Prescription Drug Presentation-Consumer Action Conference

Good morning. I’m Michael DeLong, and I work for David Balto, an expert antitrust lawyer and a former Policy Director of the Federal Trade Commission who has devoted his career to protecting consumers, opposing harmful mergers, and lowering prescription drug costs. He is very sorry he could not be here. I will do my best to fill in.

Rising prescription drug prices are a huge problem for American consumers. Skyrocketing costs mean that many people are being forced to choose between the medicines they need and paying for basic necessities such as groceries, housing, and education. Earlier this year in February the Kaiser Family Foundation conducted a poll and found that three out of ten people reported not taking their medicines as prescribed in the past year because of costs.

From 2011-2016, prescription drug spending grew by more than 2.5 times the rate of inflation. The Department of Health and Human Services estimated that in 2016 Americans spent over $460 billion on drugs, 16.7% of our total health care spending. And the problem is getting worse. In the first six months of 2019, over 3,400 drugs saw their list prices go up, an increase of 17% from last year. The average price hike is 10.5%, or five times the rate of inflation.

Insulin is one of the most prominent examples that affects the most people. Over 100 million Americans are diabetic or pre-diabetic and insulin was invented in 1922-a century ago! The inventors of this drug sold the patent for $1 so that it would be freely available to all.

But a century later, insulin’s price adjusted for inflation has at least tripled between the 1990s and our present day. Just from 2012 to 2016, insulin costs nearly doubled from $2,864 to $5,075. And there have been dozens of cases of people dying because they can’t afford it. One of the most recent cases was Jesimya David Scherer-Radcliff; he died this July because he was rationing the insulin he needed to treat his diabetes. He was 21 years old.

The United States is the center of pharmaceutical innovation and produces many incredible medicines. But as David Mitchell of Patients for Affordable Drugs says, “Drugs don’t work if people can’t afford them.”

So why are prescription drug prices so high, and what can be done to make drugs affordable? The system is quite complicated and opaque, which is what many companies want so they can engage in price gouging. But here are the most important reasons why drug prices are so high:

**First, drug prices are so high and getting higher because of prescription drug companies and their monopolies**. Patents and other government granted exclusivities give corporations the power to set prices. Drug companies are taking advantage of this to launch new drugs at tens or hundreds of thousands of dollars per year.

**Second, there are no laws prohibiting price gouging and the federal government does not take steps to lower drug costs**. Medicare is the country’s largest purchaser of prescription drugs, but current law prohibits the program from bargaining with drug companies to reduce prices. The federal government also doesn’t set a maximum limit on prices or take other measures to stop price gouging.

If Medicare had the power to negotiate lower costs, it would bring prices down substantially, not just in the Medicare program and but in other markets. The Veterans Administration has the power to negotiate lower drug prices and it works. A few years ago the list price for three months’ supply of Harvoni (a drug to treat Hepatitis C) was $94,500. The VA bargained with Gilead and got it down to $37,500 for three months. There is no reason for Medicare not to negotiate drug prices. In fact, our current system leads to higher costs for the federal government and ordinary Americans.

In this Congress there are a whole bunch of federal bills to end them and allow Medicare to negotiate costs; more on that later.

**Third, there is a lack of transparency and accountability in prescription drug markets and the prescription drug supply chain**. When people leave the doctor’s office to pick up new prescriptions, most of the time they don’t know how much it will cost. The United States pays much more for drugs than any other country. And drug prices at various pharmacies can vary a lot. A generic version of the cholesterol drug Lipitor can cost $9 at one pharmacy but $226 at another pharmacy in the same town. And there is a lack of transparency in the supply chain too-policymakers and ordinary people and even health care experts often don’t know where the money is going.

Meanwhile, drug companies and other actors such as pharmacy benefit managers fight attempts to promote transparency. When California passed SB 17, which requires drug companies to report information about prices and provide at least 60 days’ notice before they increase drug prices by over 16%, the drug companies fought it tooth and nail and claimed it was unconstitutional. When states pass laws requiring greater reporting of data from pharmacy benefit managers, they lobby against the laws and then file lawsuits claiming they are unconstitutional.

**Fourth, middlemen companies known as pharmacy benefit managers (PBMs) profit from higher drug prices**. PBMs are companies that operate like credit card companies-they are transfer money and information and act as intermediaries between insurers, drug companies, and other members of the health care industry. The PBM market lacks the essential ingredients for a competitive market-transparency, choice, and a lack of conflicts of interest.

Consumers need meaningful alternatives to force competitors to vie for their loyalty by offering fair prices and better services. Transparency is necessary for consumers to evaluate products carefully and make informed choices. But three PBMs-CVS Caremark, Optum Rx, and Express Scripts-control the vast majority of the market, between 70% and 85%. They form a tight oligopoly and are one of the least regulated sectors of the health care economy.

PBMs get paid rebates by drug companies in order for preferred access to formularies. But rebates aren’t disclosed, and since PBM rebates are usually based on a percentage of the drug’s list price, they can actually profit from higher drug prices, since this will lead to higher rebates. Some PBMs get rebates from drug companies in exchange for exclusivity agreements that keep drugs off the market. Other PBMs switch patients to more expensive drugs to take advantage of the higher rebates. They are also getting money from other sources, such as egregious fees from pharmacies.

PBMs claim they are passing rebates on to consumers and lowering drug prices. But drug prices have been going up over the past twenty years, so they aren’t doing a very good job. There have been also been cases where PBMs have been accused of overcharging the state governments. In 2018, Ohio found that the PBMs were overcharging the state for prescription drugs, and it is currently suing OptumRx for $16 million.

Until the practice was outlawed last year, PBMs would often put gag clauses in their contracts with pharmacies, preventing them from telling consumers if it were cheaper to buy drug out of pocket instead of with their insurance. They are not friends of consumers.

**Fifth, consolidation of prescription drug companies and PBMs and their anticompetitive conduct increases prices**. Between 1995 and 2015, mergers and acquisitions in the pharmaceutical industry caused sixty drug companies to merge into ten. This consolidation harms innovation. Research and development of new drugs is expensive, yields inconsistent returns, and is time consuming. So the largest drug companies are increasingly resorting to access research and development by buying other companies. Academic studies show that big mergers tend to reduce innovation-drug companies in the more concentrated marketplaces cut back on research.

And the PBM market is even worse. As I previously noted, three PBMs control over 70% of the market, so it lacks effective competition. The FTC approved this consolidation-they did not challenge any of the mergers that resulted in there being three major PBMs. Without more competitors, consumers do not have meaningful choices and prices tend to increase and stay high.

Recently Mr. Balto submitted a letter to the Federal Trade Commission from over a dozen prominent consumer groups and unions opposing a recent merger—the $63 billion merger of the drug companies AbbVie and Allergan. This merger would create the world’s fourth largest drug company, and both these companies have engaged in anticompetitive behavior to prevent cheaper and better drugs from coming to market.

**And finally, patent abuse by drug companies** to prolong their monopolies and exclusive periods and stifle competition. One example: Humira, made by AbbVie, is the world’s bestselling drug. It was approved in 2002 and AbbVie has filed and received a huge number of patents on the drug and various stages of its development. Its initial patent would have expired in 2016, but Humira applied for and got over 75 patents that would extend its monopoly to 2034 and prevent cheaper generic alternatives.

A couple of the patents have been found to be invalid and thrown out. But in order to break this monopoly, other companies have to engage in long, expensive patent litigation. Another example is Lantus, a kind of insulin produced by Sanofi. Sanofi has filed 74 patent applications on this drug to discourage competition and enable it to keep hiking prices.

I also wanted to counter a couple of arguments that drug companies and PBMs and some misguided people make. First, drug companies claim that if we stop price gouging and ensure drugs are affordable, that innovation will suffer. They claim that high drug prices may be excessive, but they are necessary in order to fund research and development of new medicines. This claim is wrong. One study by the Campaign for Sustainable Rx pricing (using data from the Securities and Exchange Commission) found that in 2017 the 10 largest drug companies spent an average of 22% of their revenues on research and development. But they spent 46% of their revenue on advertising, corporate overhead, and profits. And much of the research is being done by smaller drug companies instead of the larger ones-it is common for drug companies to buy the rights to research after the hard work has been done, so they can charge higher prices for a drug.

In still other cases, drug companies buy the rights to a drug and increase prices even though they have nothing to do with its development at all. This is what Martin Shkreli did back in 2015. His company, Turing Pharmaceuticals, bought the rights to Daraprim, an off-patent, decades old drug that treats relatively rare parasitic infections. There was no competition and so he was able to raise Daraprim’s price from $13.50 per pill to $750 per pill.

Also, a lot of drug research and development is not done by private companies but by the National Institutes of Health (NIH) and other federal programs. Over $100 billion in NIH funding contributed directly or indirectly to every one of the 210 drugs that the Food and Drug Administration approved between 2010 and 2016. And the bulk of the funding was for basic science. So if we want to promote innovation, we should really provide more funding for NIH and other research programs.

Second, PBMs claim that transparency in the drug supply chain will undermine competition. These claims are also nonsense-if PBMs are really lowering drug prices as they claim, than transparency will demonstrate this and vindicate them. And again, PBMs tried to use gag clauses in pharmacy contracts to prevent pharmacies from keeping their patients informed. Less information and transparency means that consumers have a hard time knowing what is going on, and agencies that protect consumer welfare have a harder time doing their jobs.

What are some possible ways to lower drug prices? Fortunately there are several proposals, in Congress and the executive branch, that are very promising. Below are some of the most important ones:

* H.R. 3, introduced by Speaker Nancy Pelosi. This bill would end the ban on Medicare negotiating and empower HHS to negotiate prices for the 250 most cost drugs each year. It would also establish a maximum fair price based on an international pricing index-Americans would pay no more than 120% of what other wealthy countries like Canada, Britain, Germany, and Japan pay. And drug companies would be required to offer the negotiated price to Medicare and non-Medicare insurance plans, or be subject to strict penalties. Drug companies also couldn’t increase drug prices in Medicare above the rate of inflation; if they do, they have to either lower the price or pay the entire price above inflation back to the Treasury. David Mitchell of Patients for Affordable Drugs has praised this proposal and urged that it be passed.
* Require stronger regulation of PBMs and require rebates to be passed on to consumers at the point of sale and lower drug prices. Earlier this year the Department of Health and Human Services announced a new regulation that would have eliminated safe harbor protections for the rebates that drug companies pay to PBMs, unless they are passed on to consumers. Unfortunately this proposal was abruptly withdrawn with an explanation. However, the Lower Health Care Costs Act (S. 1895) was approved by the Senate Health, Education, Labor, and Pensions Committee, and it requires rebates to be passed on to consumers and eliminates several other PBM abuses.
* The Medicare Negotiation and Competitive Licensing Act (H. 1046, S. 377). Sponsored by Rep. Lloyd Doggett, this bill has 125 Democratic cosponsors. It authorizes HHS to negotiate lower drug prices through Medicare. If drug companies refuse to negotiate in good faith, the federal government can issue competitive licenses to other companies to produce the drugs as generics.
* End patent abuse and promote generic competition. Congress should end patent “evergreening,” pay for delay schemes, and other abuses of monopoly power. It should also limit patent terms. A couple of promising bills are the CREATES Act, which would promote access to sample drugs so generic companies can use them to make more affordable generic drugs, and the Affordable Patients for Prescriptions Act
* Stronger antitrust enforcement at the state level. State Attorneys General have substantial power and influence and don’t get the attention they should. They are closer to the market and recognize the direct harm to consumers. They have the ability to secure monetary damages. States are often customers and victims of anticompetitive schemes and can bring combined antitrust and consumer protection cases. While each state has limited antitrust and consumer protection resources, states increasingly are using multistate task forces to investigate and prosecute mergers and unlawful conduct.
* Stronger antitrust enforcement at the federal level. Consumers should push both the Department of Justice and the Federal Trade Commission to apply more scrutiny to mergers and block them if needed. They should also urge both agencies to adopt a broader view of mergers and other possible negative effects resulting from them, like reduced innovation and lower wages and benefits.
* Other remedies such as Section 1498 (the government can authorize generic competition or make patented medicines for public programs in exchange for reasonable competition) and march-in rights. The Bayh-Dole Act gives the government the power to step in and license patents (say for a drug) to a third party if the company holding the patent isn’t taking steps to put it on the market at reasonable rates. So the federal government could use this power to authorize generic competition for drugs that have been developed using federal research. This has never been done before, but a new President and administration would probably look more favorably on this.

Also, fed up with federal gridlock, state governments have been taking action to reduce drug costs. So far in 2019 33 states have enacted 51 laws to lower drug prices. We submitted testimony in Maine, Minnesota, Montana, and Ohio in support of bills to regulate PBMs. Maine and Florida are developing programs to import more affordable prescription drugs from Canada and other countries. And the Trump administration, in one of its very few good actions, has endorsed these programs and says they are going to try and make them work.

Consumers should also be bold-nine out of ten Americans want to the government to take action to lower drug prices. The vast majority of consumers are with us.

Thank you very much for inviting me. Drug pricing is an immensely complicated topic and I appreciate the great work you all are doing. I will do my best to answer your questions.