



Written Statement of

Lynn Quincy, Director, Health Care Value Hub
Consumers Union

on

Impact of Surging Drug Prices on Consumers

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Introduction

Consumers Union, the policy and advocacy arm of Consumer Reports,¹ appreciates this opportunity to provide our views on increases in drug prices, the impact of high drug costs on consumers, and policy ideas to address the effects and burden of drug costs on consumers.

Consumer Reports is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers. As part of our health care work we help consumers find the best value when purchasing prescription drugs. In 2004, we launched *Consumer Reports Best Buy Drugs*. This program uses evidence-based systematic reviews of prescription drugs to clearly demonstrate the efficacy and safety of commonly used medicines in over 30 categories.² We combine this information with reliable cost information, enabling consumers to truly identify the “best buy” for many drugs.

High Drug Prices

Spikes in drug prices, as well as prices that are simply too high, have been widely reported in the news and confirmed by Consumer Reports’ own nationally representative survey. Our recent poll found that thirty percent of people who regularly take at least one prescription drug experienced unexpected spikes in their out-of-pocket drug costs in the past 12 months—anywhere from just a few dollars to more than \$100 per prescription.³

Denise Nolan, 49, of Lincoln Nebraska, experienced a sudden spike in the price of her rheumatoid arthritis medicine. This past July, when she went to pick up her prescription for generic hydroxychloroquine, she was shocked to find out that the price had nearly doubled with no warning. In this case, the pharmacist explained that the reason for the sudden spike was due to a shortage in the market, which can occur for many reasons.⁴

¹ Founded in 1936, *Consumer Reports* is an expert, independent, nonprofit organization whose mission is to work for a fair, just, and safe marketplace for all consumers, and to empower consumers to protect themselves. Using its more than 50 labs, auto test center, and survey research center, the nonprofit rates thousands of products and services annually. Consumer Reports has over 8 million subscribers to its magazine, website, and other publications. Its policy and advocacy division, Consumers Union, works for health reform, food and product safety, financial reform, and other consumer issues in Washington, D.C., the states, and the marketplace. This division employs a dedicated staff of policy analysts, lobbyists, grassroots organizers, and outreach specialists who work with the organization’s more than 1 million online activists to change legislation and the marketplace in favor of the consumer interest.

² <http://www.consumerreports.org/health/best-buy-drugs/index.htm>. Note: We do not do cost-effectiveness analysis. Instead, we present price and cost data alongside the effectiveness, safety, and side-effect data. And then we let consumers—in consultation with their doctors—interpret and adapt these data according to individual preferences, clinical circumstances, and priorities (including budgetary).

³ Consumer Reports National Research Center poll of 1,037 adults. *Are you paying more for your Rx meds? A Consumer Reports’ poll shows one-third of Americans hit by high drug prices*, August 13, 2015

⁴ *Ibid.*

There are many stories in the news about *very* high-priced medications, but consumers also face challenges in affording the everyday drugs that nearly half of adult Americans take regularly. For example, an estimated 29 million Americans have diabetes — about 10 times the number of those with hepatitis C — and many of them will take diabetes drugs for the rest of their lives. In 2014, for the fourth year in a row, spending on diabetes drugs was higher on a per-member basis than it was for any other class of traditional drug.⁵

A national poll by Kaiser Family Foundation indicates that drug prices are high on American's list of health care concerns – 77 percent of those surveyed said the issue was their number one health worry.⁶ And they are right to be worried. In 2014, it estimated that total U.S. prescription drug spending increased 13 percent and experts predict even higher price hikes are in our near future.⁷

Impact on Consumers

High and rising drug prices are a concern for the nearly 50% of Americans who regularly take a prescription drug.⁸ Our own survey, as well as the research of others, shows that when people are unable to afford their medications, they frequently cut corners in ways that could be harmful to their health. They might skip filling a prescription or they might take less of a medication than what has been prescribed. Sixteen percent of diabetes patients in Medicare fail to fill at least one prescription a year because of the cost, according one study.⁹ This can lead to poorer health outcomes and higher health care costs in the long run.

Causes of High Drug Prices

There are myriad reasons for high and rising drug prices. Consumers may report high prices because they are personally paying a greater share of the cost for a number of reasons. Consumer cost sharing could increase because their drugs may have been placed in a higher cost-sharing tier by their insurance company. This is a common story we hear and, in some instances, this activity is being investigated to see if these changes are in violation of the anti-discriminatory benefit design protections in the Affordable Care

⁵ *The Express Scripts 2014 Drug Trend Report*, March 2015. See also: https://www.washingtonpost.com/national/health-science/people-with-diabetes-are-facing-rising-prices-for-lifesaving-drugs/2015/08/24/dec2abd8-476f-11e5-8e7d-9c033e6745d8_story.html

⁶ [Kaiser Family Foundation Health Tracking Poll](#), October 2015.

⁷ See: IMS Institute for Healthcare Informatics (<http://bit.ly/1DzzWMw>) and *Rx Costs: A Primer for Health Care Advocates*, Consumers Union Research Brief No. 5, April 2015

⁸ Researchers find that more than half of Americans take two drugs. <http://newsnetwork.mayoclinic.org/discussion/nearly-7-in-10-americans-take-prescription-drugs-mayo-clinic-olmsted-medical-center-find/>

⁹ Marc-Andre Gagnon and Sidney Wolfe. *Mirror, Mirror On The Wall: Medicare Part D Pays Needlessly High Brand-Name Drug Prices Compared With Other OECD Countries And With U.S. Government Programs*, Carleton University School of Public Policy and Administration and Public Citizen Policy Brief, July 23, 2015.

Act.¹⁰ Consumers may also see spikes in their drug cost if the formulary drops their prescription medicine, a change that can happen in the middle of the plan year.

While examining how cost-sharing is structured to ensure adequate consumer protections is very important, it is critically important to look at the underlying factors driving the overall cost of drugs. The reasons for high drug prices include increasing research costs, long periods of market “exclusivity,” insufficient competition, and drug shortages.

To compensate companies for the research and development costs incurred to bring a new drug to market, drug manufacturers are issued patents, usually giving a pharmaceutical company exclusivity that prevents competition for 20 years, from when the patent is issued. Because patents are filed while drugs are still being tested, that clock starts ticking long before the drug actually goes on the market. Typically, new drugs are under monopoly protection for roughly a dozen years.

Upon approval of a new drug, the FDA also grants exclusivity, or exclusive marketing rights, which may or may not run concurrently with a patent, and also serves to protect companies from competition. Exclusivity was designed to promote a balance between new drug innovation and generic drug competition.

The recent uproar caused by Turing Pharmaceuticals is an example of a branded drug with no competitors because no company filed to make a generic version of the drug. Turing raised the price of Daraprim, the only approved treatment for a rare, life-threatening parasitic infection, by more than 5,000 percent to \$750 a pill.

The effects on drug costs of these long periods of market protection are compounded by the costs to manufacture some of the newer specialty drugs. These are the most-exorbitantly priced new drugs are biologics, which are produced by living cells under very precise conditions, a process that is far more expensive than traditional drug development. Not only are biologics expensive to manufacture but they also require special handling when shipped and stored.

Lack of robust generic competition also presents a challenge and is due to the large backlog of generic drugs awaiting U.S. regulatory approval. This long wait time means that, for some off-patent drugs, only one or two generic versions have been approved. Limited competition among generics lessens reductions from the brand-name drug’s price. Finally, some older, once-cheap generics have been in short supply over the last decade. Reasons include raw material shortages and manufacturing deficiencies.

Unlike many countries, where government agencies negotiate prices for every drug, the U.S. does not regulate prices. In the U.S., drug makers set prices based on what the market will bear.

¹⁰ Some insurers are placing high-cost medications for chronic conditions into the highest-priced tiers of the drugs they cover, which would force patients to pay potentially thousands of more dollars out of pocket for essential medications. <https://www.washingtonpost.com/news/wonk/wp/2015/01/28/health-insurers-may-be-finding-new-ways-to-discriminate-against-patients/>

Addressing High Drug Costs

A recent Kaiser Family Foundation poll finds that most people believe the costs of prescription drugs are “unreasonable,” with 77 percent citing drug company profits and 64 percent citing the high cost of medical research as major factors contributing to high costs.¹¹ Both our research¹² and research from the Kaiser Family Foundation¹³ shows that Americans on both sides of the political aisle believe that only government can address high drug costs and take on the powerful pharmaceutical industry.

Short-term relief for consumers can be provided by:

- Limit consumers’ out-of-pocket payments for high-priced medications and make this amount more predictable by limiting how often plan administrators can make changes to the formulary. For example, legislation Consumers Union recently helped pass in California caps a consumer’s share of payment at no more than \$250 for a 30-day prescription.
- Strongly enforce, and monitor state enforcement, of anti-discrimination benefit design protections for ACA plans and Medicare Part D plans.

Other immediate steps include transparency measures such as:

- Require pharmacy benefit managers to reveal the negotiated cost of medications to employers. This should include rebates, plus PBMs’ payments to retail pharmacies and mark-ups related to a PBM’s own mail order service.¹⁴
- Pilot transparency rules like those being debated in Massachusetts and other states. In April 2015, Massachusetts introduced a bill that would require drug companies to report a wide range of cost and pricing information.¹⁵ The Massachusetts bill does not stop at transparency; if the state determines the price of a prescription drug is “significantly high,” they may set the maximum allowable price that the manufacturer can charge for that prescription drug sold for use in Massachusetts.
- Publish what the Veterans Administration and other countries pay for drugs as a benchmark price that employers, consumers and others can use.
- Prohibit gag clauses that prevent pharmacists from offering drugs at a lower price, if one exists, before a consumer asks.¹⁶

¹¹ Kaiser Family Foundation Health Tracking Poll: June 2015 (<http://bit.ly/1FZSWFW>)

¹² Consumers Union, Engaging Consumers on Health Care Cost and Value , October 2014 <http://consumersunion.org/wp-content/uploads/2014/10/Engaging-Consumers-on-Health-Care-Cost-and-Value-Oct-2014.pdf>

¹³ Some 83% said they support allowing the government to negotiate with drug companies, Kaiser Family Foundation Health Tracking Poll: August 2015. This includes 93% of Democrats and 74% of Republicans.

¹⁴ Consumers Union Testimony on PBM pricing: *The State of Competition in the Pharmacy Benefits Manager and Pharmacy Marketplaces*, Before the Subcommittee on Regulatory Reform, Commercial and Antitrust Law Committee on the Judiciary United States House of Representatives, November 17, 2015.

¹⁵ [Massachusetts S. 1048](#)

¹⁶ Please see our January 2016 article in which pharmacists told us that its contracts for Medicare Part D plans prohibit them from offering a better cash price to a customer unless a customer asks. SAVE MONEY ON YOUR MEDS, *Prices can vary widely from store to store, even in the same town* , *Consumer Reports*, January 2016

These are short-term solutions. As a nation, we must tackle the underlying causes of high and unpredictable drug pricing. Measures that more directly address the underlying causes of high prices worth of consideration include:

- Patent Reform -- Patent terms must be reasonable and granted only for real advances rather than minor tweaks or reformulations of existing drugs. Limiting the monopoly period that drug companies enjoy would speedup competition that could drive prices down.
- Exclusivity --The FDA should take a hard look at the criteria for granting periods of exclusivity that allow manufacturers to price drugs according to "what the market will bear".¹⁷
- Comparative Effectiveness Research -- Increase funding for true comparative effectiveness research, rather than rely on performance against a placebo. Many expensive drugs provide significant consumer benefits but it is often difficult for payers to know if the benefits outweigh the costs when a cheaper, but slightly different alternative is available. We must stop approving drugs that are not effective or that perform no better than existing, lower-cost alternatives (including non-pharmaceutical options).
- Medicare Negotiation -- Study allowing Medicare to negotiate prices¹⁸ directly if the prices paid by Part D beneficiaries exceed the weighted average of what other developed countries pay.
- Drug Re-importation -- Study solutions that would legalize re-importation from Canada in a way that is overseen by FDA and ensures consumer safety.

Conclusion

In the US, there is little in the way of a functioning, transparent market that will deliver well priced drugs and clear information about the comparative value of treatment options. In his seminal article for *Time* magazine, "Bitter Pill," Steven Brill used investigative journalism to pull back the curtain on drug pricing.¹⁹ He uncovered that a cancer drug, Rituxan, cost just \$300 to manufacture and ship, but the manufacturer then charged \$3,500 to the hospital for the drug and the hospital, in turn, charged the patient \$13,702 for this life-saving drug. Neither patients, nor the health care financing system, can support these levels of health care markup.

Ensuring that consumers can afford the drugs they need and that they have access to reliable information on the comparative effectiveness of treatments will provide to a better consumer experience, better treatment compliance, and better health outcomes.

Consumer Union supports efforts to study and enact a range of solutions that would

¹⁷ Note: Exclusivity periods are distinct from patent terms.

¹⁸ Medicare pays 83% of a brand-name drug's official price, on average, according to a recent [study](#) by Carleton University and Public Citizen, an advocacy group. Medicaid pays 48% and the Veteran Health Administration 46%.

¹⁹ Steven Brill, "Bitter Pill: Why Medical Bills are Killing Us," *Time* magazine, March 4, 2013.

address consumers' difficulties affording their critical medications. We appreciate the Steering Committee's attention to this issue of profound importance to our health care system and to consumers.