ConsumersUnion
POLICY & ACTION FROM CONSUMER REPORTS

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BEFORE THE

SUBCOMMITTEE ON ANTITRUST, COMPETITION POLICY, AND CONSUMER RIGHTS

SENATE COMMITTEE ON THE JUDICIARY

ON

THE CREATES ACT: ENDING REGULATORY ABUSE, PROTECTING CONSUMERS, AND ENSURING DRUG PRICE COMPETITION

June 21, 2016

Chairman Lee, Ranking Member Klobuchar, Subcommittee Members, thank you for the opportunity to be here today. Consumers Union, the policy and advocacy division of Consumer Reports,[1] appreciates your continuing leadership in promoting competition in the availability of more affordable generic alternatives to prescription drugs.

From our founding 80 years ago, one of our top priorities has been to make health care available and affordable for all Americans.

As part of our work to 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 identify the "best buy."

One of the key ways consumers find the best buy for the drugs they need is through the availability of generic alternatives to the original brand-name version of a drug. That can make a dramatic difference in whether a drug is affordable or not.

A feature article in the August issue of Consumer Reports, now available on our website, asks in its title: "Is There a Cure for High Drug Prices?"

The article reports on the results of a nationally representative telephone poll of more than 2,000 consumers who take a prescription medication, conducted by Best Buy Drugs in March, finding that high drug prices are taking a serious toll on consumers.

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[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. It 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 the laws 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 their budgets.

We found that 45 percent of people regularly take a prescription drug, and on average take between four and five medications. Three in ten people told us their out-of-pocket costs for one of their prescriptions has gone up in the past 12 months, costing them an average of $63 more for a drug they routinely take – with a few being hit with increases of $500 or more. And for those consumers:

- 47 percent took less of the drug than the prescription called for, to save money, with 17 percent skipping or splitting doses, and 30 percent not filling the prescription at all.

- 28 percent put off a doctor's visit.

- 19 percent took an expired medication.

- 19 percent postponed paying other bills to pay for their medications.

We tell the story of Marlene Condon, a nature writer living in Crozet, Va. Two years ago, she paid about $32 for 180 tablets of hydroxychloroquine – a generic available for almost two decades – to treat her rheumatoid arthritis. When the drug's price more than doubled to $75, Condon says she was annoyed but paid the bill anyway.

Then, last September, the price of her drug skyrocketed, costing her $500 out of pocket. Condon panicked and did what thousands of Americans do under those circumstances: She stopped taking the drug. Her arthritis pain grew much worse. Walking and doing simple household chores such as washing the dishes have become almost impossible.

The number one reason for the high cost of drugs Marlene Condon and millions of consumers are facing is that is that there are no effective constraints on prices.

The case of Turing Pharmaceuticals jacking up the price of Daraprim – the best treatment for toxoplasmosis, an infection to which those with HIV/AIDs or cancer are susceptible – from $13.50 per tablet to $750, is only the most notorious example.

Last year, when Valeant Pharmaceuticals acquired the lifesaving heart drug Isuprel and the blood pressure medication Nitropress, it immediately raised their prices. A single dose of Isuprel jumped from $180 to $1,472, and Nitropress jumped from $215 to $1,346. The company also purchased Cuprimine (penicillamine) – a drug used to treat Wilson's disease, a rare genetic disorder – and hiked up its price from $8.88 to $262 per capsule. None of the drugs had a generic alternative available for consumers to choose, so Valeant had the market cornered, with a built-in base of customers.

We found recent price hikes on everything from longtime generics used to treat common conditions such as diabetes, high blood pressure, and high cholesterol to new treatments for diseases such as hepatitis C.

For most products and services sold in our market economy, prices are held in check by competition. For a number of reasons, that doesn't work the way it should in the case of drugs.

One reason is that, to encourage brand-name drug makers to invest in research and development, the government grants the new drug a patent, which is a legal monopoly. That patent doesn't last forever, but the brand-name drug maker gets used to those monopoly profits, and has a natural business incentive to look for ways to prolong them.

Three decades ago, in the Hatch-Waxman Act, Congress established a national policy of encouraging competition from affordable generic alternatives, consistent with patent laws. But enacting that law didn't change that underlying business incentive of the brand-name drug makers. And so we have had to continue fighting roadblocks thrown up against availability of generics, such as pay-for-delay schemes to buy off generic drug makers, and "ever-greening" strategies, also called "product-hopping," to prolong a brand-name patent beyond its natural life. These schemes and strategies block generic entry for a further extended period of time, restricting access to lower-cost generic alternatives of the drug.

The legislation the Subcommittee is considering today, the CREATES Act, deals with other roadblocks brand-name drug makers are now throwing up.

Roadblocks that deny generic and biosimilar drug makers access to a sufficient supply of the brand-name drug, or to the established testing processes, that the generic needs in order to be able to do the necessary testing to satisfy the FDA's bio-equivalency requirements and ensure that the generic is safe and effective.

Daraprim's astronomical price hike by Turing Pharmaceuticals is propped up by this kind of restricted distribution. The drug went off-patent about 40 years ago. And until recently, it was available on ordinary distribution channels to wholesalers and retail pharmacies. But it was taken off those ordinary channels two months before Turing acquired it, reportedly as a condition of the deal.[3] As a result of that change, Turing only distributes the drug through a "closed" pharmacy system, and obtaining samples of Daraprim in order to make and market a lower-cost alternative has become difficult.

These restrictive roadblocks could very well be a violation of the antitrust laws. They have the familiar hallmarks for a monopolization case.[4] But antitrust lawsuits are generally costly, complex, and lengthy.

We've just been through more than a decade of sustained effort on the part of the Federal Trade Commission and private parties to establish the basic principle that brand-name drug companies could be held accountable under antitrust law for the "pay for delay" deals they were making to forestall entry by affordable generic competitors, buying off the ones closest to coming on the market and blocking the path for others.

Even after the Supreme Court definitively ruled in the 2013 *Actavis* decision that the antitrust laws *do* apply to "pay for delay," that still did not settle the matter. The brand-name drug makers shifted to other, more subtle forms of pay-off, claiming that the Supreme Court's decision only applies to pay-offs in cold, hard cash.

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[3] Andrew Pollack and Julie Creswell, *Martin Shkreli, the Mercurial Man Behind the Drug Price Increase That Went Viral* , N.Y. Times, Sept. 22, 2015, http://www.nytimes.com/2015/09/23/business/big-price-increase-for-an-old-drug-will-be-rolled-back-turing-chief-says.html.

[4] *See* Carrier, Michael A., Levidow, Nicole, and Kesselheim, Aaron S., *Using Antitrust Law to Challenge Turings' Daraprim Price Increase*, 31 Berkeley Tech. L.J. ____ (forthcoming 2016), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2724604.

And the brand-name drug makers also turned to product-hopping, using minor alterations to the way a drug is packaged or delivered as a basis for getting a new patent.

Both these kinds of schemes are now the subject of government enforcement actions and private challenges wending their way through the courts.

Now we have these new schemes. Whether these new supply and testing restrictions could ultimately be shown in the courts, after extensive and expensive litigation, to be antitrust violations, in any case they are clearly anti-competitive – and anti-consumer. Rather than wait to see where another decade-long litigation process might lead, we support your straightforward proposal to simply clarify that these practices are unlawful and give the affected generics a way to stop them.

We look forward to working with you to enact your legislation into law.

Thank you again for the opportunity to testify on this important issue for consumers.