RAND HEALTH

Regulating Drug Prices

U.S. Policy Alternatives in a Global Context

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U.S. consumers spend roughly twice as much on drugs as their European counterparts. This gap arises partly from Americans' greater use of high-cost drugs and partly from higher drug prices in the United States relative to the European Union (EU). Pressure is building in U.S. policy circles for the federal government to take action to regulate the cost of drugs. At the same time, there is debate about the pros and cons of doing so. Proponents contend that consumers will benefit from lower prices, while critics raise concerns that regulation will cut pharmaceutical revenues, which will slow the pace of innovation. The debate thus centers on the trade-off between benefiting the current generation (with lower prices) and benefiting future generations (with greater pharmaceutical innovation and access to new drugs) as well as the extent to which alternative policy approaches can balance this trade-off.

To shed light on this debate, a team of RAND researchers examined the impact of drug price regulation. The study had two phases. First, to provide a global context for understanding the impact of drug price regulations, the team analyzed recent global trends in drug price regulation and its effects. Second, they used a modeling approach to simulate the effects of alternative approaches to price regulation on consumer costs, life expectancy, and overall well-being. The results showed that

- Globally, the regulation of pharmaceutical prices has increased in recent years.
- In most cases, regulation reduces pharmaceutical revenues.
- Regulatory approaches that reduce pharmaceutical revenues may generate modest consumer savings in the best cases, but risk much larger costs as decreased innovation leads to reductions in life expectancy.
- Approaches that reduce consumer costs (by cutting copayments) without affecting pharmaceutical revenues are more likely to benefit current and future generations of consumers.

Key findings:

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- **In most cases, regulation has reduced pharmaceutical revenues.**
- **Regulatory approaches that reduce pharmaceutical revenues may generate modest consumer savings in the best cases, but risk much larger costs as decreased innovation leads to reductions in life expectancy.**
- **Approaches that reduce consumer costs (by cutting copayments) without affecting pharmaceutical revenues are more likely to benefit both current and future generations of consumers.**

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This Highlight summarizes RAND Health research reported in the following publications:

Lakdawalla DN, Goldman DP, Michaud P-C, Sood N, Lempert R, Cong Z, de Vries H, and Gutierrez I, "U.S. Pharmaceutical Policy in a Global Marketplace," *Health Affairs*, Vol. 28, No. 1, January 2009.

Sood N, de Vries H, Gutierrez I, Lakdawalla DN, and Goldman DP, "The Effect of Regulation on Pharmaceutical Revenues: Experience in 19 Countries," *Health Affairs*, Vol. 28, No. 1, January 2009.

The Effect of Regulation on Pharmaceutical Revenues: Recent Experience in 19 Nations

Research points to an underlying link between manufacturer revenues and the pace of pharmaceutical innovation: Though some have challenged this link, evidence suggests that lower profits delay the development and introduction of new drugs. Therefore, an important first step in understanding the impact of drug price regulation is examining how regulation affects revenues. To date, there has been little systematic study of this relationship across the full range of developed countries. To remedy this gap, the RAND team examined the regulatory environment from 1992 to 2004 and the impact of regulation on pharmaceutical revenues in 19 nations that are members of the Organisation for Economic Co-operation and Development. They also looked at the full array of regulatory mechanisms, ranging from direct price controls to policies for increasing the use of generics, and used a microsimulation model to estimate the effects of regulation on drug revenues. The main results showed that (1) drug price regulation increased during the period in question; (2) most regulations significantly reduced revenue, with direct price controls having the greatest effect; (3) the effect of regulation in a previously unregulated market was greater than the effect of added regulation in a regulated market; and (4) the revenue-reducing impact of regulation increased over time.

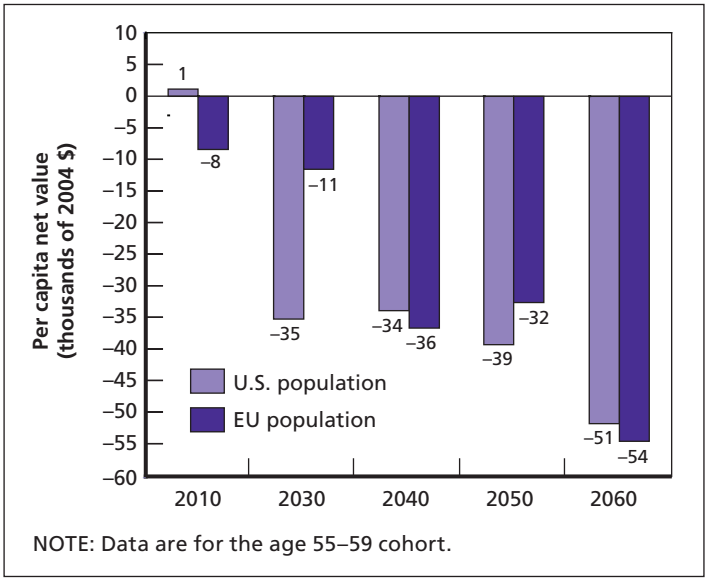
Modeling the Effects of Alternative Drug Price Regulation Policies in the United States

Against the backdrop of this historical overview, the RAND team estimated the potential effects of drug price regulation in the United States. The team used the Global Pharmaceutical Policy Model, a demographic and economic tool for estimating the effect of baseline health, health behavior, and rates of innovation on population health and mortality several decades into the future. The model incorporates the effect of pharmaceutical breakthroughs. The estimates were based on data on the near-elderly in the United States and the EU, and they focused on the youngest cohort of this population: those age 55–59 in each of the next six decades (2010–2060). The analysis simulated the effects of two kinds of regulation: (1) price controls (in which consumer prices remain constant but manufacturer revenues are reduced) and (2) reduced copays (in which manufacturer revenues remain constant but consumer copays are reduced). The simulation compared both kinds of policies against a baseline estimate of the status quo in terms of their effects on three outcomes:

- consumer drug and health care spending
- life expectancy
- the net effect—the per capita net present value—as measured by the monetized value of life expectancy minus the monetized value of medical and drug spending.

Increasing Price Controls. In general, price controls reduced life expectancy over time. The price control scenario simulated the effect of a 20-percent reduction in manufacturer revenue while holding consumers' out-of-pocket prices constant. Price controls would have small negative effects on life expectancy for current cohorts, but more significant negative effects in the future. For instance, the researchers' best estimates suggest that life expectancy would fall by somewhere in the range of 0.2 years for Americans age 55–59 in 2010 and by approximately 0.1 years for Europeans in the same cohort and year. By 2060, this effect would increase for both Americans and Europeans to approximately 0.7 years. On the benefit side of the ledger, however, U.S. price regulations would reduce spending on drugs and medical care. Annual per capita spending in 2010 would fall for Americans age 55–59 by an amount in the range of $9,000 annually and for Europeans of the same age by an amount in the range of $400. For those age 55–59 in 2060, the savings would be even larger for both groups and, again, greater for Americans than Europeans. The higher number for Americans is attributable to both reduced spending and reduced life expectancy; for Europeans, the savings come entirely from reduced life expectancy. Overall, as shown in Figure 1, the net value of price controls is positive in the short term (2010) for Americans age 55–59, producing approximately $1,100 in per capita savings, but negative for Europeans in the same cohort and year, who face increased costs in the range of $8,000. For both Americans and Europeans, price controls have higher per capita costs over the longer term: By 2060, reductions in life expectancy, after accounting for medical cost

Figure 1
U.S. Drug Price Controls Estimated to Have Long-Term Negative Effect



NOTE: Data are for the age 55–59 cohort.

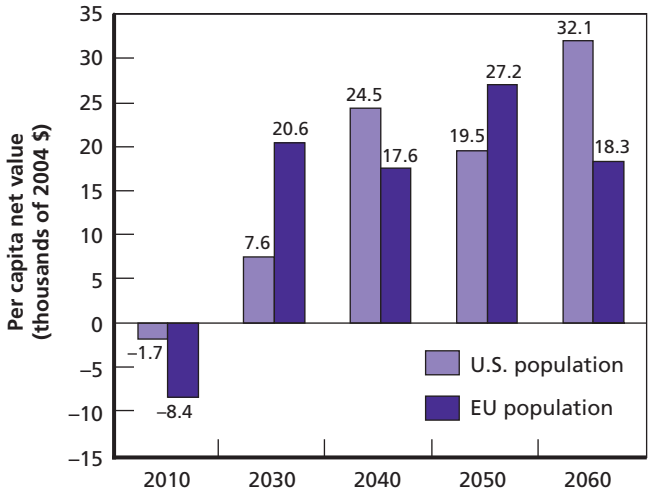
savings, would cost the equivalent of $51,000 and $54,000, to age 55-59 Americans and Europeans respectively.

Reducing Copays. By contrast, the copay-reduction scenario produced modestly higher costs in the short term but substantial benefits over the longer term. The copay-reduction scenario simulated the effect of a 20-percent decrease in consumer copays, financed by the government. Under this scenario, U.S. spending increased in the short term by $4,100 for Americans, with virtually no change for Europeans. In 2060, lifetime drug and medical spending for those age 55–59 increased by $7,900 in the United States and by $1,200 in the EU. Life expectancy in both the United States and the EU declined for the 2060 cohort—by about 0.5 and 0.2 years, respectively—but less than it did in the price control scenario. Overall, as shown in Figure 2, copay reduction had a negative net value in 2010 but a positive value over the longer term, generally increasing over time. By 2060, the net lifetime value of a copay reduction was approximately $32,000 for each American and $18,000 for each European.

How Robust Are the Results?

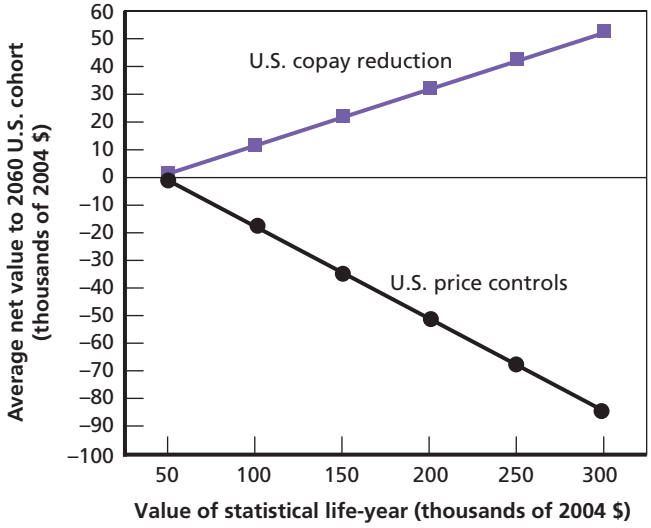
Would these results change if the model used different assumptions? When the researchers posed this question, two important findings emerged. First, as the value of life expectancy (that is, the economic value of a human life-year) increased, copay reductions became more beneficial and price controls became more costly for those age 55–59 (see Figure 3). Assigning a dollar value to a year of human life is highly uncertain; this result suggests, however, that a central finding—the net positive effect of copay reduction and the net negative effect of price controls—does not depend on any specific value assigned to a year of life. Second, different assumptions about the responsiveness of innovation to manufacturer revenues affected the results. Empirical research in health economics has concluded that 1-percent increments in pharmaceutical revenue lead to approximately 3-percent increases in the annual number of new pharmaceuticals approved for use. Assuming that innovation does not respond to revenues at all—not considered a plausible relationship—price controls generate a modest net benefit to Americans age 55–59 and have no impact on Europeans. As this responsiveness increases, price controls become costlier. Conversely, copay reduction is beneficial throughout, except at implausibly low levels. Moreover, copay reductions pose little risk of major negative outcomes.

Figure 2
Copay Reduction Estimated to Have Long-Term Net Benefits



NOTE: Data are for the age 55–59 cohort.

Figure 3
As Value Assigned to Life Expectancy in the Model Increased, the Benefit of a Copay Regime Also Increased but Value of Price Controls Decreased



NOTE: Data are for the age 55–59 cohort.

Conclusions and Implications for U.S. Policy

The results illustrate that imposing price controls would offer a modest benefit to the current generation but pose substantial risks and potentially high costs for later ones. By contrast, financing consumer price reductions without affecting manufacturer revenues appears robust and beneficial for both current and future generations across a range of assumptions. Given uncertainty about pharmaceutical markets, policymakers may find copay-reduction strategies less risky than price controls over the long term and more beneficial than the status quo. ■

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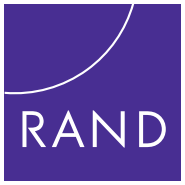

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