

“It is time to deal with skyrocketing out-of-pocket costs and runaway prescription drug prices that are going up last year by 12 percent. I mean, it’s disgraceful.”¹

HILLARY CLINTON

“The greed of the pharmaceutical industry is a public health hazard to the American people. That has got to change.”²

BERNIE SANDERS

On the Record

“Drug price controls would do little to reduce overall health care spending but would greatly damage an innovative and lifesaving industry.”

Yevgeniy Feyman, deputy director and fellow, health policy, Manhattan Institute



Drug Price Controls Hurt Patients Most

Paul Howard and Yevgeniy Feyman

In Reality

Proposals to control drug prices may have populist appeal, but they miss the mark by ignoring the root cause of high health care costs—poor health—and the relatively modest role that medicines play in U.S. health care spending. More important, the assumption that European-style price controls would have no effect on innovation is deeply misguided.

Because America is the world’s largest pharmaceutical market, its market-pricing structure for pharmaceuticals generates the lion’s share of the profits necessary to fund drug development. Cutting into these profits would dampen incentives for innovation, shorten lives, and impose higher costs on future patients. Price controls are a losing proposition—for industry and for patients who receive little, if any, benefit from currently available therapies.

Key Findings

- U.S. drug spending is not out of control; reducing it will not substantially affect overall health care costs.
 - ◆ U.S. spending on drugs accounts for a smaller share of total health care spending—about 10 percent—than in Europe, where drug price controls are in place.
 - ◆ U.S. drug spending as a share of health care spending is expected to remain flat; the out-of-pocket share of drug spending is expected to decline.
- Drug spending is cyclical. After a decade of low increases in drug spending, driven by generic competition (drug spending by private insurers actually declined by 0.5 percent in 2013), more new, powerful drugs are coming to market. Eventually, these drugs will lose patent protection and become cheap generics.
- Drug companies do not earn excessive profits. Investors treat the pharmaceutical industry as 25 percent–37 percent riskier than other industries and therefore require a higher rate of return. The industry’s profit margins reflect the greater risk and long timeline required to develop successful U.S. Food and Drug Administration (FDA)–approved medicines.
- Drug price controls cost more than they save by slowing innovation.
 - ◆ Modest price controls that reduce pharmaceutical industry revenue by 20 percent would shorten life expectancy for children today by nearly one year by 2060, imposing costs of \$51,000 per capita.
 - ◆ Aggressive price controls that reduced prices by half would slash the number of products under development by 30 percent–60 percent.

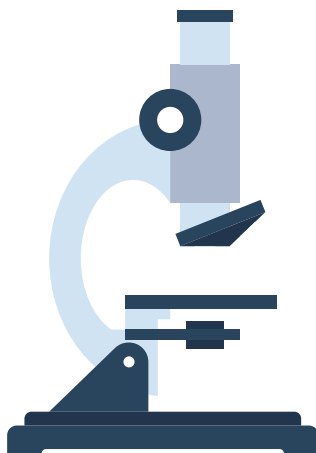
On the Record

“Reducing drug revenues today imposes a tax on patient health tomorrow—including that of our children and grandchildren. Advocates of European-style price controls ignore the suffering and death of future patients, in America and around the globe, from lost innovations.”

Paul Howard, director and senior fellow,
health policy, Manhattan Institute



Drug price controls mean fewer life-saving drugs developed



In a recent survey conducted by the Kaiser Family Foundation, nearly three-quarters of those questioned believe that the cost of prescription drugs in the U.S. is unreasonable; roughly the same percentage share the view that drug company profits are excessive. Nevertheless, most patients taking prescription medicines report that paying for medicines is easy.³ True, some patients with serious chronic diseases may face high out-of-pocket costs due to the coinsurance or co-pays required by their health plans. But an understanding of the dynamics underlying drug spending, development, and pricing makes clear that price controls are an inappropriate and counterproductive response to this challenge.

The Drug Pricing Problem

In 2014, retail prescription drug spending amounted to \$305 billion (about 9.9 percent of total U.S. health care spending), according to the Centers for Medicare and Medicaid Services.⁴ Accounting for physician-administered drugs brings the total to about \$427 billion, or 13.9 percent of total spending.⁵ However, because of the way in which deductibles and other cost-sharing tools are implemented, drug spending tends to make up the bulk of routine out-of-pocket costs facing patients.

Out-of-pocket drug costs can be especially burdensome for patients with serious chronic conditions. During 2001–05, drug spending made up more than half of out-of-pocket expenses for patients with two or more chronic conditions.⁶ Analysts have also noted that insurance plans available on the Affordable Care Act’s exchanges typically require high out-of-pocket spending: high co-pays or coinsurance from enrollees, without cost-sharing subsidies.⁷

The wholesale prices of prescription drugs—especially those used in oncology, HIV/AIDS, and other chronic-disease areas—have drawn significant public attention, too. A nearly \$100,000 price tag for Gleevec, a leukemia drug, led more than 100 oncologists to demand government action (ostensibly in the form of price controls) on such drugs.⁸ More recently, in its outrage over prices for new hepatitis C drugs, Express Scripts, the pharmacy benefit manager (PBM), lambasted drug companies for the “irrational” pricing of new drugs.⁹

Drug Prices Are Driven by Development Costs

In rare instances, regulatory failures and other quirks in particular drug markets can lead to unjustifiably high prices (such as in the recent high-profile case of Turing Pharmaceuticals raising the price of generic Daraprim).¹⁰ Yet most of the time, drug prices are justified and are determined by their value to patients, therapeutic alternatives, and development costs.

Development costs drive up drug prices: the fully capitalized cost of getting a drug to market now totals \$2.6 billion.¹¹ Further, only about 12 percent of drug candidates reach the FDA-approval stage, with the rest failing trials along the way; drugs that do reach this final stage often wait ten years before receiving FDA approval.¹²

Compared with alternative investments, the high risk of failure and vast cost of developing drugs lead investors to demand hefty profits from drug companies. One common measure of risk—the weighted average cost of capital (WACC)—for pharmaceuticals is estimated at 7.4 percent–8.1 percent, compared with a 5.9 percent average for all industries. This implies that pharmaceutical investment is 25 percent–37 percent riskier than investment in other industries.¹³

Faced with less risk and lower costs, more drug companies will likely compete in even the most expensive drug-development areas. Recent examples of positive, market-based competition include the massive discount—46 percent, on average—that insurers and PBMs negotiated¹⁴ once a second and third hepatitis C drug arrived to compete with Sovaldi and Harvoni; and the decision by CVS not to cover PCSK9 inhibitors without a competitor on the market.¹⁵

While drug-company critics decry “me-too” drugs, having multiple therapeutic substitutes for a given condition gives insurers powerful leverage to negotiate large list-price discounts from manufacturers. But in other areas, such as biologics, the lack of an FDA approval process (until relatively recently) for generic versions has blunted the emergence of new, less expensive competitors. As the FDA and drug companies become more comfortable developing and approving generic drugs, this will likely change. And a new user-fee program for generics, instituted in 2012, will clear a large backlog of hundreds of generic drug applications stalled at the FDA.¹⁶

In reality, the drug industry’s natural cycle is defined by bursts of productivity and higher-priced new drugs, followed by patent expirations and lower prices. We are emerging from a period of lagging industry innovation and low spending growth and entering a period of significant progress and attendant higher prices. Indeed, as recently as 2013, private insurance spending on prescription drugs ac-

tually declined by 0.5 percent.¹⁷ Meanwhile, 41 new medicines, the highest since 1996, were approved by the FDA in 2014.¹⁸

Drug Price Controls Solve Nothing...

Government price controls are not likely to reduce the share of spending that goes to pharmaceuticals. Though retail drug prices—and, by extension, per-capita spending—are higher in the U.S. than in countries that employ price controls, pharmaceuticals as a share of total health spending are lower in the United States. This implies that price controls are unlikely to reduce the share of U.S. health care spending going to pharmaceuticals—in part, because price controls would narrow the pricing gap between branded medicines and generics, encouraging more people to switch to branded drugs. America’s share of generic drug prescriptions (nearly 90 percent) is the highest in the OECD.¹⁹

Similarly, because retail prescription-drug spending represents 10 percent of total U.S. health care spending,²⁰ modest price controls would have little effect on overall health care spending; all else being equal, a 10 percent reduction in drug spending would translate only into a 1 percent reduction in total U.S. health care spending.

The overall burden of U.S. drug spending is also expected to remain relatively stable over the next decade, growing only by 0.4 percentage points, while the out-of-pocket share of spending is expected to fall more than 3 percentage points.²¹ Even were price controls good policy, they would have, at best, a marginal effect on overall health care spending.

Focusing on discrete price increases for individual drugs misses the forest for the trees. From 2000 to 2015, prices for prescription drugs grew more or less in tandem with overall medical inflation—both increasing roughly 50 percent—while hospital prices grew 90

percent. In the context of the broader health care system, it is not clear that drug price growth is significantly out of line.²²

Of course, reducing burdens on patients with serious chronic diseases represents a different challenge and requires different solutions. But it also requires confronting the reality that current patients and payers bear most of the costs of drug development, and future patients will reap most of the benefits from access to high-quality generics.

...but Will Dramatically Curtail Innovation

Lower revenues for pharmaceutical firms reduces their incentive to innovate. This would lead to lower investment in R&D—and, thus, fewer innovative medicines available to save lives in the future. One analysis of pharmaceutical firms’ response to the 1993 Health Security Act found that merely the threat of price controls helped reduce pharmaceutical R&D by \$1.6 billion.²³ Another study projects that “cutting [drug] prices by 40 to 50 percent in the U.S. will lead to between 30 to 60 percent fewer R&D projects being undertaken.”²⁴

The nonpartisan RAND Corporation found that while price controls initially benefit patients—by reducing spending on drugs—future patients suffer massive negative effects as a consequence of less R&D investment by drug companies: “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.”²⁵

RAND estimated that a 20 percent reduction in pharmaceutical industry revenues would impose costs on people aged 55–59 in 2060 of about \$51,000 per capita, and the average life expectancy of today’s children would be shortened by nearly one year. Overall, RAND found that the costs of drug price controls would exceed benefits by 3.5 times.²⁶

With a 50% price cut,
**development on a majority
of drugs would cease**

Drug price controls are misguided: they fail to address hospital and physician spending, the largest cost drivers in America's health care system (about 60 percent of the total). More important, the economic literature consistently finds that, however well intentioned, artificial limits on pharmaceutical revenue can have devastating long-term consequences for patients. High out-of-pocket drug prices should be a concern for policymakers. But price controls are the wrong solution.

Endnotes

- 1 See <http://www.theatlantic.com/business/archive/2015/09/hillary-clinton-drug-plan/406861>.
- 2 See <https://www.washingtonpost.com/news/post-politics/wp/2015/10/08/bernie-sanders-to-oppose-obamas-nominee-to-lead-the-fda/>.
- 3 See <http://kff.org/health-costs/poll-finding/kaiser-health-tracking-poll-august-2015>.
- 4 National Health Expenditure Projections as of October 2, 2015. See <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountsprojected.html>.
- 5 We assume that the ratio of nonretail to retail drug spending is 0.40, as estimated by the Altarum Institute. See <http://altarum.org/sites/default/files/uploaded-publication-files/Non-Retail%20Rx%20Forecast%20Data%20Brief%2010-14-14.pdf>.
- 6 See http://www.commonwealthfund.org/~media/Files/Publications/Issue%20Brief/2009/Jul/Chronic%20Burdens/1303_Cunningham_chronic_burdens_high_OOP_expenses_chronic_conditions_ib.pdf.
- 7 See http://avalere-health-production.s3.amazonaws.com/uploads/pdfs/1395680762_20140220_-_Avalere_-_Exchange_Rx_Coinsurance.pdf.
- 8 See <http://www.bloodjournal.org/content/bloodjournal/early/2013/04/23/blood-2013-03-490003.full.pdf?sso-checked=true>.
- 9 See <http://www.forbes.com/sites/theapothecary/2014/06/17/the-sovaldi-tax-gilead-cant-justify-the-price-its-asking-americans-to-pay>.
- 10 See <http://www.wsj.com/articles/a-clintonian-misdirection-on-drug-prices-1443568738>.
- 11 See http://csdd.tufts.edu/news/complete_story/pr_tufts_csdd_2014_cost_study.
- 12 For the most recent estimates, see http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf.
- 13 Data as of January 5, 2015. See http://people.stern.nyu.edu/adamodar/New_Home_Page/data.html.
- 14 See <http://www.bloomberg.com/news/articles/2015-02-03/gilead-hepatitis-c-sales-surge-as-drugmaker-announces-dividend>.
- 15 See <http://www.reuters.com/article/2015/08/10/us-health-cholesterol-costs-idUSKCN0QF05120150810>.
- 16 See <http://www.raps.org/focus-online/news/news-article-view/article/2142>.
- 17 Centers for Medicare and Medicaid Services, historical National Health Expenditure Accounts. See <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountshistorical.html>.
- 18 See <http://innovation.org/successes-for-patients-despite-randd-challenges>.
- 19 See <http://www.pbs.org/newshour/updates/americans-spend-much-pharmaceuticals>.
- 20 See n. 3 above.
- 21 Ibid.
- 22 Bureau of Labor Statistics, Consumer Price Index Database. Indexes used are CPI-M, and CPI-M for prescription drugs and hospital services. See <http://www.bls.gov/cpi/data.htm>.
- 23 See <http://www.nber.org/papers/w11229.pdf>.
- 24 See <http://www.nber.org/papers/w11114.pdf>.
- 25 See http://www.rand.org/content/dam/rand/pubs/research_briefs/2008/RAND_RB9412.pdf; and http://www.rand.org/content/dam/rand/pubs/reprints/2009/RAND_RP1380.pdf.
- 26 RAND researchers find that, by 2060, the net present value of lifetime health care spending is reduced by \$14,400—implying that total costs are \$65,400 (\$51,000 + \$14,400 = \$65,400). Therefore, the ratio of costs to benefits is \$65,400/\$14,400 = 4.54—meaning that costs are about 3.5 times greater than benefits.

