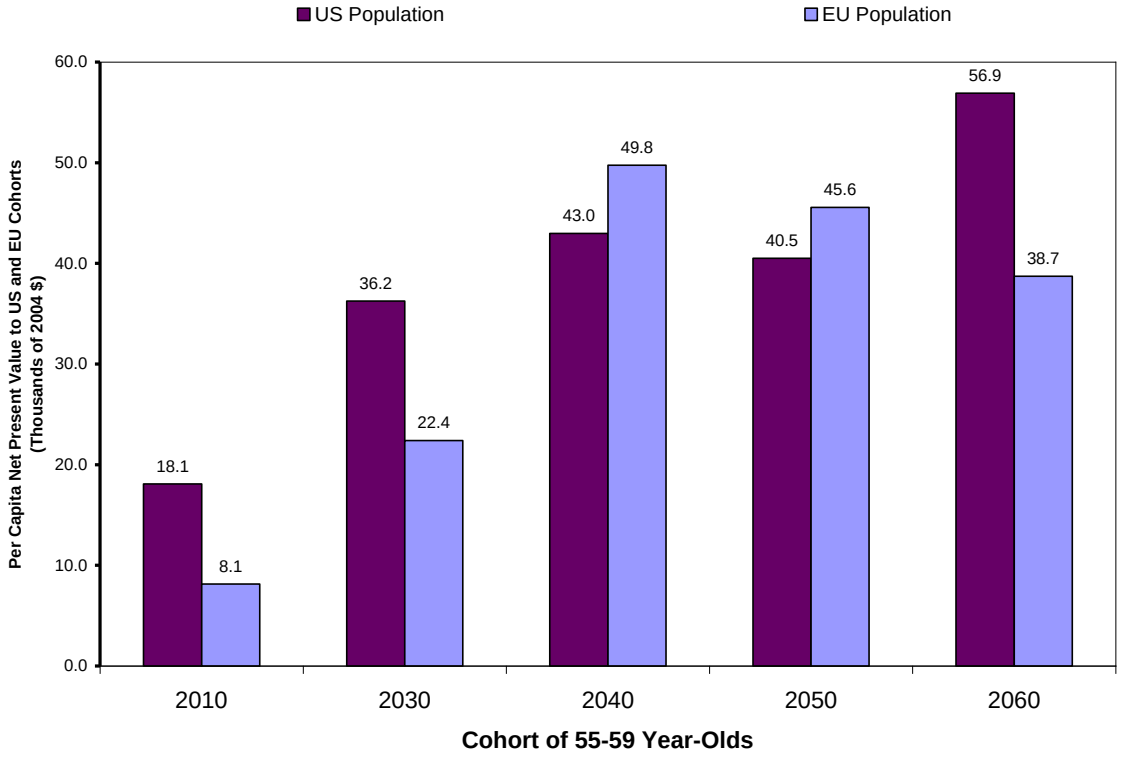


Figure 8: Net present value of EU price increases to 55+ population in the US and Europe, by cohort.

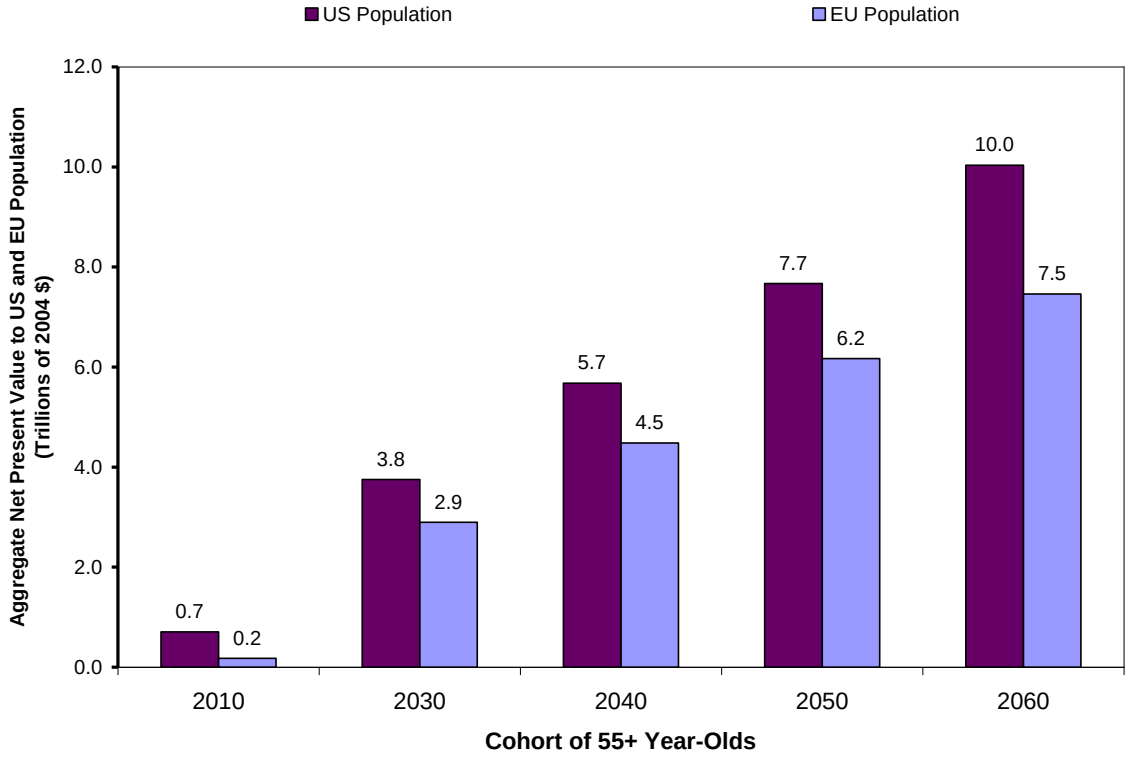


Figure 9: The Value of a Statistical Life-Year and Model Implications.

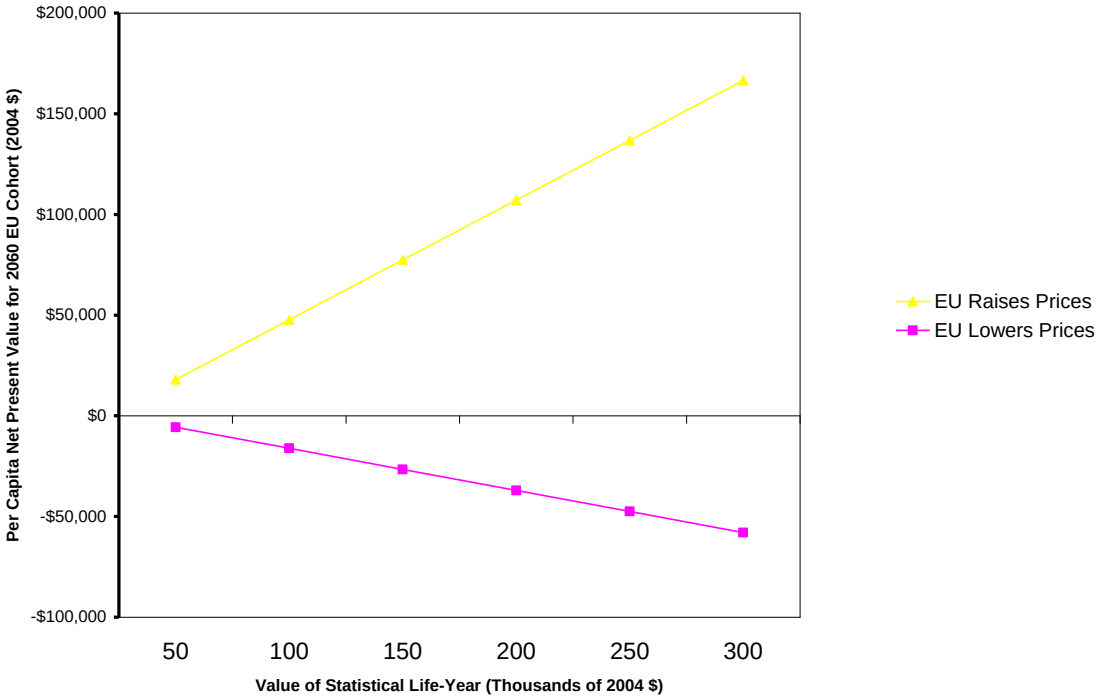


Figure 10: Likelihood of blockbuster and model implications.

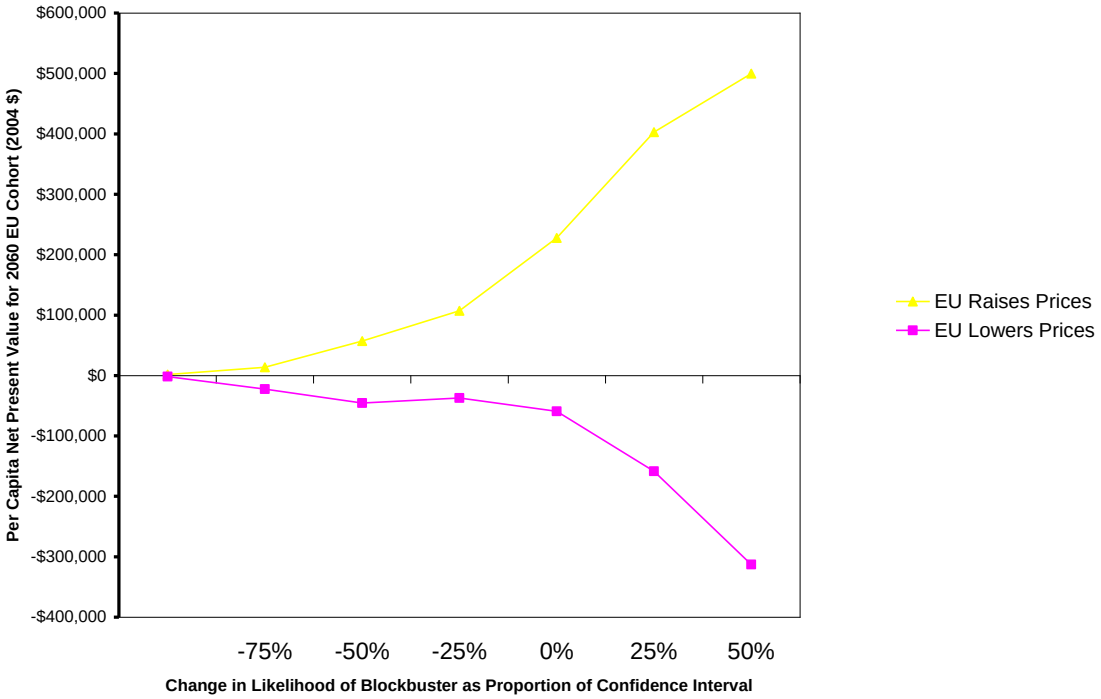


Figure 11: Access effect and model implications.

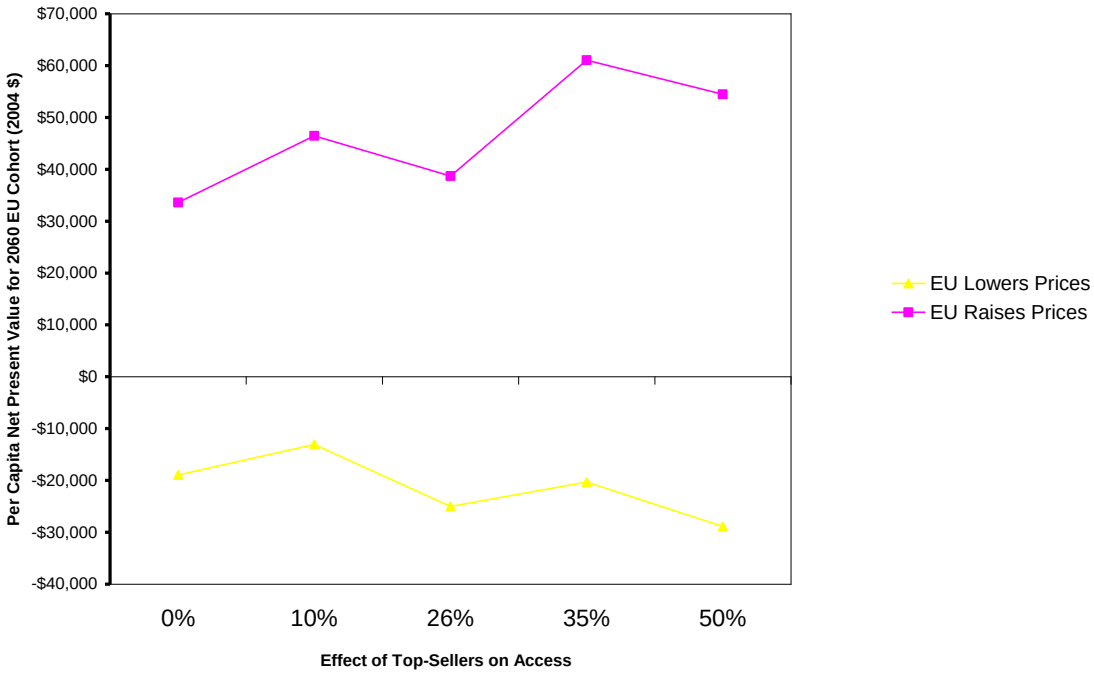
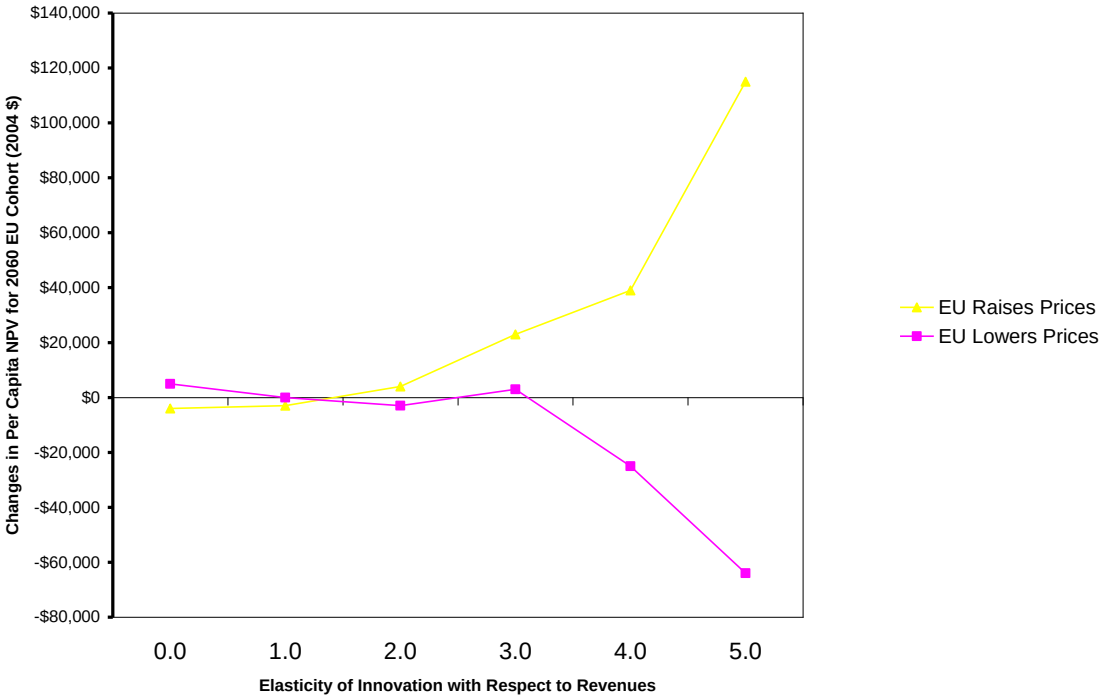


Figure 12: Innovation-responsiveness and model implications.



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