

WHY ARE SOME GENERIC DRUGS SKYROCKETING IN PRICE?

HEARING

BEFORE THE

SUBCOMMITTEE ON PRIMARY HEALTH AND AGING

OF THE

COMMITTEE ON HEALTH, EDUCATION,
LABOR, AND PENSIONS

UNITED STATES SENATE

ONE HUNDRED THIRTEENTH CONGRESS

SECOND SESSION

ON

EXAMINING THE PRICING OF GENERIC DRUGS

NOVEMBER 20, 2014

Printed for the use of the Committee on Health, Education, Labor, and Pensions



Available via the World Wide Web: <http://www.gpo.gov/fdsys/>

U.S. GOVERNMENT PUBLISHING OFFICE

24-459 PDF

WASHINGTON : 2017

For sale by the Superintendent of Documents, U.S. Government Publishing Office
Internet: bookstore.gpo.gov Phone: toll free (866) 512-1800; DC area (202) 512-1800
Fax: (202) 512-2104 Mail: Stop IDCC, Washington, DC 20402-0001

COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS

TOM HARKIN, Iowa, *Chairman*

BARBARA A. MIKULSKI, Maryland	LAMAR ALEXANDER, Tennessee
PATTY MURRAY, Washington	MICHAEL B. ENZI, Wyoming
BERNARD SANDERS (I), Vermont	RICHARD BURR, North Carolina
ROBERT P. CASEY, JR., Pennsylvania	JOHNNY ISAKSON, Georgia
KAY R. HAGAN, North Carolina	RAND PAUL, Kentucky
AL FRANKEN, Minnesota	ORRIN G. HATCH, Utah
MICHAEL F. BENNET, Colorado	PAT ROBERTS, Kansas
SHELDON WHITEHOUSE, Rhode Island	LISA MURKOWSKI, Alaska
TAMMY BALDWIN, Wisconsin	MARK KIRK, Illinois
CHRISTOPHER S. MURPHY, Connecticut	TIM SCOTT, South Carolina
ELIZABETH WARREN, Massachusetts	

DEREK MILLER, *Staff Director*

LAUREN MCFERRAN, *Deputy Staff Director and Chief Counsel*

DAVID P. CLEARY, *Republican Staff Director*

SUBCOMMITTEE ON PRIMARY HEALTH AND AGING

BERNARD SANDERS, Vermont, *Chairman*

BARBARA A. MIKULSKI, Maryland	RICHARD BURR, North Carolina
KAY R. HAGAN, North Carolina	PAT ROBERTS, Kansas
SHELDON WHITEHOUSE, Rhode Island	LISA MURKOWSKI, Alaska
TAMMY BALDWIN, Wisconsin	MICHAEL B. ENZI, Wyoming
CHRISTOPHER S. MURPHY, Connecticut	MARK KIRK, Illinois
ELIZABETH WARREN, Massachusetts	LAMAR ALEXANDER, Tennessee (ex officio)
TOM HARKIN, Iowa (ex officio)	

SOPHIE KASIMOW, *Staff Director*

KRISTEN CHAPMAN, *Minority Staff Director*

C O N T E N T S

STATEMENTS

THURSDAY, NOVEMBER 20, 2014

Page

COMMITTEE MEMBERS

Sanders, Hon. Bernard, Chairman, Subcommittee on Primary Health and Aging, opening statement	1
Burr, Hon. Richard, a U.S. Senator from the State of North Carolina	3
Warren, Hon. Elizabeth, a U.S. Senator from the State of Massachusetts	60

GUEST CONGRESSMAN—PANEL I

Cummings, Hon. Elijah E., Ranking Member, House Committee on Oversight and Government Reform, Washington, DC	5
Prepared statement	7

WITNESSES—PANEL II

Schondelmeyer, Stephen W., BS Pharm, MA Pub Adm, Pharm.D., Ph.D., FAPhA, Professor and Director, Prime Institute, University of Minnesota College of Pharmacy, Minneapolis, MN	9
Prepared statement	11
Frankil, Robert, RPh, President, Sellersville Pharmacy, Inc., Sellersville, PA ..	36
Prepared statement	37
Riha, Carol Ann, West Des Moines, IA	40
Prepared statement	41
Gottlieb, Scott, M.D., Resident Fellow, American Enterprise Institute, Washington, DC	43
Prepared statement	44
Kesselheim, Aaron S., M.D., J.D., M.P.H., Associate Professor of Medicine, Brigham and Women's Hospital and Harvard Medical School, Boston, MA ..	50
Prepared statement	52

ADDITIONAL MATERIAL

Statements, articles, publications, letters, etc.:	
Senator Burr	63
Senator Mikulski	64

WHY ARE SOME GENERIC DRUGS SKYROCKETING IN PRICE?

THURSDAY, NOVEMBER 20, 2014

U.S. SENATE,
COMMITTEE ON HEALTH, EDUCATION, LABOR, AND PENSIONS,
Washington, DC.

The subcommittee met, pursuant to notice, at 1 p.m., in room SD-430, Dirksen Senate Office Building, Hon. Bernard Sanders, chairman of the subcommittee, presiding.

Present: Senators Sanders, Burr, and Warren.

OPENING STATEMENT OF SENATOR SANDERS

Senator SANDERS. Thank you all very much for being with us today on a hearing that I consider to be very important.

And we especially want to thank our panel of expert witnesses.

And a special thanks goes to Congressman Elijah Cummings. Congressman Cummings and I have been working on this issue together for quite a while now, and I very much appreciate all the efforts that he has made in the House. And we're going to turn to the Congressman in a few minutes.

The issue that we are discussing today is of huge consequence to the American people. When we talk about healthcare, we are talking about the need of the American people to be able to afford the medicine that their doctors prescribe. That's pretty commonsensical. Unfortunately, however, drug prices in this country are, by far, the highest in the world. Because the United States lacks a national healthcare program which is able to negotiate with the pharmaceutical industry, drug companies are able, in many cases, to charge any price they want for their product. And people see, time and time again—they walk into their pharmacy, and the price of their medicine has gone way up—no particular explanation for that.

Today, according to the most recent reports, more than one out of four Americans do not fill their prescriptions because they cannot afford the cost. Think about that for a second. People walk into the doctor's office because they are sick, they or their insurance company pays for that visit, doctor spends time with them, the doctor diagnoses the illness, the doctor writes out a prescription, and one out of four people are unable to afford to fill that prescription. What happens to those people? They go home, their illness continues, maybe they end up in the hospital. Totally absurd situation.

All of us understand that one of the important breakthroughs in medicine in recent years is the advent of generic drugs. And what

that means is that, while protecting the intellectual rights of the company that developed a drug, the patent expires at a certain point, and that drug can then be manufactured by other companies. And that's what generics are about.

The result of that has been that millions of people are purchasing generic drugs at far lower prices than the same drug sold under a brand name. And more and more people use generic drugs. And that is, to my mind, a good thing. And this has been an enormously helpful development in alleviating illness and suffering.

The purpose of this hearing is to take a hard look at the generic drug industry and to make certain that generics remain affordable to the patients who need them; because if that does not happen, if generic drug prices continue to rise, then we are going to have people all over this country who are sick, who need medicine, and who simply will not be able to afford to buy the medicine that they need.

On October 2d, Representative Cummings and I launched an investigation into the price increases of 10 generic drugs. Now, as it happens, the manufacturers, the companies who manufacture these drugs, have complained that we just cherry-picked a handful of drugs that have seen the largest price increases. And they said, "It's not really fair. You know, you only picked on a few drugs." But, in my view, that criticism is not valid. While we are focusing on 10 individual drugs that have seen extraordinary price increases, what we are also seeing in the industry is that many other generic drug prices are rising, as well.

I should mention here that, according to a November 10th article in the Wall Street Journal, some of the price increases that we are looking at, at this hearing, and the companies involved, are being investigated by the U.S. Department of Justice for possible violations of antitrust laws.

According to Medicare and Medicaid data, between July 2013 and July 2014, half of all generic drugs went up in price. During this same time period, over 1,200 generic drugs, nearly 10 percent of all generic drugs, more than doubled in price. More than doubled in price. In fact, these drugs went up in price by an average of 448 percent. Dozens of drugs went up by 500, 600, 1,000 percent. To say that we're just looking at 10 drugs is not accurate. There appears to be, now, a trend in the industry, where a number of drugs are going up at extraordinary rates.

Let me give you a few examples. I am probably going to mispronounce half of these drugs. From July 2013 to July 2014, the price of Pravastatin Sodium, which is used to treat high cholesterol, went up 577 percent. The price of Divalproex Sodium, a migraine medication, went up by 797 percent. The price of Digoxin, a medication used to treat congestive heart failure, went up by 828 percent. Et cetera, et cetera.

Let us be clear that these huge increases in generic drug prices not only drive up healthcare prices throughout America, which is a huge issue, but they impact the lives of very real people, many of whom are struggling economically. And if you don't have a whole lot of money, and you go to the drugstore, and the druggist tells you that you're now going to be paying 10 times more for a medication that you need, this has a huge impact on your life. Maybe you

don't get the food you need, maybe you don't heat your home the way you should, because you don't have the money to spread around.

Several months ago on my website, I asked people in Vermont and throughout the country to tell me what this impact—what this increase in drug prices meant to them. What did it mean to them? And we got some 1,600 responses. Don't worry, I'm not going to read all 1,600 of them, but I will mention just a few, if I might.

Barbara Heller, who wrote in through my website and was featured last week on a CBS news program, has an autoimmune disease, and she recently saw the price of her generic drug, Ursodiol, increase from \$95 to over \$1,200. Although she eventually found a lower price, it was still over three times what she previously paid.

North Carolina pharmacist Parks Thomas said, on April 9th, 2014, "I have been a pharmacist for 30 years, and I've never seen increases like this. Never." According to Thomas, antifungal creams that used to cost \$5 now cost \$77. The cost for a bottle of Doxycycline went from \$3 to \$135. The antidepressant Clomipramine, that used to cost \$35, now costs \$605.

The goal of this hearing was pretty simple—it was to have some witnesses come forward to give us their understanding of why drug prices had gone up, and to hear from the manufacturers. Congressman Cummings and I, and others, wanted to know why it is that, over the course of a year, the price of these drugs have gone up, not 5 percent, in some cases, but 500 percent—not 10 percent, but 1,000 percent. We wanted to know if there was a rational economic reason as to why patients saw these huge price increases or whether it was simply a question of greed of companies who were able to raise prices to whatever level they wanted, and that is, in fact, what they did. And those are the questions that we wanted to ask to a number of drug companies. Unfortunately, not one of the companies that we asked to testify today chose to come to respond to those questions. We invited three companies—Lannett, Teva, and Marathon—and I am disappointed, but not surprised, by their refusal to show up here.

Let me conclude by saying that Representative Cummings and I have introduced legislation that will address one part of the problem. The bill we are introducing will require generic drug companies to provide a rebate to Medicaid if their drug prices rise faster than inflation. Brand-name drugs are required to pay this rebate if their drugs go up faster than inflation, but generic drug companies are exempt. Congress should fix this loophole immediately.

Senator Burr, the mic is yours.

OPENING STATEMENT OF SENATOR BURR

Senator BURR. Thank you, Mr. Chairman.

Elijah, welcome. Thank you for "slumming it" this Thursday afternoon by coming to the Senate. It is always good to see you.

While I share the concerns regarding the importance of Americans being able to access affordable healthcare, I'm also concerned that today's hearing not interfere with the reported Federal investigation into generic drug pricing. It's my hope that today's hearing will be conducted in a manner befitting the Senate and this committee. And I think it's obvious that, if there is an investigation,

no right legal counsel would ever allow a company to come before Congress and testify if they're under Federal review.

Over the past few years, a lot of promises about affordable care were made, and a lot of promises were broken. When a patient is sick and needs a prescription drug, they are understandably most concerned about whether that drug is available and if they can afford it. As we examine the reasons behind why some generic drugs have experienced price fluctuations, I hope that the committee does not lose sight of the important role prescription drugs play in delivering quality care to patients in need of these therapies. These life-saving products not only help many Americans to meet their healthcare needs, but also improve patients' quality of life.

While we hear about a few specific drugs and circumstances, it's important to remember that there are over 13,000 approved generic drugs in the United States. Generic drugs play a valuable role in helping patients access affordable medicines.

The IMS Institute of Healthcare Informatics found that generics saved U.S. consumers nearly \$1.5 trillion over the past decade. In recent years, the shares of prescriptions filled by generic drugs has increased, lowering healthcare costs not just for patients, but for taxpayers, as well. According to the Congressional Budget Office, between 2007 and 2010, the share of prescriptions filled with generic drugs increased from 63 percent to 73 percent in Medicare Part D. And this has contributed to the program's success story. This is further affirmation that, when it comes to healthcare choice and competition, they are essential. Consumers know how to leverage these forces to make the market respond to their healthcare needs.

Let's take a look at today's generic drug landscape. Since 2012, the Food and Drug Administration has been implementing the first generic drug user-fee agreement. Since this agreement was intended to accelerate the delivery of high quality, low cost generic drugs, we have to ask ourselves, Is it working, and has it accomplished that goal?

In 2011, the median time for generic approvals was about 31 months. Two years and hundreds of million dollars later in generic user fees, it's now taking longer for generic drugs to be approved by the FDA—36 months, and counting. While FDA has taken some initial steps to address the significant backlog of generic drug applications, the fact remains that thousands of generic drug products await review by the agency. In fact, there are more generic drug applications awaiting review at the FDA today than before the generic drug user-fee agreement was put in place. In other words, the regulatory burden has gone up without realizing the full potential benefit of new generic drugs entering the market to help lower cost through increased choice and competition.

The FDA has also proposed a generic drug labeling rule that actually undermines the core tenet of the term, "sameness" under the Hatch-Waxman Act. This rule will increase the cost of generic drugs and lead to increased cost for patients. Obamacare's prescription drug tax is being passed on to patients, not only raising prescription drug prices, but also raising premium pricing.

Instead of cherry-picking a handful of examples, we need to look at what the full picture tells us. Drug shortages remain a concern.

Taxes, fees, and regulatory burdens are driving up the cost of doing business. When the cost of doing business goes up, the market responds and adjusts. We have thousands of generic drug applications awaiting FDA review. Ultimately, many factors, including the policies enacted by the Congress of the United States and this Administration's actions, are impacting the availability, the access, and the price of these lifesaving products.

The first rule of medicine is "Do no harm." If we're going to point a finger at why healthcare costs are increasing, we should start by pointing it at ourselves, the Federal Government, and ask if the policies that we're implementing are helping or hurting. When it comes to healthcare law and FDA actions in—or/and inactions, we already know the answer.

So, Mr. Chairman, by all means, let's hold a hearing on drug pricing. But, we're not doing right by the American people if that's all we look at and then proceed to ignore the fees imposed, the bureaucracies created, the hurdles erected, the regulations unleashed, and other roadblocks constructed by this Congress and this Federal Government more broadly.

I look forward to hearing from our witnesses today. And I would remind the Chairman, we're going to be challenged, because we've got a series of votes at 2 o'clock. So, I will shut up.

Senator SANDERS. OK. Senator Burr, thank you very much.

Now we're really pleased to hear from Congressman Elijah Cummings. Since 1996, Congressman Cummings has represented Maryland's 7th Congressional District in the U.S. House of Representatives, and he currently serves as the Ranking Member of the Committee on Oversight and Government Reform.

Congressman Cummings, thanks so much for being with us.

STATEMENT OF HON. ELIJAH E. CUMMINGS, RANKING MEMBER, HOUSE COMMITTEE ON OVERSIGHT AND GOVERNMENT REFORM, WASHINGTON, DC

Representative CUMMINGS. Thank you very much, Chairman, Senators and Ranking Member Burr. I consider this a magnificent and very important opportunity.

And let me say, to both of you, as I listened to your statements, we, in the Congress of the United States, do not have the right to remain silent on this issue.

I'd like to start off by highlighting two fundamental principles that I believe we all share:

First, generic drugs are critically important to the American people. Thirty years ago, Congress passed the Hatch-Waxman Act to expand a market for low-cost generic drugs. They now account for 86 percent of all drugs dispensed in the United States. They save the American people billions of dollars every year, and they reduce our Nation's healthcare costs, as well. The majority of manufacturers are upstanding companies that should be commended for delivering lifesaving drugs to patients who need them.

Second, I believe just as strongly that when drug companies increase their prices by hundreds or even thousands of percent virtually overnight, we, as Members of Congress, have an obligation to our constituents to find out why and to determine what we can

do to help the people we serve, the ones we'll see this weekend at the gas station and at the supermarket and in church.

I am sitting before you today not because I have anything against generic drug companies. Quite the contrary. But, people have been coming out in droves to warn us about the staggering price increases they are now facing for drugs they rely on every single day. We have heard from patients, doctors, pharmacists, hospitals, providers, and groups—group purchasing organizations, all raising the alarm. And I am certain that, when you travel back home for Thanksgiving next week, you will hear the same thing from your constituents.

Let me give you an example. The retail price of a certain dosage of Albuterol Sulfate tablets increased by more than 3,000 percent from November 2012 to June 2014. Three-thousand percent. I personally use the inhaler, myself, a version of the drug, so I know how important it is for people with asthma to be able to breathe. To breathe.

Let me give you another example. Doctors use a drug called Digoxin to treat heart failure and irregular heartbeats and similar conditions. In 2012, this drug cost 11 cents per tablet, but, in June of this year, it had risen to \$1.10 per tablet. Why did this happen? This drug is manufactured by a company called Lannett. In 2012, there were three manufacturers, but one stopped producing. After this occurred, Lannett increased its price by more than 1,000 percent.

I know Chairman Sanders invited the company's CEO, Arthur Bedrosian, but he declined to testify because he's speaking to potential investors in London. Hello. London. What is he telling them? According to a call he held with investors on fourth-quarter earnings for 2014, his company just recorded its highest net sales, its highest gross margin, and its highest net income in their entire 72-year history. With respect to cardiovascular drugs in particular, the company boasted that their earnings rose from \$4.5 million to \$16.9 million in a matter of months. The CEO attributed these dramatic profits to their decision to raise prices on 75 percent of their products. He also said this,

"We are an opportunistic company. We see opportunities to raise prices. Competitors drop out of products, there are shortages in the marketplace that sometimes drive it up."

This sounds like Gordon Gecko, "greed is good." But, instead of the victims being other corporate entities, the victims here are real patients, real people suffering from heart disease.

Let me close with one final example, if I may. In 2005, Jeff Aronin was the CEO of Ovation Pharmaceuticals. His company bought a drug called Indocin, which doctors use to treat life-threatening heart conditions in babies. This drug used to sell for \$77, but no other companies manufactured it, so they increased the price to \$1,500. Let me repeat that. They hiked up the price from \$77 to \$1,500 for a medicine that doctors use to treat heart conditions in premature babies.

We do not have the right to remain silent.

Today, Mr. Aronin is CEO of a new company called Marathon Pharmaceuticals, and they apparently use the same business model. I'm almost finished, Mr. Chairman. They purchased a drug

called Isuprel, which is also used for heart conditions. A box of 25 vials used to cost \$916 in 2012, but, again, no other companies manufacture this drug, so they raised the price to \$4,489. Corporate executives claim they are reinvesting 100 percent of these massive profits into production improvements and new medicines, but they refuse—refuse—to provide any documents to support this dubious claim, and they declined to send anyone here today to testify.

Finally, let me reiterate to every member of this panel, your constituents and mine are directly affected by these abuses. No doubt there are certainly legitimate reasons to increase the price of drugs on occasion, but I believe some companies are exploiting monopolies and disruptions in supply to implement massive price increases in order to reap unconscionable profits.

Chairman Sanders, Ranking Member Burr, thank you again for inviting me here today. And I promise you, I will fight this issue until I die, because there are people dying because of it.

Thank you.

[The prepared statement of Representative Cummings follows:]

PREPARED STATEMENT OF HON. ELLIAH E. CUMMINGS

Chairman Sanders, Ranking Member Burr, and members of the subcommittee, thank you very much for the opportunity to testify on this critically important issue. I would like to start by highlighting two fundamental principles I believe we all share.

First, generic drugs are critically important to the American people. Thirty years ago, Congress passed the Hatch–Waxman Act to expand the market for low-cost generic drugs. They now account for 86 percent of all drugs dispensed in the United States. They save the American people billions of dollars every year, and they reduce our Nation’s healthcare costs as well. The majority of manufacturers are upstanding companies that should be commended for delivering life-saving drugs to patients who need them.

Second, I believe just as strongly that when drug companies increase their prices by hundreds or even thousands of percent—virtually overnight—we as Members of Congress have an obligation to our constituents to find out why, and to determine what we can do to help the people we serve.

I am sitting before you today not because I have anything against generic drug companies—quite the contrary. But people have been coming out in droves to warn us about the staggering price increases they are now facing for drugs they rely on every single day.

We have heard from patients, doctors, pharmacists, hospitals, providers, and group purchasing organizations—all raising the alarm. And I am certain that when you travel back home for Thanksgiving next week, you will hear the same thing from your constituents.

Let me give you an example. The retail price for a certain dosage of albuterol sulfate tablets increased by more than 3,000 percent from November 2012 to June 2014. I personally use the inhaler version of this drug myself, so I know how important it is for people with asthma and other lung conditions.

Let me give you another example. Doctors use a drug called Digoxin to treat heart failure, irregular heartbeats, and similar conditions. In 2012, this drug cost 11 cents per tablet, but in June of this year, it had risen to \$1.10 per tablet.

Why did this happen? This drug is manufactured by a company called Lannett. In 2012, there were three manufacturers, but one stopped producing. After this occurred, Lannett increased its price by more than 1,000 percent.

I know Chairman Sanders invited the company's CEO, Arthur Bedrosian, but he declined to testify because he is speaking to potential investors in London.

What is he telling them? According to a call he held with investors on fourth quarter earnings for 2014, his company just recorded its highest net sales, its highest gross margin, and its highest net income in their entire 72-year history. With respect to cardiovascular drugs in particular, the company boasted that their earnings rose from \$4.5 million to \$16.9 million in a matter of months. The CEO attributed these dramatic profits to their decision to raise prices on 75 percent of their products. He also said this:

"We are an opportunistic company. We see opportunities to raise prices. Competitors drop out of products. There are shortages in the marketplace that sometimes drive it."

Let me close with one final example, if I may. In 2005, Jeff Aronin was the CEO of Ovation Pharmaceuticals. His company bought a drug called Indocin, which doctors use to treat life-threatening heart conditions in babies. This drug used to sell for \$77, but no other companies manufactured it, so they increased the price to \$1,500.

Today, Mr. Aronin is the CEO of a new company called Marathon Pharmaceuticals, and they apparently use the same business model. They purchased a drug called Isuprel, which is also used for heart conditions. A box of 25 vials used to cost \$916 in 2012. But again, no other companies manufacture this drug, so they raised the price to \$4,489.

Corporate executives claim they are reinvesting 100 percent of these massive profits into production improvements and new medicines, but they refused to provide any documents to support this dubious claim, and they declined to send anyone here to testify today.

Finally, let me reiterate to every member of this panel that your constituents and mine are directly affected by these abuses. No doubt, there are certainly legitimate reasons to increase the price of drugs on occasion. But I believe some companies are exploiting monopolies and disruptions in supply to implement massive price increases in order to reap unconscionable profits.

Chairman Sanders, thank you again for inviting me here today, for agreeing to work with us on this investigation, and for your tremendous leadership on this issue.

(Contact: Jennifer Hoffman, Communications Director, (202) 226-5181.)

Senator SANDERS. Congressman Cummings, thank you very much for being here, and thanks for your work on this issue.

If the second panel could come on up, we'd appreciate that.

We are very fortunate to have with us some extremely knowledgeable people on the pharmaceutical industry, and generic drugs in particular. And let us begin with Dr. Stephen Schondelmeyer, who is a professor of pharmaceutical economics at the University of Minnesota, College of Pharmacy, where he holds the Century Mortar Club Endowed Chair in Pharmaceutical Management and Economics. We're very pleased that he is here.

Dr. Schondelmeyer, we'd be delighted to hear your testimony.

STATEMENT OF STEPHEN W. SCHONDELMAYER, BS PHARM, MA PUB ADM, PHARM.D., PH.D., FAPHA, PROFESSOR AND DIRECTOR, PRIME INSTITUTE, UNIVERSITY OF MINNESOTA COLLEGE OF PHARMACY, MINNEAPOLIS, MN

Mr. SCHONDELMAYER. Thank you, sir. I'm pleased to be here.

I am a professor at the University of Minnesota, but I'm here representing my own views and my own experience after about 40 years of studying this marketplace and studying the pricing behaviors and practices in the marketplace.

Also, I will say up front, our focus today is on skyrocketing generic drug prices, and I will address that, but I think it's important for us to realize, Where do we get generic drugs? Every generic drug in the market today started as a brand-name drug. And the brand-name drug prices are equally in the Wild, Wild West today, as far as pricing, as are generics. And so, we need to, at some point, consider issues of where a drug starts out at its price, what is the value of that drug in the market, from a broad market standpoint, not just from the stockholders of the drug company, and how do we price and change prices of those drugs over time? But, all that said, then we end up with generics that come into the marketplace today.

As has been commented, Hatch-Waxman was a major innovation for the marketplace and in providing useful, viable drugs to the public. Hatch-Waxman really did two basic things with respect to generic drugs and generic drug competition. One, it put drugs in the marketplace that assured that these generics and their competitors, as well as the original brand name, all would be identical, or essentially identical. And we have a government program that we spend a lot of resources on, and I think wisely, to assure and certify, as a government, that these products are equal in the marketplace. I can't think of any other industry where we've made that type of investment or commitment.

The second thing we've done under Hatch-Waxman was to shorten the time and resources required to get a drug on the market. And I agree with your colleague that we need to look at FDA's timing and what it costs to get that drug on the marketplace, but the bottleneck at FDA has been a part of constraining the number of competitors in the market. And, when you have fewer competitors in a market, what happens to price? It goes up. I'm not blaming FDA, totally. FDA is an excellent agency, does many good works. But, we need to look at how we can loosen that bottleneck of getting generic drugs on the marketplace.

I study, with colleagues at the AARP, drug prices over time. And each year, we do an analysis, looking at not only brand names and generic drugs, but also specialty drugs. We look at each of those.

We've already completed our brand-name marketplace analysis for 2013. We're in the middle of our generic. And I'll give you a few highlights of our generic results. But, it's—I think I have to point out, first, that the brand names went up 12.9 percent last year, on average, across all of the brand names. So, with that as a baseline, that's telling us—that's pushing up our future generic prices by that much as a baseline.

Then, we looked at a market basket of 280 generics in the 2013 time period, and a third of all of those had price increases, not price decreases, as we normally expect. I don't think you can call that a series of isolated anecdotes or cases. A third of all the market is a substantial portion of the market, and the trend line is going up, rather than down, in terms of the proportion that have these increases. I think it's grossly unfair to call that anecdotal or just a few cases. I think it is a trend in the marketplace that we're going to have to deal with.

And the percent increases we're seeing for these drugs is not 2 percent or 5 percent or 10 percent, even. These drugs are going up at, as we've heard, hundreds of percents or thousands of percents at a time. Now, imagine if you're a diabetic patient and the cost of your diabetic medicine goes up 50 percent. As a diabetic patient, you don't have any choice. Either you don't buy the medicine and you get worse and you suffer the consequences or you pay the price. But, even if you pay the price, your diabetes doesn't get 50 percent better when you pay 50 percent more. It's the same drug. It works the same way, and it has the same result for the patient if they have access to it and take it.

We have to realize, these price increases aren't increasing the value of what we're delivering to the patient in the marketplace. These aren't innovations in the generic drug that are being delivered to the patient. It's the same exact generic drug. And that could apply to any therapeutic category.

I noticed among the drugs that have gone up—I didn't see on your list—but Levothyroxine is a drug for thyroid. These drugs have been around since before the 1950s, and these drugs, all of them, went up in price 35 to 50 percent in the last year. Just in the last year, a 35-to 50-percent increase in price. Again, the patients taking those drugs aren't getting 35-to-50 percent better.

You will hear from various witnesses that part of this is because the cost structure and the barriers and the burdens that we've placed on industry, and regulation, is raising their cost structure. There is some element of truth to that. That may explain 2-, 5-, 10-percent cost increases, it doesn't explain hundreds of percents or thousands of percents. You can't show me, in aggregate, all of the regulations and all of the behaviors in the market that would justify a 100-percent increase in the last year, or a 1,000-percent increase.

First these are notions thrown out to kind of sidestep what the issue is, and second, these are industrywide effects. But if they were industrywide, we would see all drugs going up at the same rate. No, we've only seen select drugs—32 percent being select—go up in price. I don't find those arguments largely compelling, that that explains why we're experiencing these drug price increases.

What all of this is leading me to is to tell you—also, we hear a lot of talk about a market. And I believe in markets, and pharmaceutical markets as well. But, this market is broken. This market is failing. And I think it’s structurally failing. If we would step back and look, consumers don’t make a choice about what drug they’re going to get. Their physician does, their PBM influences it, their insurance company, their employer. A lot of people have a role in it, but they don’t make that point.

The markets are broken, and we need to do something to fix it. And I think the government needs to step in and monitor and develop solutions.

[The prepared statement of Mr. Schondelmeyer follows:]

PREPARED STATEMENT OF STEPHEN W. SCHONDELMAYER, BS PHARM, MA PUB ADM,
PHARM.D., PH.D., FAPHA

Thank you Senator Sanders and members of the Senate Committee on Health, Education, Labor and Pensions (HELP) for this opportunity to provide information and insights on drug price trends related to generics and other pharmaceutical products. I am Stephen W. Schondelmeyer, Professor of Pharmaceutical Management & Economics at the University of Minnesota where I serve as Director of the *PRIME* Institute. The *PRIME* Institute focuses its research on policy issues related to pharmaceutical economics and the management of drug expenditures at all levels in society. These remarks are my own views based upon my research and experience in studying the pharmaceutical marketplace for over 40 years. Previously, I have had the opportunity to serve Congress as a member of the Prescription Drug Payment Review Commission (established under the Catastrophic Coverage Act of 1988), as an author or co-author of several legislatively mandated Reports to Congress, and through testimony before congressional committees on numerous occasions.

This hearing is being held to examine “Why are some generic drugs skyrocketing in price?” Various aspects of this issue are addressed in my written remarks which include comments on:

- (1) improved coverage and access to pharmaceuticals;
- (2) the role of generics in the U.S. pharmaceutical market;
- (3) recent price trends for brand and generic prescription drug products;
- (4) signals of market failure in the pharmaceutical market; and
- (5) policy options to address skyrocketing drug prices.

I will briefly address each of these topics and describe their relationship to the skyrocketing generic drug prices being observed in the market.

IMPROVED COVERAGE AND ACCESS TO PHARMACEUTICALS

Actions taken by Congress over the past decade have expanded health insurance coverage, in general, and more specifically prescription drug coverage. Two major pieces of legislation have been enacted and implemented in the past decade: (1) The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA); and (2) The Patient Protection and Affordable Care Act (PPACA)—commonly called the Affordable Care Act (ACA) (2010).

First, the MMA established the Medicare Prescription Drug Program, also known as Medicare Part D. The MMA’s most prominent feature was the introduction of an entitlement benefit for Medicare beneficiaries covering prescription drugs through tax breaks, subsidies, premiums, and other forms of cost-sharing. The Medicare Part D program was implemented on January 1, 2006. The ACA was the second major piece of legislation passed by Congress in less than 10 years. The ACA was enacted with the goals of increasing the quality and affordability of health insurance, lowering the uninsured rate by expanding public and private insurance coverage, and reducing the costs of healthcare for individuals and the government. While some of the provisions of the ACA were implemented as early as 2010, the major provisions went into effect on January 1, 2014. Both the MMA and the ACA have expanded the number of persons with health insurance including prescription drug coverage. Gallup has estimated that the uninsured rate for adults (persons 18 years of age and over) was 13.4 percent as of the second quarter of 2014, down from 18.0 percent

in the third quarter of 2013 when the health insurance exchanges created under the Patient Protection and Affordable Care Act (PPACA or “Obamacare”) first opened.¹

As a result of the MMA and the ACA, more Americans have public or private health insurance which includes coverage of prescription drugs. This expansion of health insurance and drug benefit coverage has been accomplished using a combination of premiums, subsidies, taxes and penalties for lack of coverage. The percent of Americans with prescription drug coverage is at an all-time high (about 86 percent of the U.S. population).

Drug therapy is perhaps the most widely used form of therapy in health care. Each year in the United States there are more than 4 billion outpatient prescriptions provided to 310 million Americans.² This means that each American gets 12 or more prescriptions per person per year on average. In addition to outpatient prescriptions in retail settings, patients use drug therapy in virtually all other areas of health care such as hospitals, nursing homes, physicians’ offices and clinics, dentists’ offices, government facilities, public health clinics, and other settings. Each year there are 20 to 40 new molecular entities that are approved by the Food & Drug Administration for marketing in the United States.³ These new drug (or biological) approvals are usually for innovative drug therapies that almost always have one or more patents and/or other forms of exclusivity. Often these new drug therapies hold the promise of treating a previously untreated disease or providing safer or more effective therapy to replace older drugs on the market. Also, keep in mind that today’s new and innovative drug therapies and biologicals are the drug products that will become available as generics or biosimilars in the future.

ROLE OF GENERICS IN THE U.S. PHARMACEUTICAL MARKET

In 1984, Congress enacted the Hatch-Waxman Act also known as the “Patent Term Restoration and Drug Price Competition Act.” The Hatch-Waxman Act (“the Act” or “Hatch-Waxman”) simplified the regulatory hurdles for prospective generic drug manufacturers by eliminating the need for generic companies to file lengthy and costly New Drug Applications (NDAs) in order to obtain FDA approval.⁴ The Act also eliminated the duplicative clinical trials in patients that had been required for a generic drug to obtain approval from the FDA. Instead, drug companies are permitted to file Abbreviated New Drug Applications (ANDAs) and to rely on the safety and efficacy data already supplied to the FDA by the original NDA holder for a given drug. Hatch-Waxman also added a number of provisions to the statutory scheme, which extended the time during which brand name (and patented) drugs may enjoy patent and other forms of market exclusivity.

The main purpose of the Hatch-Waxman Act was to balance two competing aims: (1) the protection of intellectual property rights of those who discover and market new and novel drug therapies, by “Patent Term Restoration,” in order to account for and to restore part of the time a drug product was under review by the FDA; and (2) the benefit to the American public that can be provided by “Drug Price Competition” resulting from prompt market entry of less expensive generic drug products that are therapeutically equivalent to the brand name drug product.

Generic drugs are essentially exact substitutes for brand name drugs which have met the same exact standards for bioequivalence and pharmaceutical equivalence set by the FDA. Generic drug products are approved by the FDA through an ANDA and contain the same active ingredient(s), in the same dosage form, in the same strength, and are bioequivalent to the reference listed drug (RLD) (i.e., the original brand name version of the drug approved by FDA through a New Drug Application (NDA)).⁵ The FDA through its review process assures the same clinical effect and safety profile for brand and generic drug products rated as therapeutically equivalent.⁶ According to the FDA, “Products classified as therapeutically equivalent can be substituted with the full expectation that the substituted product will produce the same clinical effect and safety profile as the prescribed product.”⁷

¹ Levy, Jenna, Well-Being, Gallup Release Date: October 8, 2014, found on website at: <http://www.gallup.com/poll/178100/uninsured-rate-holds.aspx>.

² IMS Institute for Healthcare Informatics. Medicine use and shifting costs of healthcare. April 2014., p. 49.

³ U.S. Food & Drug Administration. Novel New Drugs, 2013 Summary. January 2014, p. 3.

⁴ *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market*, Congressional Budget Office, July 1998, (“CBO Report”), at xii.

⁵ While a generic drug must have the same active ingredient in the same amount as the brand drug, the generic can use different inactive ingredients.

⁶ Orange Book, 27th ed. (12/31/2006) *Preface*, p. vi.

⁷ Orange Book, 27th ed. (12/31/2006) *Preface*, p. x.

Evaluations of therapeutic equivalence for prescription drugs are based on scientific and medical evaluations by the FDA. Products evaluated as therapeutically equivalent can be expected, in the judgment of the FDA, to have equivalent clinical effect and no difference in their potential for adverse effects when used under the conditions of their labeling.⁸ If the brand and generic products are shown to be therapeutically equivalent, and therefore interchangeable, they are rated as “A” by the FDA. Because there is no difference in efficacy and safety between the FDA-approved brand and generic versions of a drug product, they are freely substitutable and interchangeable from a clinical standpoint.

Brand-name drugs that are approved for sale by the FDA are sometimes protected by one or more patents or other forms of exclusivity,⁹ which provide the patent owner (or exclusivity holder) with the ability to ask a court to enforce an exclusive right to sell that drug in the United States for the duration of the patent, or patents, plus any other extension times afforded by law. The Hatch-Waxman Act requires the brand company to file with the FDA the patent number and expiration date of any patent covering the drug in question.

Patent information received by the FDA with respect to approved drugs is published in the FDA’s “Orange Book,” where such information can be found and consulted by future FDA applicants. In accepting and publishing patent information in the Orange Book, the FDA’s role is purely ministerial. The FDA does not verify the facts supplied to it by the patent holder, but instead relies on the good faith and presumed truthfulness of the original NDA holder. An invalid patent that is issued will be listed in the FDA Orange Book and may delay generic competition.

The first generic competitor to enter a market typically does so at a price substantially lower than the price of the equivalent brand name drug, and quickly takes a substantial amount of the share of the market for the particular drug “molecule” away from the brand name drug manufacturer. As additional generic competitors come to market, the prices of the generic drug competitors continue to fall compared to the brand price, and their combined share of the market for the molecule, relative to the brand name equivalent, usually continues to grow.

The price competition engendered by generic drug manufacturers affects all purchasers of the drug, who are able to buy the generically equivalent chemical substance (the molecule) at much lower prices. Pharmacies and pharmacists—the people and organizations who dispense drugs to patients—can and do substitute A-rated generic drugs for brand name drugs wherever possible in order to lower their own costs and those of their customers. The incentive for pharmacists and patients to engage in routine and easy substitution of A-rated generics has been enhanced over the years by managed care organizations, who, to encourage the use of cost-saving generic drugs, typically place A-rated generic drugs on the “first tier” of their formularies, which corresponds to a lower co-pay level.

Pharmacy-driven substitution is extremely rapid and robust in causing the share of the market for the particular drug molecule to shift away from the more expensive brand name drug product and toward the less-expensive A-rated generic equivalents. When easy and routine pharmacy substitution is possible, i.e., when there is an A-rating, all purchasers of the brand name drug—pharmacies of all types (including independent, chain, food and drug stores, and mail order pharmacies), wholesalers and distributors, managed care organizations, hospitals, group purchasing organizations (GPOs) and other “classes of trade”—rapidly begin to purchase the generic version in lieu of the brand version. In addition to my own research, there are a large number (indeed hundreds) of sources—both published and unpublished—describing the effects of generic competition in pharmaceutical markets. These sources include published articles and research papers, unpublished analyses and research papers, policy papers, government studies and documents, dissertations, data bases, and other sources describing the effects of generic competition.¹⁰ In the course of my work, I have reviewed most of this research, as it is

⁸range Book, 27th ed. (12/31/2006) *Preface*, p. x.

⁹Drug companies may receive FDA-granted exclusivity periods for several reasons including: (1) orphan designation; (2) completing FDA-requested pediatric studies; (3) conducting new clinical trials that result in substantial label changes; and (4) other reasons.

¹⁰Among the principal studies in the scientific and economic literature which analyze the effects of generic competition are the following:

a. *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market*, Congressional Budget Office, July 1998 (Ex. 96);

b. Jae P. Bae, *Drug Patent Expirations and the Speed of Generic Entry*, Health Services Research, Vol. 32, No. 1, pp. 87–101, April 1997 (Ex. 98);

c. Richard G. Frank and David S. Salkever, *Generic Entry and the Pricing of Pharmaceuticals*, Journal of Economics and Management Strategy, Vol. 6, Spring 1997, pp. 75–90 (Ex. 99);

Continued

available in the public domain. I have also conducted studies on the generic pricing and generic penetration rates of nearly all new molecular entities (drug molecules) that have faced generic competition since 1983.

Testimony by the FDA's Director of the Office of Generic Drugs before the Senate Special Committee on Aging in July 2006 reported that "[t]he Hatch-Waxman Amendments have been very successful and have provided for the approval of over 8,000 generic drug products. These products are lower cost, high quality products that have saved the American public and the government billions of dollars."¹¹ The Congressional Budget Office has credited the Hatch-Waxman Act and, importantly, the process for easy and routine A-rated generic substitution by pharmacists with providing meaningful economic competition from generic drugs, and with achieving billions of dollars of savings for drug purchasers such as consumers and employers.¹² The rate of generic dispensing has reached an all-time high with generic drug products being dispensed for 77 percent to 85 percent of all outpatient prescriptions in 2012 and 2013.^{13 14}

In other words, generic drug products play a critical role in the U.S. market because they are the only form of direct economic and price competition from identical, therapeutically equivalent drug products which can be legally substituted for brand name prescription drugs. Generics can perform this critical function effectively, however, only through the A-rated substitution mechanism. Generic drugs are essentially exact substitutes for brand name drugs which have met standards for bio-equivalence and pharmaceutical equivalence set by the FDA. Without the presence of, or ability of, purchasers to choose an A-rated therapeutically equivalent generic alternative, brand name products will face relatively little effective price or economic competition. The availability and use of FDA-approved A-rated generics provides the key mechanism for assuring that a competitive market for drug products exists, allowing patient-users to achieve equivalent efficacy and safety with in-

d. Henry Grabowski and John Vernon, *Longer Patents for Increased Generic Competition in the U.S.: The Hatch-Waxman Act After One Decade*, PharmacoEconomics, 1996 (Ex. 100);

e. *How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry*, Congressional Budget Office, 1996 (Ex. 101);

f. *Pharmaceutical R&D: Costs, Risks, and Rewards*, Office of Technology Assessment, February 1993 (Ex. 102);

g. Henry Grabowski and John Vernon, *Brand Loyalty, Entry, and Price Competition in Pharmaceuticals After the 1984 Drug Act*, Journal of Law and Economics, October 1992, p. 339 (Ex. 103);

h. Richard E. Caves, Michael D. Whinston, and Mark A. Hurwitz, *Patent Expiration, Entry, and Competition in the U.S. Pharmaceutical Industry*, Brookings Papers on Economic Activity: Microeconomics, 1991, pp. 1–66 (Ex. 104);

i. Alison Masson and Robert L. Steiner, *Generic Substitution and Prescription Drug Prices: Economic Effects of State Drug Product Selection Laws*, Federal Trade Commission, 1985 (Ex. 105);

j. Jerry I. Treppel, Andrew S. Forman, Daniel A. Seto, Geoffrey G. O'Brien, *Specialty Pharmaceuticals Industry: The Thrifty Fifty* (New York: Warburg Dillon Read, May 5, 1999) (Ex. 106);

k. Kirking D.M., Ascione F.J., Gaither C.A., Welage L.S., *Economics and Structure of the Generic Pharmaceutical Industry*, Journal of the American Pharmaceutical Association, 41: 578–584, 2001(Ex. 107);

l. Ascione F.J., Kirking, D.M., Gaither C.A., Welage L.S., *Historical Overview of Generic Medication Policy*, Journal of the American Pharmaceutical Association, 41: 567–577, 2001(Ex. 108);

m. Suh, D.C., Manning W.G., Schondelmeyer, S., Hadsall, R., *Effect of Multiple-Source Entry on Price Competition after Patent Expiration in the Pharmaceutical Industry*, Health Services Research, 35: 529–547, 1993 (Ex. 109);

n. Reiffen, D. and Ward, M.R. (2002), *Generic Drug Industry Dynamics* FTC Working Paper 248 <http://www.ftc.gov/be/workpapers/industrydynamicsreiffenup.pdf> (Ex. 110);

o. Rozek, P.R., Berkowitz, R., *The Cost to the U.S. Health Care System of Extending Marketing Exclusivity for Taxol*, Journal of Research in Pharmaceutical Economics, 9(4): 21–41, 1999 (Ex. 111);

p. Hong, S.H., Shepherd, M.D. and Wan, T.T., *The Impact of Product Line Extensions on Rising Prescription Drug Prices*. Manuscript in progress (2003) abstract presented at the 130th Annual Meeting of the American Public Health Association; Philadelphia, PA (November 9–13, 2002) (Ex. 112);

q. Andrew S. Forman and David S. Moskowitz, *Specialty Pharmaceuticals: Rising to Another Level* (New York: Warburg Dillon Read, May 5, 2000) (Ex. 113).

¹¹ Statement of Gary Buehler, R.Ph., Director of the Office of Generic Drugs, Center for Drug Evaluation and Research, FDA, before Special Committee on Aging, U.S. Senate (July 20, 2006), available at <http://www.fda.gov/ola/2006/genericdrugs0720.html>.

¹² Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Market*, July 1998, p. ix (“CBO Report”).

¹³ Pharmacy Times, November 12, 2013, “2012 Generic Drug Dispensing Surpasses 2011 for New Record,” found on website at: <http://www.pharmacytimes.com/publications/issue/2013/November2013/2012-Generic-Drug-Dispensing-Surpasses-2011-for-New-Record>.

¹⁴ The Express Scripts Lab, *The 2013 Drug Trend Report*, April 2014, p.67.

creased access and decreased cost. This process of making generic drug products readily available and routinely substitutable at the pharmacy level is what brings effective economic competition to the generic segment of the prescription drug marketplace. Generic drug companies serve a vital role in the pharmaceutical marketplace, and as Hatch-Waxman intended, are meant to stimulate “Drug Price Competition.”

RECENT PRICE TRENDS FOR PRESCRIPTION DRUG PRODUCTS

What are the recent price trends for prescription drug products in the past few years? Research performed by the *PRIME* Institute at the University of Minnesota, in conjunction with the AARP Public Policy Institute, has examined the price trends for various segments of the pharmaceutical market including brand name, generic, and specialty products. Actual transaction prices¹⁵ at the retail level for prescription drugs widely used by older Americans have been examined over the time period December 31, 2005 to December 31, 2013.¹⁶ (See the AARP Public Policy Institute Report for details on the study methods.) We have completed the brand name drug price trend analysis and we are continuing to examine the generic and specialty drug price trend analysis. I will report here a summary of the brand name drug price trends for 2013 and preliminary findings from the generic drug price trends for 2013.

Brand Name Drug Price Trends for 2013. The trends reported here are annual price changes based on the 12-month rolling average for the period from December 31, 2012 to December 31, 2013. So let’s examine price changes in the market for brand name drug products in 2013.

- Retail prices for the 227 brand name drug products¹⁷ most widely used by older Americans rose 12.9 percent in 2013 (Figure 1).¹⁸
- The average annual retail price increase in 2013 for these brand name prescription drug products was more than eight times higher than the rate of general inflation (12.9 percent vs. 1.5 percent).¹⁹
- The average annual retail price increase for brand name prescription drug products in 2013 (12.9 percent) was more than two times higher than the average annual brand name drug price increase in 2006 (5.7 percent).
- The average annual cost for one brand name medication used on a chronic basis was nearly \$3,000 in 2013.
 - For a consumer who takes three brand name prescription drugs on a chronic basis, the annual cost of therapy would have been more than \$8,800 during 2013—more than double the cost seen 8 years earlier.
- Between January 2006 and December 2013, retail prices for 140 chronic use brand name drugs that have been on the market since the beginning of the study increased cumulatively over 8 years by an average of 113.0 percent.
 - The cumulative general inflation rate in the U.S. economy was 18.4 percent during the same 8-year period.
- Retail prices increased in 2013 for 97 percent (219 of 227) of the widely used brand name prescription drug products in the study’s market basket. All but two

¹⁵The retail prices used in this report are drawn from Truven Health’s MarketScan® Commercial Database and MarketScan® Medicare Supplemental Database (Truven Health MarketScan® Research Databases). The prices reflect the actual total price for a specific prescription that a pharmacy benefit manager (PBM) bills to a specific health plan for consumers enrolled in employer-sponsored or government-sponsored (i.e., Medicare or Medicaid) health plans and not simply the out-of-pocket cost (such as the copay) which a consumer would pay at the pharmacy. These amounts may or may not reflect what the PBM paid the pharmacy or the usual and customary price that a pharmacy would charge a cash pay consumer for the same prescription.

¹⁶Schondelmeyer, Stephen W. and Purvis, Leigh, Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2006 to 2013, AARP Public Policy Institute, Rx Price Watch Report #2014-03, November 2014. 38 pp.

¹⁷The market basket for this analysis had 227 brand name prescription drug products. Some critics of the Rx Price Watch reports have suggested that brand name drug products in our market basket that subsequently face generic competition should be excluded from this analysis because they may be skewing the results upward. However, when only the 169 brand name drug products with no generic competition are considered, the average annual price change was 13.2 percent in 2013—higher than the 12.9 percent price trend shown in this report (for additional information and analysis, see Appendix B).

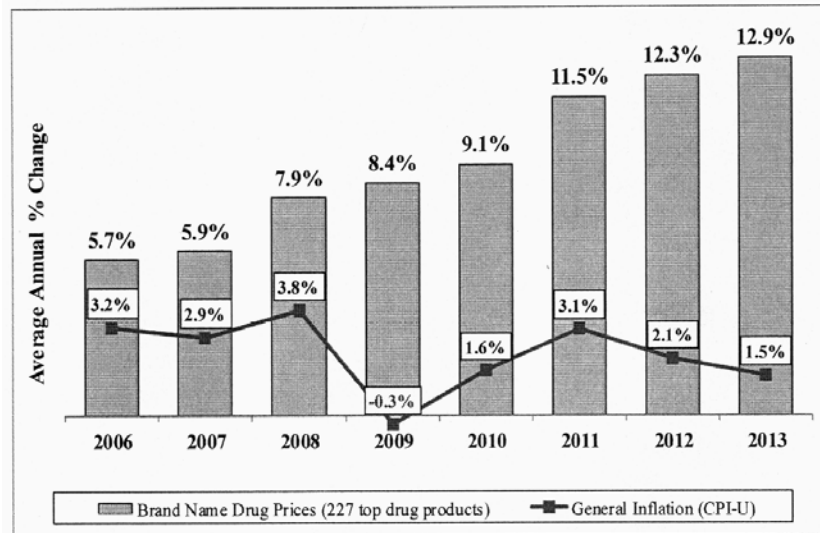
¹⁸When measured as a 12-month rolling average and weighted by actual 2011 retail prescription sales to older Americans ages 50 and above, including Medicare beneficiaries.

¹⁹The general inflation rate used in this report is based on the average annual rate of change in the Consumer Price Index-All Urban Consumers for All Items (seasonally adjusted) (CPI-U), Bureau of Labor Statistics series CUSR0000SA0.

of these retail price increases (217 of 227) exceeded the rate of general economic inflation in 2013.

- Retail prices for all 32 of the drug manufacturers with at least two brand name drug products in the study's market basket increased faster than the rate of general inflation (1.5 percent) in 2013.
- Twenty-two drug manufacturers, including the "All Other" category, had average annual price increases for their brand name drugs of 10 percent or more during 2013.
- All but two of the 46 therapeutic categories of brand name drug products had average annual retail price increases that exceeded the rate of general inflation in 2013, with price increases by therapeutic category ranging from 4.2 percent to 41.1 percent.

Figure 1. Average Annual Brand Name Drug Prices Continue to Grow Substantially More than General Inflation in 2013



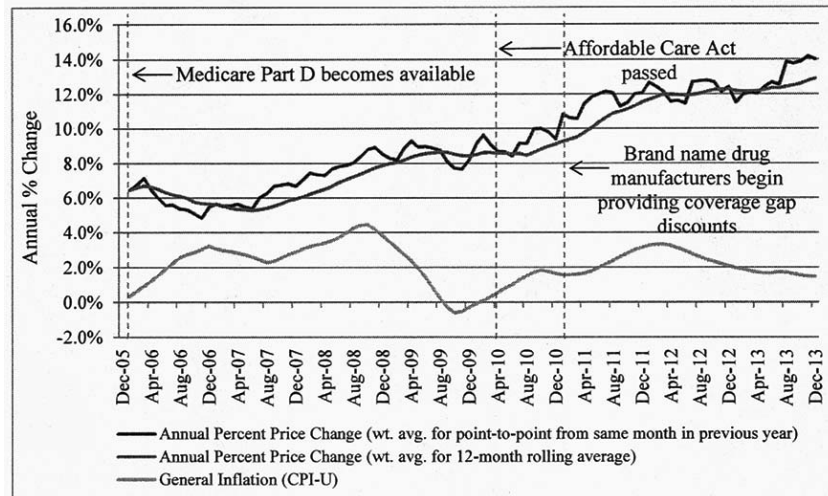
Note: Calculations of the average annual brand name drug price change include the 227 drug products most widely used by older Americans (see Appendix A).

Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Data bases.

Figure 2 shows the percent change in brand name drug prices for each month compared with the same month in the previous year. This trend is shown alongside the 12-month rolling average to allow more detailed examination of the rate and timing of retail brand name drug price changes over the entire study period. This analysis reveals three broad trends since implementation of the Medicare Part D program:

- The retail price of brand name drug products has steadily increased over time since 2006;
- Brand name drug price increases at the retail level have been substantially higher than the rate of general inflation; and
- The gap between the rate of brand name drug price change and the rate of change in general inflation has substantially widened over the period from 2006 to 2013. This gap has ranged from less than a twofold difference in 2006 to nearly a ninefold difference in 2013.

Figure 2. Rolling Average and Point-to-Point Changes in Retail Prices for Most Widely Used Brand Name Prescription Drugs Were Well Above Inflation from 2006 to 2013



Note: Calculations of the average annual brand name drug price change include the 227 drug products most widely used by older Americans (see Appendix A).

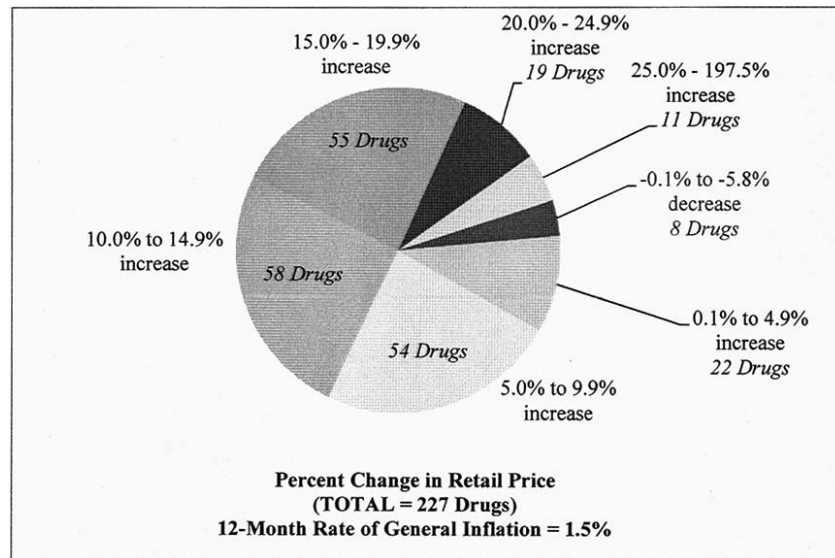
Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Data bases.

Retail prices for 97 percent (219 of 227) of the most widely used brand name prescription drug products had price increases in 2013 (Figure 6). Prices for 96 percent (217 of 227) of the most widely used brand name prescription drug products increased faster than the rate of general inflation (1.5 percent) in 2013.

Among the 87 percent (197 of 227) of brand name drug products with annual retail price increases of more than 5.0 percent—or more than three times the rate of inflation—in 2013:

- Nearly one-half (49.4 percent or 112 drug products) increased between 5.0 percent and 14.9 percent—that is, five to ten times the rate of general inflation in the economy; and
- More than one-third (37.6 percent or 85 drug products) had an annual increase of 15.0 percent or more which is ten or more times the rate of general inflation in the economy.

Figure 3. Retail Prices Increased by More than 10 Percent in 2013 for Almost Two-Thirds of the Most Widely Used Brand Name Drugs



Note: Calculations were made using brand name drug price change from December 31, 2012 to December 31, 2013, and the analysis included the 227 brand name drug products most widely used by older Americans (see Appendix A).

Prepared by the AARP Public Policy Institute and the *PRIME* Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Data bases.

Eight of the widely used brand name drug products in this study had unusually high 8-year cumulative price increases (i.e., the end of 2005 to the end of 2013). The brand name drug products with unusual price increases were:

- Uroxatal 10 mg tablets are a drug product used to treat prostatic hypertrophy. This brand name drug product had a price increase of 512.7 percent—more than a sixfold increase—over the 8-year study period ending in 2013.
- Solaraze Gel 3 percent is a transdermal topical drug product used to treat a severe skin condition. This brand name drug product had a price increase of 445.9 percent—more than a fivefold increase—over the 8-year study period ending in 2013.
- Humulin R U-500—used to treat diabetes—had an 8-year price increase of 361.0 percent over the entire 8-year study period ending in 2013. This retail price increase shows more than a fourfold jump in price over 8 years.
- It is notable that the vast majority of this increase took place over the past 3 years (i.e., 2011 to 2013). Since insulins are biological products they currently do not have generic competition but they are likely to face entry from biosimilar products within the next few years.²⁰
- Prandin 2 mg tablets—another drug for diabetes—had an 8-year price increase of 295.3 percent over the entire 8-year study period. This retail price increase is nearly a fourfold jump in price from 2006 to 2013.
- Atrovent HFA 17 mcg/actuation—a respiratory inhaler and bronchodilator—increased in retail price by 252.4 percent over the 8-year study period. This retail price increase is more than a threefold jump in price over 8 years from 2006 to 2013.
- Benicar 40 mg tablets—used to treat hypertension—had a price increase of 207.1 percent over the 8-year study period ending in 2013. This retail price increase is more than a threefold growth in price over 8 years.

²⁰ L.S. Rotenstein, N. Ran, J.P. Shivers, M. Yarchoan, and K.L. Close, “Opportunities and Challenges for Biosimilars: What’s on the Horizon in the Global Insulin Market?” *Clinical Diabetes*, Vol. 30(4) (2012): 138–150.

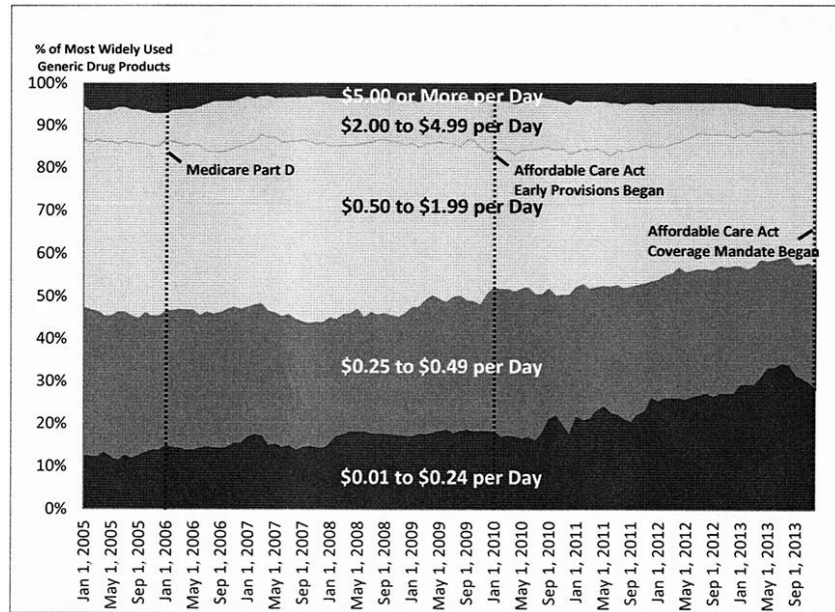
• Lunesta 3 mg tablets (and Lunesta 2 mg tablets)—drug products used for sedation—had an 8-year retail price increase of 203.7 percent. This retail price increase represents a threefold price jump in 8 years.

Generic Drug Price Trends for 2013. The trends reported here are annual price changes based on the 12-month rolling average for the period from December 31, 2012 to December 31, 2013. So let's examine preliminary findings from the generic drug price trend analysis for 2013. In the past several years (i.e., 2006 to 2012), the average generic price for widely used drugs decreased with the amount ranging from -6–7.2 percent to -14.5 percent. While the final data for 2013 has not yet been completed, the generic price effect for 2013 is also expected to be a decrease, but not as much of a decrease as seen in the previous years of the study (i.e., 2006 to 2012).

The generic market basket included 280 drug products widely used by older Americans. Nearly one-third (32.5 percent) of these generic drug products (91 of 280 drug products) had an annual price increase rather than a price decrease in 2013 (i.e., December 31, 2013 versus December 31, 2012). Fifty-four (about 20 percent) generic drug products had an increase of 15 percent or more in 2013 and 27 (about 10 percent) generic drug products had an increase of 50 percent or more in 2013. This market basket was based on outpatient prescription drugs widely used by older Americans. A list of the generic drug products with price increases in 2013 is attached as Appendix A.

More than one-half of the widely used generic drug products had an average cost per day of therapy of less than \$0.50. (See Figure 4). The good news is that the number of lower cost generics has increased. And, the bad news is, as noted above, that one-third of the widely used generic drugs products had price increases.

Figure 4. Percent of Generic Drug Products by Retail Price per Day of Therapy: (December 31, 2012 vs. December 31, 2013)



Expected Generic Drug Price Trends. The importance of A-rated generic competition can hardly be overstated. Since the FDA has determined that A-rated generics are identical in all material respects (“pharmaceutically equivalent” and “bioequivalent,” and thus “therapeutically equivalent”) to a particular brand name drug and these generics can therefore be substituted for the brand name drug by the pharmacist (unless explicitly prohibited) without the intervention of the physician. When a consumer presents a brand name prescription to a pharmacist, mandatory and permissive State drug substitution laws (present in all U.S. States and territories) allow, encourage, and often require the pharmacist to substitute an FDA-approved, A-rated generic version for the brand name drug prescribed. Effective

price competition for drug products within a drug molecule market, does not typically begin until substitutable, A-rated generic versions of that same molecule enter the market. FDA-approved, A-rated generics typically are priced substantially below their brand name counterparts. Once an A-rated generic enters the market unimpeded, a large share of purchases of the brand to which the generic is A-rated switches to the generic almost instantaneously, because the generic is identical to the brand, substantially less-expensive, and easily and routinely substitutable by the pharmacist without the intervention of the physician.

Both the price differential between the brand and its A-rated generic equivalents, and the proportion of the market for the “molecule” (typically the brand and its A-rated generic equivalents) captured by the A-rated generics, generally increase rapidly over time, and follow a predictable pattern. This pattern has been extensively studied and is generally accepted as an inherent feature of the pharmaceutical industry.²¹

The prices of A-rated generic drugs drop even further as additional generic competitors for a given drug molecule enter the market. The first A-rated generic competitor generally prices at a level of approximately 15 percent to 25 percent below the brand name price. As more A-rated generic products enter into the market, the prices of generics typically continue to decline both in absolute terms and in relation to the brand name price, a trend that typically persists for 5 years, or more. Generic prices eventually reach as low as 10 percent to 20 percent, if not lower, of the pre-generic entry brand name price when an equilibrium, or market-clearing, price point is finally reached.

When A-rated generic competition is unimpeded, the brand name drug rapidly loses sales because the lower-priced, A-rated generic(s) are being routinely substituted by pharmacists, often with the encouragement of private and public managed care organizations (through which more than 85 percent of prescriptions in the United States now flow). There are two primary mechanisms by which managed care organizations encourage A-rated generic substitution: (1) by establishing a lower member copay for A-rated generic drug products; and, (2) by setting a maximum allowable cost (MAC) for the drug product reimbursement that pharmacies will be paid for A-rated generic drug products.

Observed Generic Drug Price Trends in 2013. The pattern of generic drug prices over time for the widely used drug products in the 2013 market basket was examined at the individual drug product level. First, we found that there were a number of generic drug products whose prices performed as expected in the market. That is, the generic drug product enters the market at a price 10 percent to 25 percent below the brand name price and then the generic price rapidly declines over time until a market leveling price is reached. For example, Figure 5 shows Tamsulosin 0.4 mg capsules which entered the market with an actual retail transaction price²² of about \$3.55 per day of therapy (16 percent below the AWP) and the price rapidly declined to under \$0.50 per day or about 10 percent of the AWP (average wholesale price—a list price) and very close to the WAC (wholesale acquisition price—another benchmark price). A number of the widely used generic drug products had this expected pricing pattern.

A variant on the expected generic pricing pattern was also observed for generic drug products that had some form of formal or functional exclusivity in the market from one or more of the following: (1) an FDA granted exclusivity period; (2) entry of an authorized generic licensed from the NDA holder; (3) an FDA granted 180-day generic exclusivity period; (4) an at-risk generic launch while a patent challenge is on-going in the courts; (5) a pay-for-delay generic situation; or (6) other reasons for delay of more than one true generic entering the market. For example, see Figure 6 (Sertraline HCl 50 mg tablets, Greenstone). This generic entered the market and was able to hold near its entry level price for about 6 months. In this case, the generic sertraline is marketed by Greenstone, which is a generic firm affiliated with Pfizer—the original marketer of the brand version of sertraline known as Zoloft.

A second example of delayed generic competition can be seen in Figure 7 (Pantoprazole Sodium 40 mg tablet DR, Teva Pharmaceuticals). The delay in generic price competition for this drug product was secondary to the at-risk launch of several generic versions before the patent had expired and during the time in which the patent challenge was on-going in the courts. Note that the delay in effective price competition was about 3 years (Dec. 2007 to Jan. 2011). Once, the challenged patent did expire; then, the typical rapid price decline expected from generic drug products was observed.

²¹ See footnote 10.

²² See footnote 15.

There were several generic drug products whose price rose over time after generic entry. See Figures 8, 9 and 10. The generic drug products presented in these figures include an oral suspension, an ophthalmic solution, and a delayed release tablet formulation. In many ways the price pattern of these generic drug products exhibits the traits commonly seen for a brand name drug product. Often generic drug products that are unique dosage forms (e.g., oral liquids; topical ointments, creams, and patches; ophthalmic products; injectable products; or other unique dosage forms) will have pricing behavior like a brand name drug product. Even though a generic drug product market for oral solid dosage forms (i.e., tablets or capsules) may be able to support entry of several generic firms, the market demand for these more unusual dosage forms is often quite limited and may only be able to support one firm in the market. Consequently, the one firm in the market may be able to function as if it had market exclusivity, even though it does not formally have any exclusivity. This functional market exclusivity may allow a generic drug product to raise its price at one point in time or over time.

As noted earlier, nearly 20 percent (27 of 280) of the widely used generic drug prices saw an annual price increase of 50 percent or more in 2013. At the top of the list of generic drug products with extraordinary price increases were doxycycline hyclate 100 mg capsules (West-Ward) (see Figure 11) and doxycycline 100 mg tablets (West-Ward) with annual increases of 2,048 percent and 1,897 percent, respectively in 2013. One strategy to thwart generic substitution is to change the dosage form (i.e., tablet to capsule, or tablet to tablet extended release), since different dosage forms of the same drug molecule cannot be substituted without the doctors express written permission.

Other generic drug products with extremely high annual price hikes in 2013 were: digioxin 0.125 mg tablets (Lannett) (Figure 12) with an increase of 103 percent and digioxin 0.25 mg tablets (Lannett) with an increase of 82 percent; divalproex sodium 500 mg tablets (Mylan) (Figure 13) with an increase of 432 percent; prednisolone acetate suspension 1 percent suspension (Sandoz) (Figure 14) with an increase of 349 percent; levothyroxine sodium at 9 different strengths (Mylan) (Figure 15) with annual increases ranging from 44 percent to 63 percent; and glipizide 5 mg tablets (Mylan) (Figure 16) with an increase of 94 percent. Not all of the large price increases among the widely used generic drug products occurred in 2013. For example, hydralazine HCl 50 mg tablets (Par) (Figure 17) and meclizine HCl 25 mg tablets (Par) (Figure 18) each had increases of more than 100 percent in 2005 and 2008, respectively.

While there are a number of generic drug products with very large price increases, this is not a new phenomenon. In July 2008, I prepared a report for the Joint Economic Committee of Congress that was presented by my colleague (Madeline M. Carpinelli). This report titled “Extraordinary Price Increases in the Pharmaceutical Market.”²³ In this report, we identified drug products that had experienced one or more “extraordinary” price increases.²⁴ Our study of 35,143 drug products (at the NDC level) found that 13.5 percent of them had experienced one or more extraordinary price increases in the period 1988 to 2008. While a few of these extraordinary price increases occurred in the 1990s, the vast majority were found in the 2000s.

Clearly, the generic drug product price increases shown in these figures as a red line (the actual retail drug price per day of therapy) were dramatic. These price increases were passed on to the ultimate payer (commercial or government programs) and did increase the amount of their expenditure for these generic prescriptions.

SIGNALS OF MARKET FAILURE IN THE PHARMACEUTICAL MARKET

The market for drugs does not operate in the same way as most other markets in the United States, where the consumer freely chooses a product. Various aspects of the market for prescription drugs make it unique, including the fact that certain drugs, i.e., prescription drug products must be prescribed by one set of market players (physicians), dispensed by another market player (pharmacists), paid for by a third-party or market player (employers or the government via insurers or benefit managers, and sometimes partially by the consumer), and then ultimately consumed by the end user (the patient). One must understand and take into account the differing roles of each of these players, in order to understand how competition func-

²³ Madeline M. Carpinelli and Stephen W. Schondelmeyer, Statement on Extraordinary Price Increases in the Pharmaceutical Market, presented to the Joint Economic Committee of the U.S. Congress, by Madeline M. Carpinelli, PRIME Institute, University of Minnesota, July 24, 2008, 11 pp.

²⁴ The term “extraordinary” price increase was defined as “any price increase that is equal to, or greater than, 100 percent at a single point in time.”

tions in the market for drugs. The pharmaceutical market possesses institutional structural features and related behaviors that result in an inefficient economic market as evidenced by the unusually large price increases for generic drug products and the extremely high initial prices of brand name drug products.

The marketing of patented, single source drug products in the United States is a very unique market and has a number of atypical structural features. The patent for a drug molecule alone (and other related patents and exclusivities) creates a monopoly for a drug molecule (and related drug products) and will generate sales specifically for that molecule and related drug products, even if there are other similar molecules (and their related drug products) in the same therapeutic class. This unique market structure for pharmaceuticals is due largely to the fact that a prescription must be written by the doctor for a specific drug product and the consumer (patient) is not free to choose the drug product to be purchased, even if there are other drugs in the class that would work as well, or even better. The patient (consumer) must have the doctor's permission slip (i.e., prescription) and the pharmacist must dispense the exact drug product prescribed by the doctor, unless an FDA-approved therapeutically equivalent generic version of the drug product is available on the market—typically as a lower cost substitute.

The choice of the prescription drug product is driven by various types of “directed demand” including physicians who must prescribe the drug product; pharmacy benefit managers (PBMs) who establish formularies and manage networks of pharmacies to dispense prescriptions; pharmacies and pharmacists who must dispense single source drugs when prescribed and who chose the manufacturer source from among available FDA-approved, therapeutically equivalent generic versions of an off-patent drug; insurers and managed care organizations who have risk for providing health care for a prepaid premium; and employers who bear most of the cost for the prescriptions provided to their employees or government programs (e.g., Medicare and Medicaid) who bear most of the cost for the prescriptions provided to the recipients of these programs.

In recent years, the high prices for the new drug therapies has come under criticism for being excessive, unaffordable and unsustainable.²⁵ The issue of high drug prices has been raised by patients, doctors, health plans, insurers, and by government programs such as Medicare and Medicaid.²⁶ The various payers for drug therapy are not only complaining about the high price of individual drugs, but they are also beginning to raise concerns about the long term sustainability of the pricing patterns seen for innovative drug therapies.

There has been an explosion of concern (and articles about) very high drug prices for new and, sometimes, innovative drugs introduced in the United States. One recent story in the Wall Street Journal detailed the reaction of physicians at Memorial Sloan Kettering in New York when faced with a new drug whose price was almost double the standard therapy, yet was not appreciably safer or more effective.²⁷ Not only were the physicians upset by the exorbitant pricing of this new cancer drug, but also private insurers and the Federal Medicare program have expressed concerns.²⁸ In October 2014, “Medicaid chiefs from red and blue States are urging Congress to stem the cost of revolutionary new drugs for hepatitis C, cancer, and other diseases.”²⁹ A recent New York Times editorial argued that “Medicare should consider withdrawing coverage for high-priced cancer drugs that have “modest” benefits.”³⁰ Some have argued that the high prices are needed to fuel the fire of innovation, but others have suggested that “the market is telling us the opposite: that prices have become the prize.”³¹

One of the more recent drugs to enter the market at an astronomical price is Sovaldi—used to treat patients with hepatitis C. Sovaldi costs about \$84,000 per course of therapy in the United States, while in other countries the price is as low

²⁵ Lee, Jaimy. Sovaldi fuels triple-digit rises in Gilead revenue and profits. Modern Healthcare. October 28, 2014.; see also, Silverman, Ed. ‘Financial Toxicity:’ Who’s Really to Blame for High Cancer Drug Prices? The Wall Street Journal, October 7, 2014.

²⁶ Comments on pricing by patients, doctors, health plans, insurers, and by government programs such as Medicare and Medicaid.

²⁷ Silverman, Ed. ‘Financial Toxicity:’ Who’s Really to Blame for High Cancer Drug Prices? The Wall Street Journal, October 7, 2014.

²⁸ Herper, Matthew. Could High Drug Prices Be Bad for Innovation? Forbes, Oct. 23, 2014.

²⁹ Associated Press. States Ask Congress to Intervene on Drug Prices. ABC News. Oct. 26, 2014. Found at this website: http://abcnews.go.com/Health/print?id=26524476_11/.

³⁰ Howard, Paul. High-Priced Cancer Drugs: Are They Worth It? The New York Times. July 8, 2011.

³¹ Herper, Matthew. Could High Drug Prices Be Bad for Innovation? Forbes, Oct. 23, 2014.

as \$900 to \$2,000 per course of therapy.³² Gilead Sciences, the company that markets Sovaldi, had a triple digit rise in profits in early 2014 after introduction of its new drug.³³ Another drug therapy for hepatitis C has just been approved by FDA (October 2014). This new hepatitis C drug, Harvoni, is also marketed by Gilead Sciences and has an even higher price tag—\$94,500 for a 12-week course of treatment.³⁴

The high price of Sovaldi has had such a dramatic impact that “many payers and pharmacy benefit managers have begun to push back against Sovaldi’s price, with some threatening to stop using the drug once a rival medicine is approved in the United States. State Medicaid directors have also raised concerns, saying that taxpayers will have to shoulder much of Sovaldi’s costs since many hepatitis C patients get their health care from the government.”³⁵

The debate surrounding the price of Sovaldi is part of a much larger issue related to escalating specialty drug prices that are widely viewed as unsustainable. “Specialty drugs now account for 28 percent of total drug spending in the United States even though they make up less than 1 percent of all prescriptions.”³⁶

In fact, high price is the most frequently cited characteristic defining the new class of drugs that we call “specialty drugs.”³⁷ In addition, to being high cost, the specialty drugs also have a high rate of patient cost-sharing. Specialty drugs are placed by commercial and by Medicare Part D plans in a separate “Tier 4” or specialty tier. The specialty tier usually uses a percentage co-insurance rather than a fixed rate copay.³⁸ The percentage of coinsurance as a cost share of the total prescription price may range from 20 percent to 50 percent and it is not unusual for a specialty prescription to cost \$1,000 to more than \$50,000 per prescription.

Another new drug in the past few years, Alexion Pharmaceutical’s only drug, Soliris, has proved effective at treating the rare disease, atypical Hemolytic Uremic Syndrome (aHUS). This drug therapy has a price tag of one-half a million dollars per patient per year.³⁹ As the *Forbes* reporter said, “That’s not a typo. By my reckoning Soliris is the priciest drug in the world.” (See: Herper, Matthew. *The World’s Most Expensive Drugs*, *Forbes*, 02–22–10). There are at least nine other drugs on the *Forbes* list that cost more than \$200,000 a year for the average patient who takes them. Most of these very high cost drugs treat rare genetic diseases that afflict fewer than 10,000 patients. Since there are no other therapies for these diseases, the “biotech companies can charge pretty much whatever they want.”⁴⁰

The battle over high drug prices is pitting large insurers against the drug companies. “The insurance lobby, America’s Health Insurance Plans, has criticized drugmakers for spiraling medicine prices.”⁴¹ “Whenever the high price of pharmaceuticals is in the news, drugmakers try desperately to change the subject and distract from the issue,” said a spokesman for the insurer lobby. The cost of medication in the United States might be higher than in other countries where there’s negotiated prices and trade agreements.⁴²

New brand name drugs have much higher prices in the United States than in other countries and their prices have been increasing at supra-competitive prices. Brand name drug prices in 2013 increased last year by 21.2 percent, while brand-name drug use dropped by 15.5 percent.⁴³ Given the growing frustration of payers and concern about overall sustainability of drug price levels, at least two major con-

³² Whitman, Debra B., Executive Vice President for Policy, Strategy and International Affairs, AARP. Expensive New Hepatitis C Drug Raises Alarms. *Huffington Post*, 05/27/2014.

³³ Lee, Jaimy. Sovaldi fuels triple-digit rises in Gilead revenue and profits. *Modern Healthcare*. October 28, 2014.

³⁴ Lee, Jaimy. Sovaldi fuels triple-digit rises in Gilead revenue and profits. *Modern Healthcare*. October 28, 2014.

³⁵ Whitman, Debra B., Executive Vice President for Policy, Strategy and International Affairs, AARP. Expensive New Hepatitis C Drug Raises Alarms. *Huffington Post*, 05/27/2014.

³⁶ Whitman, Debra B., Executive Vice President for Policy, Strategy and International Affairs, AARP. Expensive New Hepatitis C Drug Raises Alarms. *Huffington Post*, 05/27/2014.

³⁷ EMD Serono Specialty Digest™, 10th Edition, Managed Care Strategies for Specialty Pharmaceuticals, 2014, p. 10.

³⁸ EMD Serono Specialty Digest™, 10th Edition, Managed Care Strategies for Specialty Pharmaceuticals, 2014, p. 10.

³⁹ Herper, Matthew. \$500,000-A-Year Drug Is Bright Light for Phrma. *Forbes*. Oct. 21, 2010.

⁴⁰ Herper, Matthew. \$500,000-A-Year Drug Is Bright Light for Phrma. *Forbes*. Oct. 21, 2010.

⁴¹ Wayne, Alex. Cancer Patients Assail Insurer Policies on Costly Drugs. *Bloomberg*. Jun 11, 2014.

⁴² Wayne, Alex. Cancer Patients Assail Insurer Policies on Costly Drugs. *Bloomberg*. Jun 11, 2014.

⁴³ Evans, Melanie. Healthcare prices are up, and patients are buying less. *Modern Healthcare*, October 28, 2014.

sulting groups have released reports suggesting a new payment model for pharmaceuticals is needed. One of the consulting groups described that

“Makers of brand-name pharmaceuticals are competing over a shrinking piece of the prescription drug pie . . . Several forces are changing the way pharmaceutical companies and other health organizations engage with one another and how they attach value to medications.”⁴⁴ The second consulting group explained that “It is well established that large pharmaceutical companies tend not to compete on price, particularly in the largest market, the United States (U.S.).”⁴⁵ The consulting report went on to say, “By competing on price publicly, this would lower the cost of treatment for consumers, while arguably generating greater revenue for the company than received currently for these marginalized agents.”⁴⁶

The market for pharmaceuticals appears to be failing when it comes to efficient resource use. The United States is the world’s largest drug market, yet the United States pays the world’s highest prices for prescription drugs. The PBMs who manage drug benefit programs for employers often make more revenue from drug manufacturer rebates and other payments than they make from administrative fees to their clients (i.e., employers or health plans). This raises serious issues of fiduciary responsibility and conflict of interest. The drug prescribers (i.e., physicians) are not necessarily price-conscious or price-sensitive when it comes to prescribing drugs. Consumers are told to engage in consumer-driven choice of health care, yet the price of prescription drugs is not readily available when the consumer is ready to make a decision about purchasing a prescription. Even if the physician and the consumer want to make price-conscious decisions, the real net cost of prescription drugs is hidden and is not transparent and available.

In summary, the high price of drugs, whether brand name or generic, is a critical issue. Most payers are signaling that they cannot afford the level of resources needed, individually and collectively, to pay for new and innovative therapies at the prices that are being charged. Payers are accustomed to saving money by encouraging patients to appropriately use generic prescriptions. Now these payers are nervous because they see that generic drug prices are increasing by 100’s and 1,000’s of percents a year. Old generic drugs are being re-purposed therapeutically and their prices are increasing dramatically. These troubling trends in pharmaceutical spending indicate failures in the market for pharmaceuticals. A growing number of observers in the pharmaceutical market are calling for a new approach to pharmaceutical decisionmaking and to the pricing model for drug therapy.

In other words, the market for pharmaceuticals is out of balance. Prices are not transparent. Without actual price data, it is not possible to make true value-based decisions. Certainly price is not the only issue in a value-based decision, but price is always an issue in value-based decisions. In many ways the pharmaceutical market is very asymmetric—the seller knows a lot more about the product than does the buyer. For example, drug manufacturers know much more about the safety, effectiveness, and cost of their drugs than does the physician, the PBM, the employer, or the consumer. Three Americans received the Nobel prize in economics in 2001 for their work defining the market for lemons.⁴⁷ No; their work was not about little yellow fruits, but rather about the market for used cars and the effect of the imbalance in information between the buyer and the seller.⁴⁸ Their work found that markets don’t work when there is asymmetry of information—that is, when the seller knows a lot more than the buyer, the seller can take advantage of that buyer. Since then, Joseph Stiglitz and some of his colleagues have developed much further the concepts of asymmetric markets, market signals, and their economic impact. If there was ever a market that was asymmetric, it is health care and especially pharmaceuticals. The lessons we can learn from these Nobel Prize winners are that: (1) the imperfect markets are not “all-knowing and self-correcting,” (2) “imperfect information corrupts markets,” (3) “markets, when confronted with imperfections, may not

⁴⁴ Health Research Institute, PWCHHealth. Unleashing value. The changing payment landscape for the United States pharmaceutical industry. May 2012

⁴⁵ Gorkin, Larry. Time for pharmaceutical companies to compete on price regarding Non-Differentiated (“Me-Too”) Drugs. Eye for pharma. 2012.

⁴⁶ Gorkin, Larry. Time for pharmaceutical companies to compete on price regarding Non-Differentiated (“Me-Too”) Drugs. Eye for pharma. 2012.

⁴⁷ Uchitelle, Louis, “3 Americans Awarded Nobel for Economics,” The New York Times, October 11, 2011.

⁴⁸ Akerlof, George, “The Market for ‘Lemons’: Quality Uncertainty and the Market Mechanism,” The Quarterly Journal of Economics, Vol. 84, No. 3 (Aug., 1970), pp. 488–500, Oxford University Press, URL: <http://www.jstor.org/stable/1879431>.

be the best way to allocate resources,” and (4) “government must play a strong role in a market system, to prevent damage from imperfect information.”⁴⁹

Policymakers and legislators continue to call health care a market—and in one sense health care is a market; however, health care is replete with imperfect information. While health care has some structural features that appear to be a market, the information in this market is very asymmetric. With so much “imperfect information” throughout health care, efficient and effective policy decisions will not necessarily follow. We must recognize and address the issues of imperfect information in health care and assure that accurate, transparent, and useful information is available in the market in order for more effective market-based decisions to be made.

The advice of the Nobel Prize winners is that “government must play a strong role in an imperfect market.” Government doesn’t have to run or dominate health care, but government has to set the rules for the game to correct for the many types of imperfect information. Government has to put some boundaries on the health care market so that it begins to function like an economically efficient market again. Finally, the health care market is very asymmetric for a whole lot of reasons, such as the isolating effect of directed demand, and the insulating effect of insurance coverage. Insurance is a great thing, but in some ways it takes away the market function. Health insurance programs give the appearance of having a fairly low cost when one only focuses on the amount of copays made at the time of service. The consumer only sees the impact of the full cost of their health care a year later when the premiums increase, or when the employer does not provide a wage increase because health care cost went up.

There are many forms of imperfect information about prescription drugs including, but not limited to, hidden prices, rebates, and discounts; undisclosed relationships and transactions; and complex technical products. This imperfect information may inhibit, or even prevent, value-based decisions at every level of the pharmaceutical market.

CONCLUSIONS

The prices and change in prices of both brand name and generic drug products have a direct impact on the costs borne by individual consumers and by all other payers. Brand name and generic drug price increases often result in higher out-of-pocket costs for beneficiaries at the pharmacy, especially for those who pay a percentage of drug costs rather than a fixed copayment. Higher brand name and generic drug prices are also passed along to consumers, or the end payer, in the form of increased premiums, higher deductibles, and other forms of cost sharing.⁵⁰

Prescription drug price increases also affect taxpayer-funded programs like Medicare and Medicaid. For example, the Medicare Payment Advisory Commission recently attributed the majority of “excess” growth in Medicare Part D spending to growth in the average price of drugs provided to beneficiaries. Higher government spending driven by large drug price increases will eventually affect all Americans in the form of higher taxes, cuts to public programs, or both. If recent trends for brand name and generic drug prices and related price increases continue unabated, the cost of drugs will prompt increasing numbers of older Americans to stop taking necessary medications.⁵¹ This will lead to poorer health outcomes and higher health care costs in the future.⁵²

The expansion of health care and prescription drug coverage has provided more Americans with access to important and valuable drug therapies. Given the expansion of the number of people with coverage for prescription drugs,⁵³ without effective measures to evaluate and manage the appropriateness, utilization, and price of drug therapies—Congress has essentially written a blank check to the pharmaceutical firms. It is unclear what factors are driving the price levels and the contin-

⁴⁹ Louis Uchitelle, “3 Americans Awarded Nobel for Economics,” *The New York Times*, October 11, 2001.

⁵⁰ D.I. Auerbach and A.L. Kellermann, “A Decade of Health Care Cost Growth Has Wiped Out Real Income Gains for an Average U.S. Family,” *Health Affairs*, Vol. 30(9) (2011): 1630–36.

⁵¹ H. Naci, S.B. Soumerai, D. Ross-Degnan, F. Zhang, B.A. Briesacher, J.H. Gurwitz, and J.M. Madden, “Medication Affordability Gains Following Medicare Part D Are Eroding among Elderly with Multiple Chronic Conditions,” *Health Affairs*, Vol. 33(8) (2014): 1435–43.

⁵² Z.A. Marcum, M.A. Sevik, and S.M. Handler, “Medication Nonadherence A Diagnosable and Treatable Medical Condition,” *Journal of the American Medical Association*, Vol. 309(20) (2013): 2105–6.

⁵³ A.M. Sisko, S.P. Keehan, G.A. Cuckler, A.J. Madison, S.D. Smith, C.J. Wolfe, D.A. Stone, J.M. Lizonitz, and J.A. Poisal, “National Health Expenditure Projections, 2013–23: Faster Growth Expected with Expanded Coverage and Improving Economy,” *Health Affairs*, Vol. 33(10) (2014): 1–10.

ued price increases of brand name and generic prescription drugs. Policymakers interested in reducing the impact of brand name and generic prescription drug prices should focus on options that balance the need for pharmaceutical innovation with the need for improved health and the financial security of consumers and taxpayer-funded programs like Medicare and Medicaid.

APPENDIX A

Actual Transaction Price Changes at the Retail Level for Widely Used Generic Drugs in 2013 (December 31, 2012 vs. December 31, 2013)

D	F	G	H	I	J	O	T	T	T
National Drug Code	Generic Name	Dose Form	Strength	Manufacturer	Usual Dose/Day	Retail \$/Day (Median)	Retail \$/Day (Median)	% Change from Same Mo. in Previous Yr.	2013 v 2012
00143-3142-05	doxycycline hyclate	Capsule	100 MG	West-Ward	2.00	\$ 0.34746	\$ 7.46247	2047.7%	
00143-2112-05	doxycycline hyclate	Tablet	100 MG	West-Ward	2.00	\$ 0.36154	\$ 7.21887	1896.7%	
00378-0473-01	divalproex sodium	Tablet ER 24 Hr	500 MG	Mylan	2.00	\$ 1.01462	\$ 5.39401	431.6%	
61314-0637-10	prednisolone acetate	Suspension	1 %	Sandoz	0.33	\$ 0.56934	\$ 2.55771	349.2%	
00378-0014-01	methotrexate sodium	Tablet	2.5 MG	Mylan	1.00	\$ 0.74336	\$ 2.67062	259.3%	
00603-4975-28	oxybutynin chloride	Tablet	5 MG	Qualitest	2.00	\$ 0.23875	\$ 0.55005	130.4%	
68382-0137-01	losartan potassium	Tablet	100 MG	Zydus Pharmaceuticals USA	1.00	\$ 0.39322	\$ 0.87400	122.3%	
00093-8121-01	doxazosin mesylate	Tablet	2 MG	Teva Pharmaceuticals USA	1.00	\$ 0.22447	\$ 0.47015	109.4%	
00172-5412-11	fluconazole	Tablet	150 MG	Ivax Pharmaceuticals	1.00	\$ 1.76095	\$ 3.58117	103.4%	
00527-1324-10	digoxin	Tablet	0.125 MG	Lannett	1.00	\$ 0.19652	\$ 0.39965	103.4%	
00093-7202-98	pravastatin sodium	Tablet	40 MG	Teva Pharmaceuticals USA	1.00	\$ 0.26452	\$ 0.53696	103.0%	
00378-1105-05	glipizide	Tablet	5 MG	Mylan	1.00	\$ 0.13780	\$ 0.26743	94.1%	
00527-1325-10	digoxin	Tablet	0.25 MG	Lannett	1.00	\$ 0.21161	\$ 0.38406	81.5%	
55111-0180-15	tiizandine HCl	Tablet	4 MG	Dr. Reddy's Laboratories	2.52	\$ 0.50050	\$ 0.88140	76.1%	
00143-1473-10	prednisone	Tablet	10 MG	West-Ward	3.00	\$ 0.31398	\$ 0.54257	72.8%	
00093-7201-98	pravastatin sodium	Tablet	20 MG	Teva Pharmaceuticals USA	1.00	\$ 0.26420	\$ 0.44680	69.1%	
00093-7270-98	pravastatin sodium	Tablet	80 MG	Teva Pharmaceuticals USA	1.00	\$ 0.46336	\$ 0.77111	66.4%	
00378-1817-01	levothyroxine sodium	Tablet	175 MCG	Mylan	1.00	\$ 0.27772	\$ 0.45403	63.5%	
00093-8122-01	doxazosin mesylate	Tablet	4 MG	Teva Pharmaceuticals USA	1.00	\$ 0.22254	\$ 0.36244	62.9%	
64679-0926-02	enalapril maleate	Tablet	20 MG	Wockhardt USA	1.00	\$ 0.13414	\$ 0.21386	59.4%	
00378-1805-01	levothyroxine sodium	Tablet	75 MCG	Mylan	1.00	\$ 0.22007	\$ 0.34504	56.8%	
00591-0932-01	oxycodone w/acetaminophen	Tablet	10-325 MG	Watson Labs	5.00	\$ 2.51581	\$ 3.92472	56.0%	
00378-1110-05	glipizide	Tablet	10 MG	Mylan	2.00	\$ 0.20166	\$ 0.31260	55.0%	
00378-1809-01	levothyroxine sodium	Tablet	100 MCG	Mylan	1.00	\$ 0.22422	\$ 0.34703	54.8%	
00378-1807-01	levothyroxine sodium	Tablet	88 MCG	Mylan	1.00	\$ 0.22853	\$ 0.34932	52.9%	
00378-1819-01	levothyroxine sodium	Tablet	200 MCG	Mylan	1.00	\$ 0.29933	\$ 0.45710	52.7%	
00378-1811-01	levothyroxine sodium	Tablet	112 MCG	Mylan	1.00	\$ 0.25125	\$ 0.38077	51.6%	
00378-1815-01	levothyroxine sodium	Tablet	150 MCG	Mylan	1.00	\$ 0.26280	\$ 0.39359	49.8%	
00378-1813-01	levothyroxine sodium	Tablet	125 MCG	Mylan	1.00	\$ 0.25031	\$ 0.36775	46.9%	
00406-0512-01	oxycodone w/acetaminophen	Tablet	5-325 MG	Mallinckrodt Pharm	6.00	\$ 1.01691	\$ 1.48719	46.2%	
00378-5222-93	omeprazole	Capsule DR	40 MG	Mylan	1.00	\$ 0.54705	\$ 0.78619	43.7%	
00378-1800-01	levothyroxine sodium	Tablet	25 MCG	Mylan	1.00	\$ 0.18659	\$ 0.26770	43.5%	
00591-5443-01	prednisone	Tablet	20 MG	Watson Labs	2.00	\$ 0.37382	\$ 0.51585	38.0%	
00093-0771-98	pravastatin sodium	Tablet	10 MG	Teva Pharmaceuticals USA	1.00	\$ 0.29679	\$ 0.40647	37.0%	
00172-4280-60	verapamil HCl	Tablet ER	240 MG	Ivax Pharmaceuticals	1.00	\$ 0.39671	\$ 0.54330	37.0%	
00378-1803-01	levothyroxine sodium	Tablet	30 MCG	Mylan	1.00	\$ 0.23054	\$ 0.31536	36.8%	
00228-2057-50	lorazepam	Tablet	0.5 MG	Actavis Elizabeth	2.00	\$ 0.22872	\$ 0.30826	34.8%	
00378-2146-05	spironolactone	Tablet	25 MG	Mylan	1.00	\$ 0.26174	\$ 0.34602	32.2%	
59762-0246-01	dionezil hydrochloride	Tablet	10 MG	Greenstone	1.00	\$ 0.41614	\$ 0.54200	30.2%	
00378-1355-05	triamterene & HCTZ	Tablet	75-50 MG	Mylan	1.00	\$ 0.25753	\$ 0.33449	29.9%	
64679-0925-02	enalapril maleate	Tablet	10 MG	Wockhardt USA	1.00	\$ 0.13353	\$ 0.16349	22.4%	
68180-0211-09	losartan potassium	Tablet	50 MG	Lupin Pharmaceuticals	1.00	\$ 0.43096	\$ 0.52244	21.2%	
00093-0012-98	pantoprazole sodium	Tablet DR	40 MG	Teva Pharmaceuticals USA	1.00	\$ 0.44873	\$ 0.54185	20.8%	
45802-0064-05	tramadolone acetate	Cream	0.1 %	Perrigo Pharmaceuticals	15.00	\$ 0.98104	\$ 1.17596	19.9%	
68180-0589-01	ramipril	Capsule	2.5 MG	Lupin Pharmaceuticals	1.00	\$ 0.35514	\$ 0.42522	19.7%	
64679-0924-02	enalapril maleate	Tablet	5 MG	Wockhardt USA	1.00	\$ 0.13608	\$ 0.16240	19.3%	
61314-0144-10	primidone tartrate	Solution, Ophth	0.15 %	Sandoz	0.33	\$ 4.48284	\$ 5.32053	18.7%	
55111-0158-10	omeprazole	Capsule DR	20 MG	Dr. Reddy's Laboratories	1.00	\$ 0.33622	\$ 0.39661	18.0%	
68180-0468-09	lovastatin	Tablet	20 MG	Lupin Pharmaceuticals	1.00	\$ 0.18572	\$ 0.21816	17.5%	
00591-5782-01	atenolol & chlorthalidone	Tablet	50-25 MG	Watson Labs	1.00	\$ 0.18238	\$ 0.21382	17.2%	
68180-0590-01	ramipril	Capsule	5 MG	Lupin Pharmaceuticals	1.00	\$ 0.32890	\$ 0.38084	15.8%	
00591-0933-01	oxycodone w/acetaminophen	Tablet	7.5-325 MG	Watson Labs	6.00	\$ 3.23484	\$ 3.74394	15.7%	
00378-0033-10	metoprolol tartrate	Tablet	50 MG	Mylan	2.00	\$ 0.16079	\$ 0.18564	15.5%	
68462-0248-05	ranitidine HCl	Tablet	150 MG	Glenmark Pharmaceuticals	2.00	\$ 0.25081	\$ 0.28839	15.0%	
00093-7364-98	losartan potassium	Tablet	25 MG	Teva Pharmaceuticals USA	1.00	\$ 0.33840	\$ 0.38390	13.4%	
00093-0787-01	atenolol	Tablet	25 MG	Teva Pharmaceuticals USA	1.00	\$ 0.14570	\$ 0.16453	12.9%	
00093-0753-01	atenolol	Tablet	100 MG	Teva Pharmaceuticals USA	1.00	\$ 0.14344	\$ 0.16184	12.8%	
00093-1049-01	metformin HCl	Tablet	850 MG	Teva Pharmaceuticals USA	2.00	\$ 0.21528	\$ 0.24100	11.9%	
00378-0047-10	metoprolol tartrate	Tablet	100 MG	Mylan	2.00	\$ 0.20293	\$ 0.22570	11.2%	

APPENDIX A—CONTINUED

D	F	G	H	I	J	O	T	T	T
National Drug Code	Generic Name	Dose Form	Strength		Manufacturer	Usual Dose/Day	Retail \$/Day (Median)	Retail \$/Day (Median)	% Change from Same Mo. in Previous Yr.
							2012 (Dec. 31)	2013 (Dec. 31)	2013 v 2012
59762-4960-01	sertraline HCl	Tablet	25 MG		Greenstone	1.00 \$	0.21612 \$	0.24020	11.1%
00093-5711-01	glyburide-metformin	Tablet	2.5-500 MG		Teva Pharmaceuticals USA	3.00 \$	0.39331 \$	0.43471	10.5%
00378-0222-01	chlorthalidone	Tablet	25 MG		Mylan	1.00 \$	0.42865 \$	0.47364	10.5%
00093-5126-01	benazepril HCl	Tablet	20 MG		Teva Pharmaceuticals USA	1.00 \$	0.20180 \$	0.22293	10.5%
00093-5127-01	benazepril HCl	Tablet	40 MG		Teva Pharmaceuticals USA	6.00 \$	0.16005 \$	0.17656	10.3%
00093-6816-73	budesonide	Suspension	0.5 MG/2ML		Teva Pharmaceuticals USA	2.00 \$	7.42644 \$	8.10935	9.2%
13668-0010-01	citalopram hydrobromide	Tablet	20 MG		Torrent Pharmaceuticals	1.00 \$	0.13346 \$	0.14555	9.1%
00591-0503-05	hydrocodone-acetaminophen	Tablet	10-650 MG		Watson Labs	4.10 \$	1.03315 \$	1.12119	8.5%
68180-0591-01	ramipril	Capsule	10 MG		Lupin Pharmaceuticals	1.00 \$	0.42357 \$	0.45841	8.2%
00172-2083-80	hydrochlorothiazide	Tablet	25 MG		Ivax Pharmaceuticals	1.00 \$	0.09072 \$	0.09807	8.1%
00115-5522-10	fenofibrate	Tablet	160 MG		Global Pharmaceutical Corp	1.00 \$	1.68611 \$	1.81553	7.7%
59762-5033-01	glipizide	Tablet ER 24 Hr	10 MG		Greenstone	1.00 \$	0.48351 \$	0.52045	7.6%
68180-0503-01	meloxicam	Tablet	7.5 MG		Lupin Pharmaceuticals	1.00 \$	0.16250 \$	0.17479	7.6%
00591-0540-05	hydrocodone-acetaminophen	Tablet	10-500 MG		Watson Labs	6.00 \$	2.08695 \$	2.24364	7.5%
00093-5117-98	diltiazem HCl	Capsule CR 24 Hr	180 MG		Teva Pharmaceuticals USA	1.00 \$	0.66418 \$	0.71179	7.2%
00591-0241-05	lorazepam	Tablet	1 MG		Watson Labs	2.00 \$	0.23162 \$	0.24723	6.7%
68180-0517-03	lisinopril	Tablet	40 MG		Lupin Pharmaceuticals	1.00 \$	0.24411 \$	0.25909	6.1%
00093-5713-01	glyburide-metformin	Tablet	5-500 MG		Teva Pharmaceuticals USA	3.00 \$	0.54643 \$	0.57981	6.1%
00591-0844-01	glipizide	Tablet ER 24 Hr	5 MG		Watson Labs	1.00 \$	0.30863 \$	0.32535	5.4%
00378-0018-01	metoprolol tartrate	Tablet	25 MG		Mylan	2.00 \$	0.17307 \$	0.18151	4.9%
00143-1475-10	prednisone	Tablet	5 MG		West-Ward	1.00 \$	0.08148 \$	0.08508	4.4%
00574-2008-02	nystatin (Nystop)	Powder	100000 UNIT/GM		Peddock	3.99 \$	4.21999 \$	4.40523	4.4%
00172-4096-60	baclofen	Tablet	10 MG		Ivax Pharmaceuticals	3.00 \$	0.25505 \$	0.26388	3.5%
00781-1123-05	triamterene & HCTZ	Tablet	37.5-25 MG		Sandoz	1.00 \$	0.30536 \$	0.31583	3.4%
64720-0321-10	metaxalone	Tablet	800 MG		Corepharma	3.00 \$	10.74831 \$	11.11366	3.4%
00555-0612-14	pramipexole dihydrochloride	Tablet	0.25 MG		Teva Pharmaceuticals USA	1.09 \$	0.32922 \$	0.33768	2.6%
00093-0073-01	zolidem tartrate	Tablet	5 MG		Teva Pharmaceuticals USA	1.00 \$	0.16205 \$	0.16561	2.2%
00591-0385-05	hydrocodone-acetaminophen	Tablet	7.5-500 MG		Watson Labs	4.00 \$	0.67209 \$	0.68422	1.8%
59762-4910-05	sertraline HCl	Tablet	100 MG		Greenstone	1.00 \$	0.23781 \$	0.24187	1.7%
00603-2115-21	allopurinol	Tablet	100 MG		Qualitest	1.00 \$	0.13313 \$	0.13505	1.4%
00555-0899-02	estradiol	Tablet	0.5 MG		Teva Pharmaceuticals USA	1.00 \$	0.13977 \$	0.14165	1.3%
00093-5171-44	alendronate sodium	Tablet	70 MG		Teva Pharmaceuticals USA	0.14 \$	0.30395 \$	0.30660	0.9%

APPENDIX B

Actual Transaction Prices at the Retail Level for Widely Used Generic Drugs (January 1, 2005 to December 31, 2013) Case Studies of Selected Drug Products

Figure 5. Tamsulosin HCl 0.4 mg Capsule (Zydus Pharmaceuticals) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

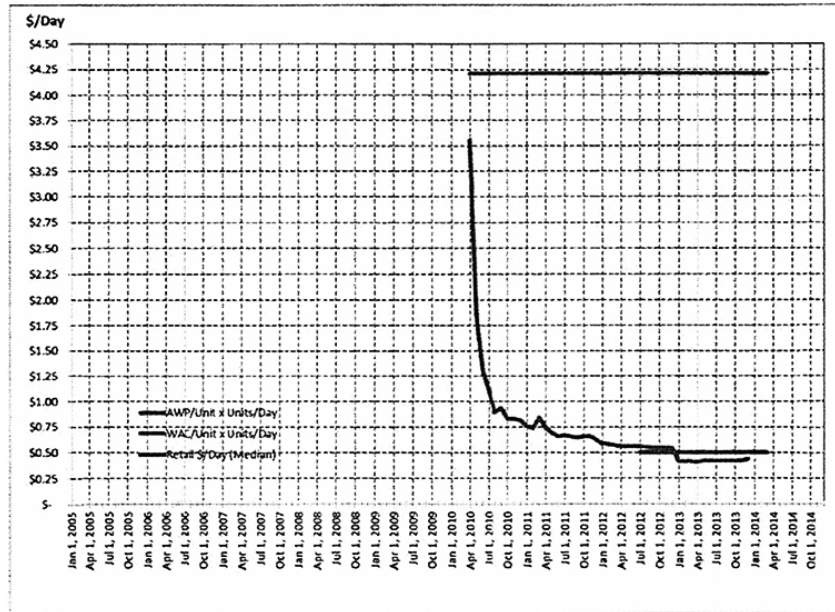


Figure 6. Sertraline HCl 50 mg Tablet (Greenstone) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

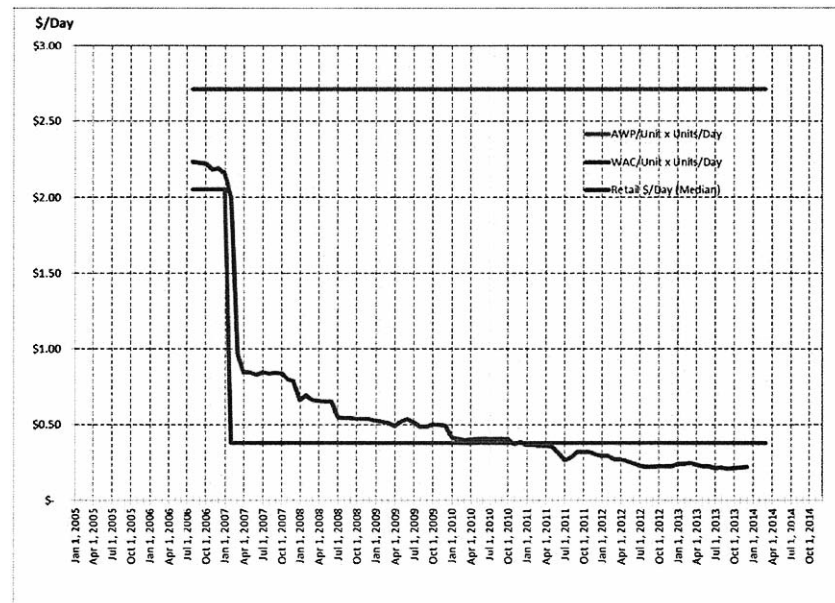


Figure 7. Pantoprazole Sodium 40 mg Tablet DR (Teva Pharmaceuticals) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

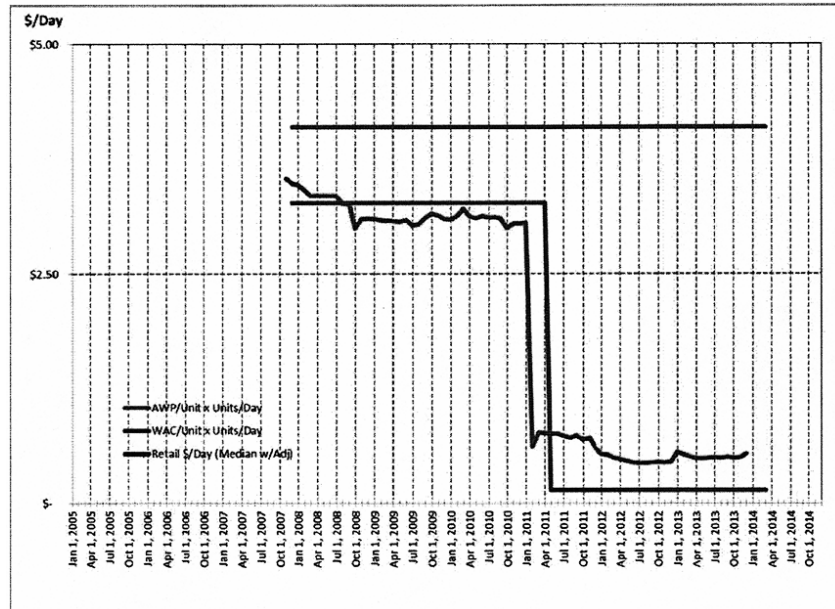


Figure 8. Budesonide 0.5 mg/2ml Suspension (Teva Pharmaceuticals) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

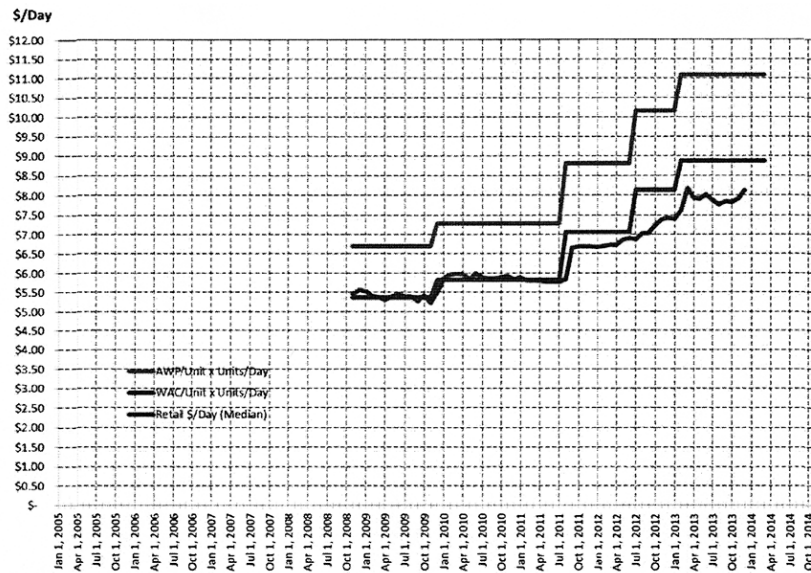


Figure 9. Brimonidine Tartrate 0.15 percent Ophthalmic Solution (Sandoz) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

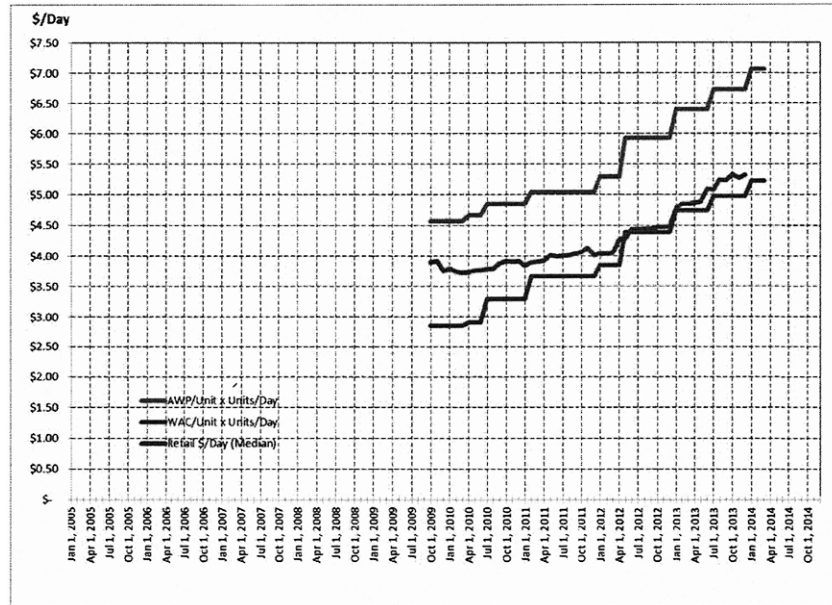


Figure 10. Potassium Chloride 10 MEQ Capsule ER (Watson Labs) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

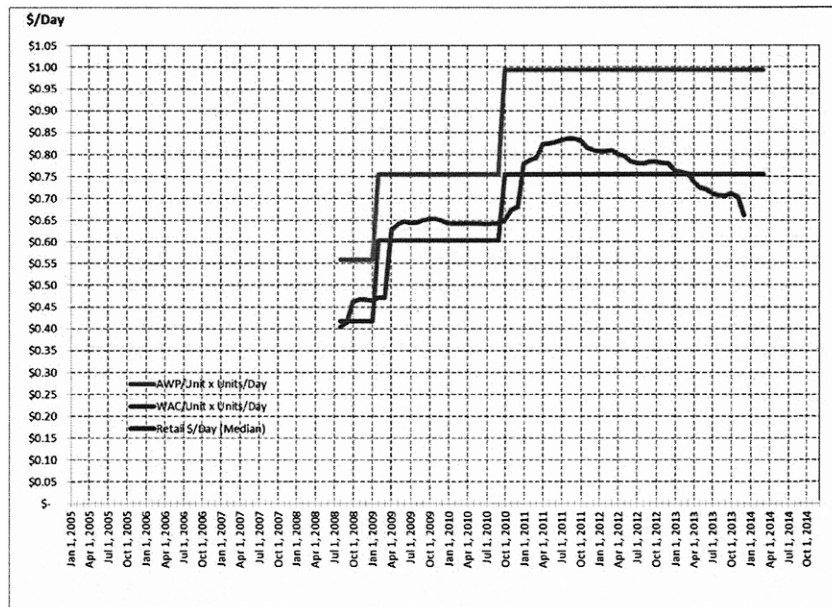


Figure 11. Doxycycline Hyclate 100 mg Capsule (West-Ward) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

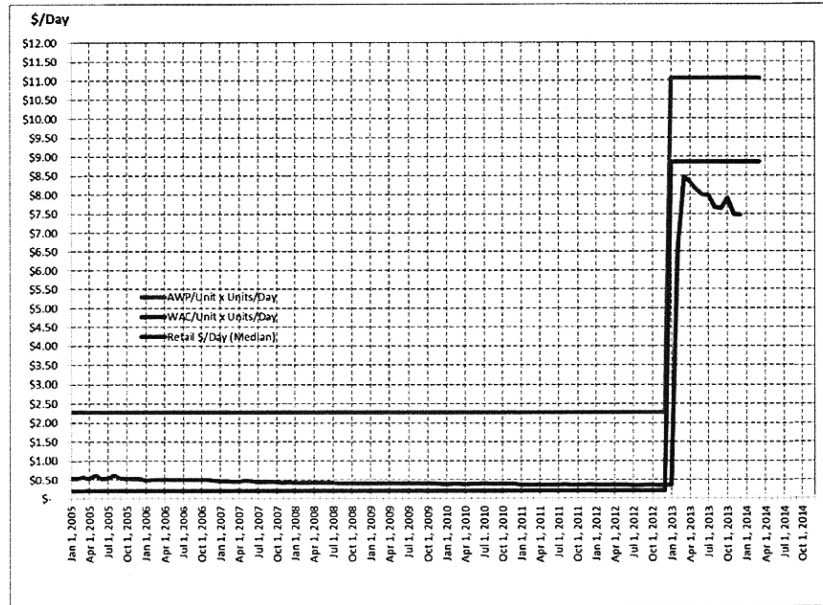


Figure 12. Digoxin 0.25 mg Tablet (Lannett) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

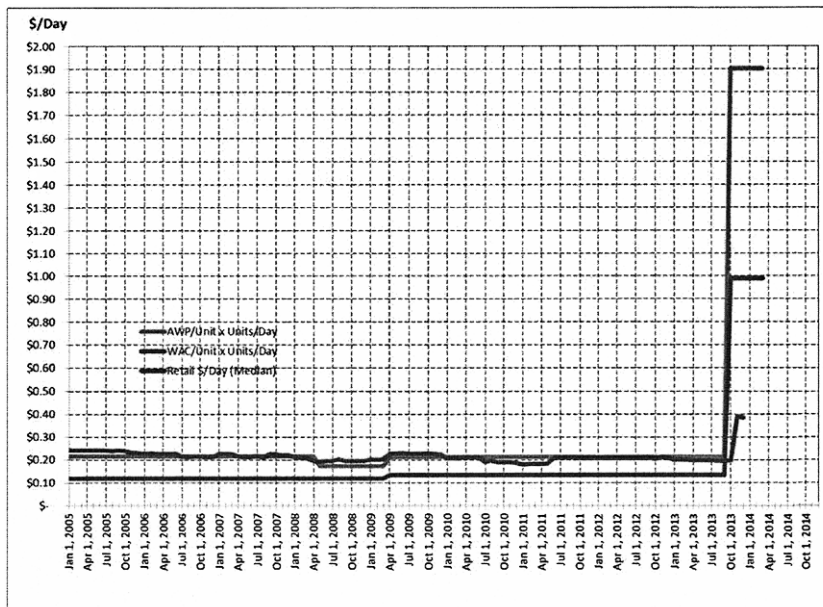


Figure 13. Divalproe Sodium 500 mg Tablet ER 24 Hr (Mylan) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

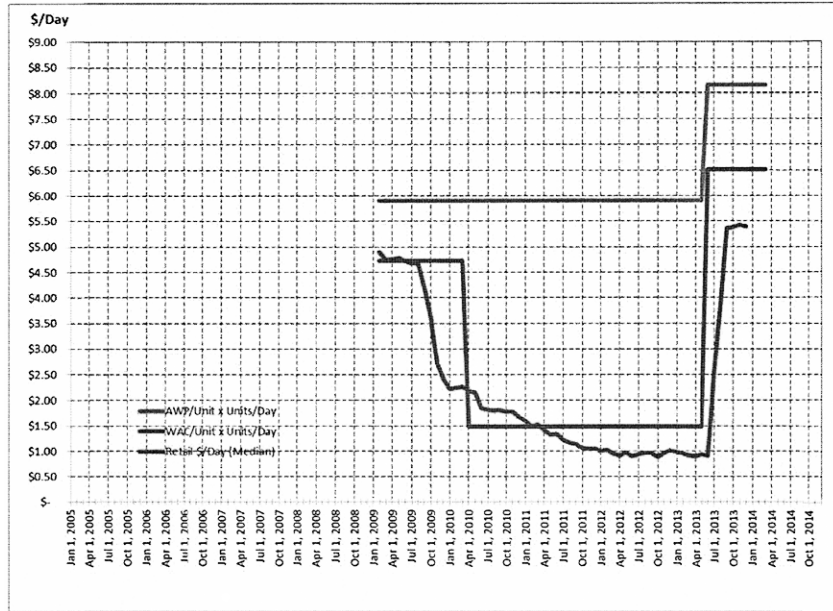


Figure 14. Prednisolone Acetate 1 percent Suspension (Sandoz) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

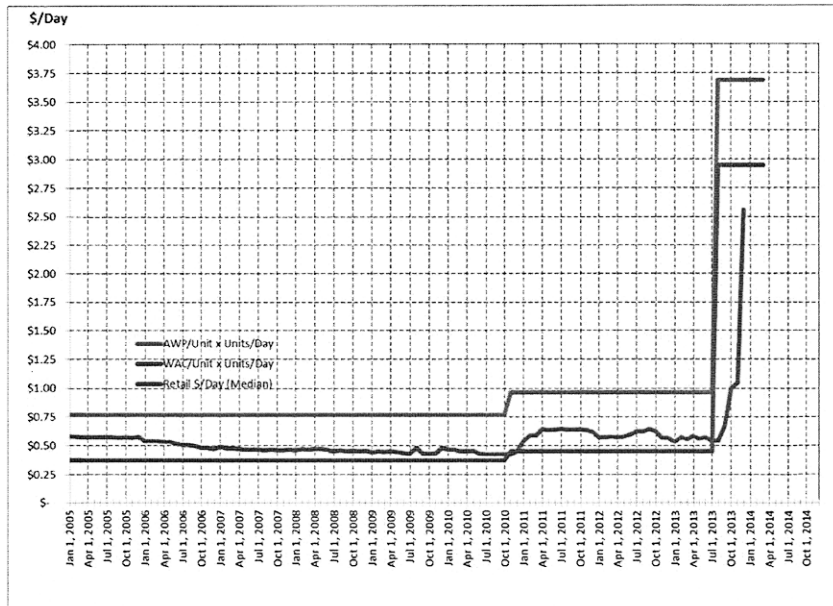


Figure 15. Levothyroxine Sodium 175 mcg Tablet (Mylan) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

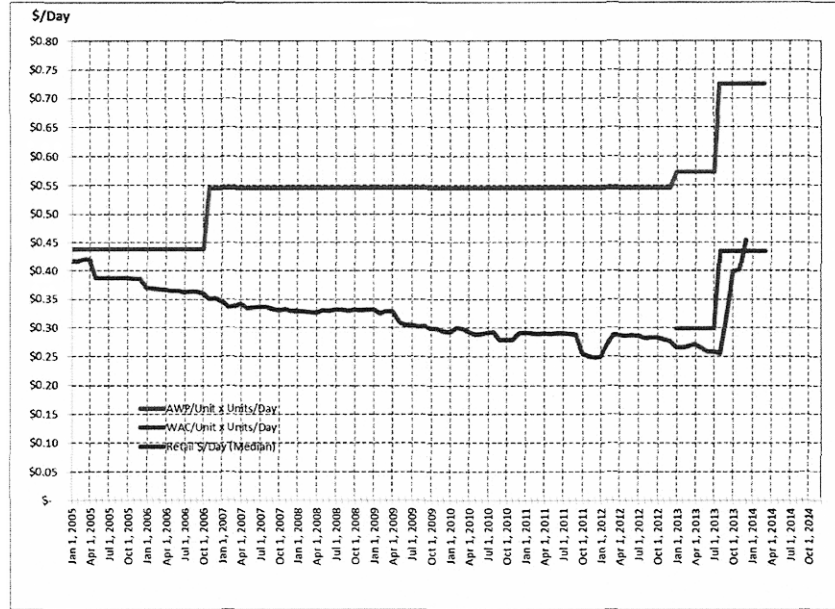


Figure 16. Glipizide 5 mg Tablet (Mylan) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

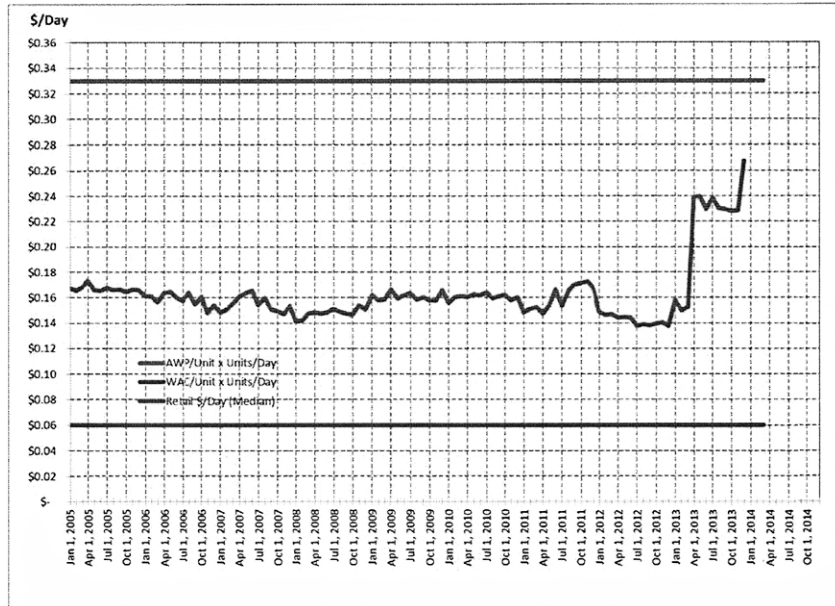


Figure 17. Hydralazine HCl 50 mg Tablet (Par) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)

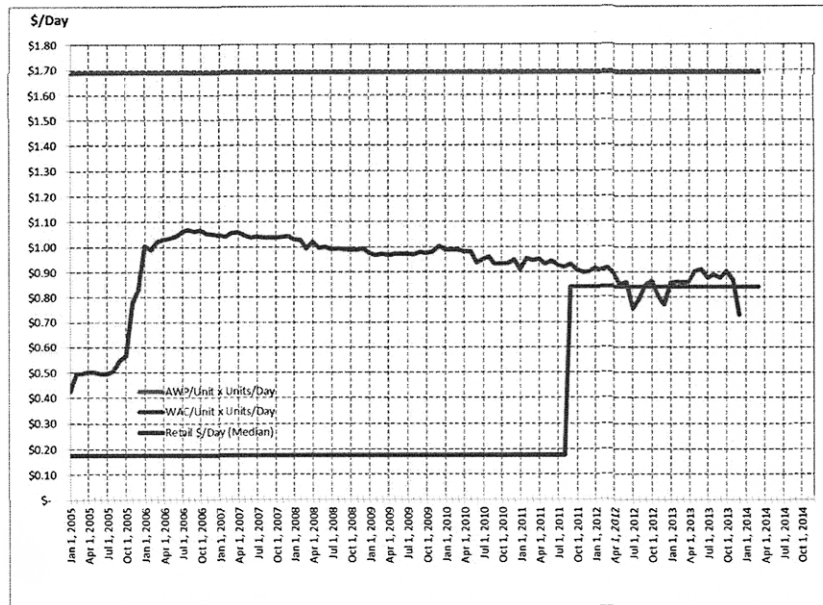
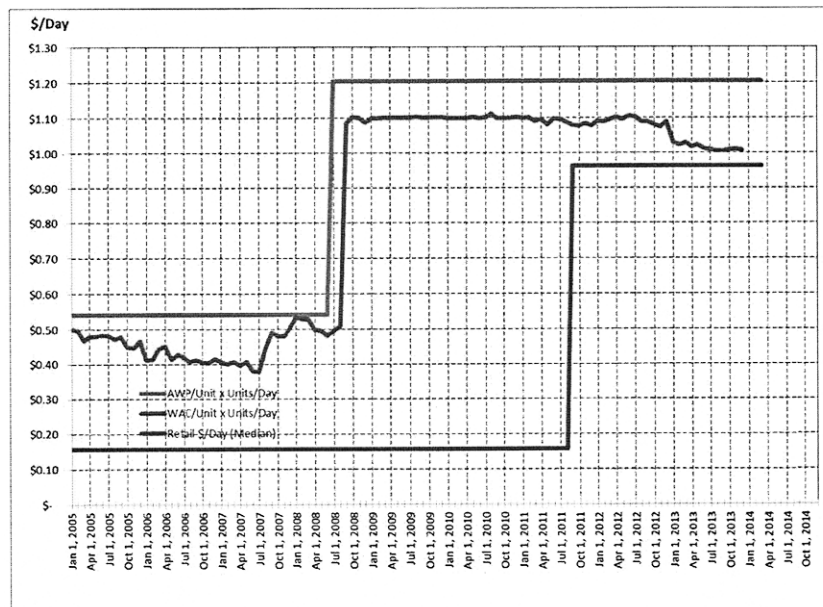


Figure 18. Meclizine HCl 25 mg Tablet (Par) Price per Day of Therapy: (January 1, 2005 to December 31, 2013)



Senator SANDERS. Thank you very much.

If you could, please, keep your remarks to 5–6 minutes, because we want to leave time for questioning.

Our next panelist is Robert Frankil. Mr. Frankil is a pharmacist and owner and president of Sellersville Pharmacy in southeastern Pennsylvania. He is a member of the National Community Pharmacist Association and past president of the Pennsylvania Pharmacist Association.

Mr. Frankil, thank you so much for being with us.

**STATEMENT OF ROBERT FRANKIL, RPH, PRESIDENT,
SELLERSVILLE PHARMACY, INC., SELLERSVILLE, PA**

Mr. FRANKIL. Thank you, Chairman Sanders and Ranking Member Burr, for conducting this hearing and providing me the opportunity to share my thoughts and observations regarding the puzzling skyrocketing cost of common generic drugs.

As Chairman Sanders said, my name is Robert Frankil. My business is in southeastern Pennsylvania, consists of a traditional community pharmacy and a long-term care pharmacy, closed door, on the campus of a mental institution. We serve the elderly, underserved, and needy. I'm also a member of NCPA, which represents nearly 23,000 independent pharmacies that provide 40 percent of all the prescription drugs dispensed. I also serve on many boards in Pennsylvania as well as the State Board of Pharmacy.

You have my written testimony, so I'll keep it short here and only give you a few highlights.

Just a little background. Approximately 86 percent of all prescriptions dispensed are for generic drugs. Historically, this represents huge savings for both patients and payers, including the Federal Government. Therefore, it was quite concerning when, about a year ago, community pharmacists began to see a dramatic price increase in generic drugs. NCPA conducted a survey and showed that prices spiked as much as 2,000 percent, or more, on some generic drugs. We've heard plenty of that already. These spikes usually happen overnight, with little or no notice. All drug classes were affected. And I've got a list of examples here that mirrors everyone's examples, but I want to stress to you that I am the buyer and seller of these prescription drugs. I am seeing it in real dollars and cents, in black and white, on my invoices when I buy drugs, and I am seeing it on the receipts when I sell prescriptions to patients. We're talking about increases of 2,000, even 8,000, percent. I'm not going to list the drugs again. They've been discussed already. But, it's not just those, it's many more, as you previously said.

One of the things this hearing is for is to find out why this is happening. It will be debated whether it's due to raw-material problems, production problems, FDA issues, or a reduction in competition among manufacturers. We can speculate why. And there should be a full-blown investigation on that. And there is. In my opinion, it seems to be more than a coincidence that, when manufacturers exit the marketplace for a specific drug, leaving fewer competitors, there's often a spike in the price of the drug. But, I don't believe in coincidences.

But, I'm here to tell you what's happening in pharmacies across the country. As I mentioned, these spikes happen overnight. I can pay \$100 for a bottle of drug today and \$1,000 for the same bottle tomorrow, and I have no advance notice.

Pharmacy benefit managers, or PBMs, are the entities that—and the middlemen—in the majority of all prescription drug claims in the United States, and typically set reimbursements to pharmacies. Even though PBMs have immediate, realtime knowledge of these drastic price spikes, they continue to reimburse pharmacies at the pre-spike price, putting pharmacies underwater on these drugs, often for months at a time. That puts pharmacy in a position between choosing to lose money, turning the patient away, or going back to the prescriber to see if there's another medication that can be used. Since pharmacists are sworn to take care of patients first and pay the bills later, we usually lose money and fill the script. This is an unfair position to put pharmacists and pharmacies in.

This problem is not limited to independent pharmacies. It's my understanding that national chains that are not connected with a PBM, and most grocery-store chains, are also affected.

Patients also feel it big-time, as we all know. A real example. A patient of mine bought his Digoxin while he was in his coverage gap or his donut hole in 2013, and paid about \$15 for it. This year, he came in, in his coverage gap, and paid over \$120 for it. He accused me of price-gouging. I don't set the price of the drug, and I don't do anything to set the reimbursement terms. This was a pretty bad situation at the pharmacy counter, if you can imagine. I had nothing to do with the price spike, and I couldn't do anything about it.

Payers are also affected. The Federal Government, as I said, is the largest buyer of prescription drugs in the country, and, inevitably, there is eventually a trickle-down to the taxpayers, who fund the Medicare and Medicaid plans.

Thank you for inviting me to this hearing today on a critical issue. This is a big problem that must be addressed. Unprecedented spike prices on generic medications are now commonplace, and it is wreaking havoc on patients, pharmacists, and healthcare payers alike. In addition, payment lags are jeopardizing the ability of independent pharmacies to remain viable and to continue to provide critical medications to patients.

Thank you very much.

[The prepared statement of Mr. Frankil follows:]

PREPARED STATEMENT OF ROBERT FRANKIL, RPH

Chairman Sanders, Ranking Member Burr and members of the subcommittee, thank you for conducting this hearing and for providing me the opportunity to share my thoughts and observations regarding the recent skyrocketing costs of many common generic medications. My name is Rob Frankil, pharmacist and owner/president of Sellersville Pharmacy, Inc., DBA as two locations: Sellersville Pharmacy, a traditional community pharmacy, and Sellersville Pharmacy at Penn Foundation, a closed door pharmacy serving a mental health foundation. Both locations serve primarily elderly, needy and underserved patients. I am also a member of the National Community Pharmacists Association (NCPA) that represents the pharmacist owners, managers and employees of nearly 23,000 independent community pharmacies across the United States that provide approximately 40 percent of all community-based prescriptions. I am also the past president of the Pennsylvania Pharmacist Association (2012–13), and serve on many boards in Pennsylvania including the Philadelphia Association of Retail Druggists, Bucks-Mont Pharmacists Association, and the PA State Board of Pharmacy.

GENERIC PRICE SPIKES AND NCPA SURVEY

The IMS Institute for Healthcare Informatics recently reported that approximately 86 percent of all prescriptions filled in the United States are for generic drugs. Historically, generic drugs have provided significant cost savings to payers and consumers alike by providing safe and effective alternatives to typically more costly brand name drugs. Therefore it was extremely concerning when about a year ago; pharmacies began noticing a rash of dramatic price increases for many common, previously low-cost generic drugs. In response, NCPA conducted a member survey on this issue in January of this year to try to gauge the prevalence of generic price spikes. NCPA received an overwhelming response from more than 1,000 members who reported instances of generic drugs that had spiked by as much as 600 percent, 1000 percent or more.

Seventy-seven percent of pharmacists reported 26 or more instances of a large up-swing in a generic drug's acquisition price over the past 6 months. Nearly all (86 percent) said that it took the pharmacy benefit manager (PBM) or other third party payer between 2 to 6 months to update its reimbursement rate to pharmacies (putting these critical health care providers "underwater" on these medications). In other words, pharmacists are filling prescriptions and are being reimbursed significantly less than what it cost them to acquire the drug. In addition, 84 percent of pharmacies said that the acquisition price spike and associated lagging reimbursement trend was having a "very significant impact on their ability to remain in business to continue serving patients." In some instances, community pharmacies were faced with having to refrain from filling prescriptions that would have resulted in losses of \$40, \$60, \$100 or more per prescription filled.

The generic drugs most frequently cited in the survey included drugs from virtually every therapeutic category and included Benazepril (high blood pressure); Clomipramine (antidepressant); Digoxin (controls heart rate); Divalproex (treats seizures and psychiatric conditions); Doxycycline (antibiotic); Budesonide (asthma); Haloperidol (psychotic disorders); Levothyroxine (hypothyroidism); Methylphenidate (ADHD); Morphine (pain); Nystatin/Triamcinolone (fungal skin infections); Pravastatin (high cholesterol); and Tizanidine (muscle relaxant).

The prevalence of these generic drug price spikes has not abated since the initial survey was completed and NCPA has been unable to identify any definitive cause for these price increases. There has been speculation that these spikes may be due to manufacturing delays, production problems, shortages of raw materials and a dwindling number of manufacturers of these products.

IMPACT OF GENERIC PRICE SPIKES ON PATIENT COST AND ACCESS TO MEDICATION

These severe disruptions in the market are having a profound effect on patients—particularly the elderly and those that are either uninsured or are enrolled in a prescription drug plan with a high deductible. Medicare beneficiaries enter the coverage gap or "donut hole" when the accumulated costs of both their co-pays and the charges to their drug plan reach a certain threshold. After a Medicare beneficiary exhausts the initial coverage of the prescription drug plan, the beneficiary is financially responsible for a higher cost of prescription drugs until he or she reaches the catastrophic-coverage threshold. Precisely because of this dynamic, many pharmacist responders to the NCPA survey reported instances in which Part D beneficiaries were either refusing to refill their prescriptions or were planning to take less than the prescribed dose of their medication in an attempt to "stretch" their remaining supply and in order to avoid having to go into the donut hole.

Patients without prescription drug coverage are solely responsible for the entire cost of the drug and also may ultimately decide not to fill needed prescriptions. Patients with a high deductible prescription drug plan are in a similar situation as they are solely responsible for the cost of medications until such time as they reach a certain monetary threshold. Patient non-adherence to prescribed medications for any reason can often trigger more serious health conditions that may require emergency room visits or hospitalizations—that are ultimately more costly to both the patient and health care system as a whole. Ultimately, everyone pays for these cost increases, now or later. Insurance plans aren't likely to simply just absorb these higher costs, so even those with generous insurance plans will pay the price in higher future premiums.

A recent example from my own experience is the price of Digoxin—a drug used to treat heart failure. The price of this medication jumped from about \$15 for 90 days' supply, to about \$120 for 90 days' supply. That's an increase of 800 percent. One of my patients had to pay for this drug when he was in the coverage gap in 2014. Last year, when in the coverage gap he paid the old price. This year he paid the new price. Needless to say, the patient was astounded, and thought I was over-

charging him. The patient called all around to try to get the medicine at the old, lower price, but to no avail. This caused him lots of stress and time, and caused us lots of stress and time in explaining the situation, reversing, and rebilling the claim. This example is typical of how these price spikes put consumers and pharmacists in a bad position, often grasping at straws for explanations. And all the while, everyone pays more, including the patient, the pharmacy, and the insurer (often the Federal Government).

IMPACT OF GENERIC PRICE SPIKES ON FEDERAL GOVERNMENT COSTS

In addition to the potential negative effects that this situation is having on health outcomes for the Nation's seniors, the financial impact to the Federal Government itself cannot be ignored. The Federal Government pays for more than a third of all prescription drug costs in America. In fiscal year 2014, the Centers for Medicare and Medicaid (CMS) will serve almost 116 million Medicare, Medicaid and CHIP beneficiaries, more than one-in-three Americans. In addition to CMS, other Federal prescription drug programs impacted by this situation include the Department of Defense TRICARE program, the Veterans Health Administration (VHA), the OPM Federal Employees Health Benefit Plan (FEHBP) and the Indian Health Service (IHS). These generic drug price spikes that we are seeing are perhaps one of the most egregious examples of hyperinflation in the United States health care system at the present time and must be addressed.

NEGATIVE IMPACT OF GENERIC PRICE SPIKES AND REIMBURSEMENT LAGS ON COMMUNITY PHARMACY

When the price of these common generic medications increase so dramatically and insurance middlemen known as pharmacy benefit managers (PBMs) do not correspondingly update their reimbursement rates to pharmacies—community pharmacies are put in the untenable position of having to absorb the difference between the large sums of money that they spent to acquire the drugs and the lower amounts that they are paid by the PBM (that are still “stuck” on the lower (pre-spike) prices).

In this era of instant communication, it is indefensible for PBMs to wait weeks or even months before updating their payment benchmarks in the wake of these price spikes—without reimbursing pharmacies retroactively. Pharmacists' appeals to PBMs are consistently denied or ignored, and this situation is untenable particularly for small business community pharmacies. This trend also raises a troubling fiscal question for employers, government agencies and health plan sponsors. Are PBM middlemen taking advantage of these price spikes by reimbursing pharmacies low, charging health plans high and pocketing the difference? This practice of “spread pricing” was examined in a recent *Fortune* magazine article entitled “*Painful Prescription*.”¹

On a practical level, when we (pharmacists) process a claim and are reimbursed at below our cost, the computer flags it and we are notified. At this point, the claim must be initialed and processed. This happens in about 1 out of every 10 claims. With independent pharmacies on average producing over 90 percent of their revenue from prescription sales, this really hurts. I have a file about two inches thick of unresolved underpaid claims (appeals with PBMs) where we lost money. I do not send in appeals where we lose less than \$50. If I did, I would not have time to take care of patients. Specifically, Carbamazepine used for seizure disorders, spiked in price about 6 months ago. One of the largest PBMs in the country is still reimbursing at the old price (new price is \$60 per 100 tablets; old price was \$4 per 100 tablets). I appealed this price and got an answer last week. The PBM refused to make an adjustment, and offered no explanation.

In recognition of this problem, earlier this year CMS finalized a provision in the Part D Final Rule that will require PBMs to update generic pricing benchmarks (otherwise known maximum allowable cost (MAC) lists) in the Medicare Part D program beginning in plan year 2016. However, this rule does not address any of the other Federal health care programs or any of the many commercial health plans currently in operation in the United States. I feel strongly that pharmacists deserve to be fairly compensated for the medications and associated patient counseling that they provide. To that end, I urge your support for the bipartisan legislation known as The Generic Drug Pricing Transparency Act, H.R. 4437, introduced by Reps. Doug Collins (R-Georgia) and Dave Loebsack (D-Iowa). The proposal would allow a pharmacy to know how its individual maximum allowable cost (MAC) reimburse-

¹ <http://money.cnn.com/2013/10/10/news/companies/pbm-pharma-management.pr.fortune/#sthash.osxYRm7O.dpuf>.

ment rates for multisource generic drugs would be determined and would also require that payments be updated more frequently to keep pace with actual market costs. To date, 16 States have passed similar legislation recognizing the value of ensuring that critical pharmacy care providers are able to provide needed medications and related patient care services to patients.

CONCLUSION

Thank you for inviting me to testify today on this critical issue. The current situation in which unprecedented spikes in previously inexpensive generic medications are becoming commonplace is one that cannot be allowed to continue. These prices are wreaking havoc on patients, pharmacists and health care payers alike. In addition, the associated payment lags on these medications are jeopardizing the ability of small business pharmacies to remain viable and continue to provide critical medications and related care to patients. I am pleased to answer any questions that you may have.

Senator SANDERS. Thank you very much.

Our next panelist is Carol Ann Riha, of West Des Moines, IA.

Ms. Riha, thank you so much for being with us.

STATEMENT OF CAROL ANN RIHA, WEST DES MOINES, IA

Ms. RIHA. Thank you, Senator Sanders, for the honor and opportunity to testify before this subcommittee. Thank you, distinguished panel members, for taking the time to address this important issue which affects millions of Americans.

My name is Carol Ann Riha. I and my husband, both early retirees, live in West Des Moines, IA. I was laid off in 2011 from the Associated Press, where I was Iowa bureau chief. After leaving AP, I worked a couple of years at the Des Moines Register, and retired last year after 38 years in journalism. My husband left Nationwide Insurance in 2009, at the peak of the recession, and was unable to find subsequent employment. We live on a monthly limited withdrawal from my 401(k). My husband receives a pension of \$273 a month.

Senator Sanders invited consumers to share their stories, and I posted on his website my story about a generic medication I take, Pravastatin. It's a preventative that addresses problems with lipids and cholesterol to prevent heart disease. I switched, a few years ago, from a similar medication called Simvastatin after having some side effects—confusion and short-term memory loss. My doctor prescribed Pravastatin, a proven drug developed decades earlier, with lessened risk of side effects.

At the time I made the switch, my tablets, 10 milligrams, made by Teva Pharmaceuticals, sold for \$4 a month at the Target pharmacy. Then earlier this year, my \$4-a-month prescription suddenly turned into \$18.73. That's with health insurance. I asked about the increase, and the Target pharmacist had no explanation. Target's retail price for the drug is \$25.99, so insurance saved me \$7.26, but the price I pay is now four and a half times more. Since it's a simple compound that has been produced for decades, I don't understand the increase. I would think a drug that's prevalent would eventually become as cheap and readily available as aspirin.

A couple of years ago, my hormone replacement therapy pills, then sold under the brand name FemHRT and made by Warner Chilcott, suddenly became unavailable, without warning. The patent had expired. Teva was making a higher-dose generic, but there was a gap until the low-dose version became available. I was able

to track down this information online, following news reports and releases. But, I've been unable to track down any information about why my other prices have increased so much recently.

As I explained to Senator Sanders' office, I consider myself lucky. I have good credit and have a steady income from my 401(k). I absorb the price increase simply by putting it on my credit card. Obviously, it has to be paid at some point, but I think about the millions of Americans trying to make cuts elsewhere because they are tapped out.

My Pravastatin wasn't the only budget-buster this year. My Lansoprazole, an acid-reducer I've taken for years after an ulcer, was made an over-the-counter drug. Another \$4 generic, it's now available on store shelves, and that's great for availability. And I'm sure millions more Americans will now avail themselves of the drug. That's good, right? However, a 14-day package of 15-milligram capsules now sells for \$7.39, and I take two a day. That's an increase, a month, from \$4 to \$29.56. There is no copay, and over-the-counter drugs aren't tax-deductibles.

The cost of my hormone replacement therapy, Jinteli, varies month to month. In September, a 28-day supply cost me \$40 after insurance. The retail cost was \$97.49. In November, I paid \$101.86 after insurance. The retail cost was \$116.99.

How can anyone on a fixed income deal with these vagaries in the system? You sure can't budget for costs that change month to month. And it's not just a few pennies, as you can see. These are significant percentages.

The bright spot? My daily 40-milligram dose of Citalopram, which manages depression and anxiety, has not changed and is still just \$4 per month. Last year, I spent \$849 on prescription medications. This year, after going back to do the math, I anticipate that my out-of-pocket costs will exceed \$1,700. Like many Americans, I've just been slapping these extra costs on my credit card. I had no debt when I retired, and was making plans to move to sunny Sequim, WA, where I have a sister living. Now those plans are on hold until we can whittle down our debt.

I thank you again for the opportunity to speak to you today. I look forward to hearing what the drug companies have to say about generic drug pricing. And I do want them to know that their decisions have a significant impact on real people.

[The prepared statement of Ms. Riha follows:]

PREPARED STATEMENT OF CAROL ANN RIHA

Thank you Senator Sanders for the honor and opportunity of inviting me to testify before this subcommittee. Thank you distinguished panel members for taking the time to address this important issue, which affects millions of Americans. I consider it a great privilege to be here.

My name is Carol Ann Riha. I and my husband, both early retirees, live in West Des Moines, IA. I was laid off in 2011 from The Associated Press, where I was Iowa Bureau Chief. In my 27 years with AP, I also worked in Detroit and Portland, OR. After leaving AP, I worked a couple of years at The Des Moines Register and retired last year after 38 years in journalism. My husband left Nationwide Insurance in 2009 at the peak of the recession, and was unable to find subsequent employment. We live on a limited monthly withdrawal from my 401(k). My husband receives a pension of \$273 a month.

Senator Sanders invited consumers to share their stories and I posted on his website my story about a generic medication I take—pravastatin. It is a preventive that addresses problems with lipids and cholesterol to prevent heart disease. I

switched a few years ago from a similar medication called simvastatin after having side effects—confusion and short-term memory loss. My doctor prescribed pravastatin, a proven drug developed decades earlier with a lessened risk of side effects.

It was sold under the brand name Pravachol and was made a generic drug in 2006. At that time, the FDA said in a news release: “This approval is another example of our agency’s endeavor to counter rising health care costs by approving safe and effective generic alternatives as soon as the law permits.” The FDA release also said that in 2005, Pravachol was the 22d most widely used drug in the United States, with sales of \$1.3 billion. Reading that, I figured R&D costs were paid off and companies would recoup further expenses through volume. Millions of Americans are taking this drug every day.

At the time I made the switch, my 10 mg tablets, made by Teva Pharmaceuticals, sold for \$4 a month at the Target pharmacy. Then, earlier this year, my \$4-a-month prescription suddenly cost me \$18.73. That’s with health insurance. I asked about the increase and the Target pharmacist had no explanation. Target’s retail price for the drug is \$25.99, so insurance saved me \$7.26, but the price I now pay is more than 4.5 times more.

Since it’s a simple compound and has been produced for decades, I don’t understand the increase. I would think a drug this prevalent would eventually become as cheap and readily available as aspirin.

A couple of years ago, my hormone replacement therapy pills, then sold under the brand name FemHrt and made by Warner Chilcott, suddenly became unavailable without warning. The patent had expired. Teva was making a higher dose generic, but there was a gap until the low-dose version became available. I was able to track down this information online, following news report and releases. I’ve been unable to track down information about why the price has increased so much recently.

As I explained to Senator Sanders’ office, I consider myself lucky. I have good credit and I have a steady income from my 401(k). I absorbed the price increase simply by putting it on my credit card. Obviously it has to be paid at some point, but I think about the millions of Americans trying to make cuts elsewhere because they’re tapped out.

My pravastatin wasn’t the only budget buster this year. My lansoprazole, an acid reducer I’ve taken for years after an ulcer, was made an over-the-counter drug. Another \$4 generic, it’s now available on store shelves. That’s great for availability. I’m sure millions more Americans will now avail themselves of the drug. That’s good, right?

However, a 14-day package of 15 mg capsules now sells for \$7.39 and I take 2 a day. That’s an increase from \$4 a month to \$29.56. There’s no copay and over-the-counter drugs aren’t tax deductible.

The cost of my hormone replacement therapy, Jinteli, varies month to month. In September, a 28-day supply cost me \$40 after insurance. The retail cost was \$97.49. In November, I paid \$101.86 after insurance. The retail cost was \$116.99.

How can anyone on a fixed income deal with these vagaries in the system? You sure can’t budget for costs that change month-to-month. And it’s not a few pennies, as you can see. These are significant percentages.

The bright spot? My daily 40 mg dose of citalopram, which manages depression and anxiety, has not changed and is still just \$4 a month.

Last year, I spent \$849 on prescription medications. This year, after going back to do the math, I anticipate that my out-of-pocket costs will exceed \$1,700.

Like many Americans, I’ve just been slapping these extra costs on my credit card. I had no debt when I retired and was making plans to move to sunny Sequim, WA, where I have a sister living. Now, those plans are on hold until we can whittle down our debt.

I thank you again for the opportunity to speak to you today. I look forward to hearing what the drug companies have to say about generic drug pricing. I do want them to know that their decisions have a significant impact on real people.

Senator SANDERS. Thank you very much, Ms. Riha.

Senator Burr will introduce Dr. Scott Gottlieb.

Senator BURR. Thank you, Mr. Chairman.

I am pleased to introduce to the committee and the panel Dr. Scott Gottlieb. Dr. Gottlieb is a practicing physician and resident fellow at the American Enterprise Institute. Dr. Gottlieb is regarded as an expert on drug policy and FDA issues. He served as the Deputy Commissioner for Medical and Scientific Affairs at the

Food and Drug Administration from 1905 to 1907. Prior to that, 1903 and 1904, he was a senior advisor to the FDA Commissioner and served as FDA's Director of Medical Policy Development. In between those two stints at the FDA, in 2004 Dr. Gottlieb worked on the implementation of the Medicare Drug Benefit as a senior advisor to the administrator of the Centers of Medicare and Medicaid Services. Currently, Dr. Gottlieb is an editorial board member of the journal Value-Based Cancer Care, the Food and Drug Law Institutes Policy Forum, is a member of the Board of Advisors of Cancer Commons. Dr. Gottlieb has published columns in the Wall Street Journal's clinical assistant professor at New York University School of Medicine. He completed a residency in internal medicine at Mount Sinai Hospital in New York and is a graduate of Mount Sinai School of Medicine and of Wesleyan University, where studied economics.

Dr. Gottlieb, thank you for your contributions to these important issues.

**STATEMENT OF SCOTT GOTTLIEB, M.D., RESIDENT FELLOW,
AMERICAN ENTERPRISE INSTITUTE, WASHINGTON, DC**

Dr. GOTTLIEB. Thanks for having me. Thanks, Mr. Chairman, Mr. Ranking Member.

I want to offer some observations on some of the discussion that's gone on here today.

One of those observations is that the data that looks at the price increases on generic drugs isn't corrected for script volume. I think we really need to do that. It could just be that the low-volume drugs are the ones that are taking the price increases. And that would seem to make sense as manufacturers enter the market and as script volume declines overall. Once you're down to one or two manufacturers, you're going to see price increases. Now, that doesn't diminish the impact on the patients, but it does suggest that the overall cost of generic drugs to the system and to consumers generally is probably declining. And the data that I have would seem to suggest that. So, even though you've seen some price increases, and some exorbitant price increases on some very low-volume drugs, drugs that do less than \$10 million in total revenue, overall generic drug costs to the system are actually still declining.

I think it's going to absolutely be the case that, for low-volume drugs, as drugs fall out of favor clinically, as utilization is diminished, there are going to be fewer manufacturers for those drugs, and, as fewer manufacturers remain in the market, they're going to take price increases, in part to take advantage of their market position, also in part because they have to amortize the cost of manufacturing those drugs over fewer patients. There's a fixed cost to manufacturing a drug. You have to cover your fixed costs, in most cases, although generic companies do lose money on a lot of drugs.

I think the question before us is—this should be self-correcting. So, as the revenue increases that the manufacturers are earning off these drugs, it should become an attractive market for other manufacturers to enter. And the rule of thumb always was that, once a market reached around \$10 million in revenue, it became attractive to other generic manufacturers. That rule of thumb arguably was

the rule of thumb we used when I was at FDA a number of years ago. I suspect it's a lot more right now, that a category needs to generate more revenue than that to really become attractive to a number of manufacturers.

But, I think the problem is that there are higher barriers to entry, and it's harder for generic manufacturers to enter a space. So, you're seeing these product categories persist with one or two manufacturers for longer periods of time, or sometimes in perpetuity. And I think that's owed to the fact that the barriers to entry are significantly higher these days than they used to be. And that's antithetical to the spirit of Hatch-Waxman. Filing a generic application, doing the BE/BA studies for a generic application, used to cost about a million dollars, now it would cost upwards of \$5 million even for a simple generic. And, as I noted, use of generics as a category, used to see vigorous competition at \$10–15 million of total revenue for a category. Now it's much higher.

I would observe that a lot of the drugs on the list that—Senator, that you've collected—are low-revenue products. Doxycycline, for example, does \$6.9 million in total revenue annually, so it's not at the threshold where we would see bigger—more brisk competition.

I think, as big of a problem as we're observing here today, and you've rightly called attention to, if not a bigger problem, is the overall cost structure in the generic drug industry. And it's going up. And, while that's not responsible, certainly, for the price increases of these individual drugs that the committee has noted, it is going to result in price inflation eventually. We have not seen that yet, but we have to be concerned that we'll see inflation in the overall generic space as a result of the rising cost structure.

Some of that owes to rising cost of goods. The biggest single input in general manufacturing is energy input costs. Energy costs have gone up. But, we can't discount the fact that there is much higher manufacturing costs. There's many more manufacturing hurdles imposed by new regulatory requirements that either keep generic manufacturers out of the market or make it more expensive for those who have been in the market. And, while I'm not debating, and it's beyond the scope of our discussion here to debate, the merits of those regulations, I do think they have been imposed in a rather abrupt manner, and that has caused some dislocations in the market.

I think, in conclusion, a concern for all of us as we look at these individual cases where generic drug prices have gone up significantly for select drugs, an as-big concern, if not bigger concern, should be looking at the barriers to entry. If barriers to entry do continue to increase in this space, it's going to affect most—mostly, and initially, the low-volume drugs. Those are the ones that are going to be most vulnerable to it. And that may be what we're seeing. We may be seeing the canary in the coal mine to rising costs of goods overall.

Thanks a lot, Senator.

[The prepared statement of Dr. Gottlieb follows:]

PREPARED STATEMENT OF SCOTT GOTTLIEB, M.D.

In our economy for medicines, the dual principles of market-based rewards that attract entrepreneurship and deep value once patents have lapsed are longstanding

features of our system. The competition between branded and generic drug makers has enabled remarkable advances in science, and vibrant competition on price.

The compromises struck in the Hatch-Waxman legislation decades ago, have endured even as the market has changed. Generic drug makers have grown more sophisticated at challenging patents and unlocking new value for consumers. At the same time branded drug makers—recognizing this competition—have moved into new areas of science where resulting products are more specialized, unique, and beneficial. The competitive interplay between branded and generic firms, and the benefits that it affords, grows more relevant as the industries continue to evolve.

Recently, questions have been raised whether this competitive landscape is giving way to new economic features that erode some of the original intent of Hatch-Waxman. Market observers have made note of the substantial price increases observed with a select number of drugs, even though these medicines have been long subject to generic price competition. Yet in observing these cases, there is no one discernable feature, or policy shortcoming, that explains the events. In each case, there are some unique features that led cost of goods to rise, or competition to temporarily erode. At the same time, market-wide generic drug prices continue to decline when you look across all of the drugs. So what is one to conclude?

America indeed has a challenge when it comes to the original compact that gave us a vibrant market for low-priced generic drugs. But it is largely not revealed by the anecdotal cases where a select number of drugs have undergone exorbitant price increases. These situations stem from unique circumstances, many of which will be hard to solve through policy alone because the situations are exceptional, and more likely than not, temporary, as market dynamics work to correct themselves.

On the contrary, a more pervasive and concerning trend relates to market challenges and policies that are slowly raising overall generic cost of goods. Some of these policies are borne of appropriate compromises. Others are not as well thought out. While focusing on the anecdotal cases where some prices have undergone sharp increase, Congress should also take note of the broader underlying trends.

While generic drug prices, on the whole, continue to decline, that is by no means a sure thing. If this deflation eventually reverses, it won't be as a consequence of the small number of cases where select drugs underwent substantial price increases. It will likely be a result of more pervasive increases in industry wide COGS.

OVERALL GENERIC PRICES CONTINUE TO FALL

The increasing use of generic medications has helped mitigate growth of health care spending in the United States over the last decade. According to a recent report by the Government Accountability Office, on average, the retail price of a generic drug is 75 percent lower than the retail price of a brand-name drug.^{1,2} Until the early 2000s, drug spending was one of the fastest growing components of healthcare spending. However, since that time, the rate of increase has declined each year. These reductions are attributable, in part, to the greater use of generic drugs and more competition between generic drug makers that lowers the cost of generic drugs.

That same GAO report condensed a series of studies conducted for Generic Pharmaceutical Association by IMS Health that estimated the total savings generic substitution provided to the overall U.S. health care system. The studies looked at the 12-year period 1999 through 2010.³ These reports found that during this period, generic substitution saved the U.S. health care system more than \$1 trillion. In 2010 alone, generic substitution generated more than \$157 billion in savings.⁴

These studies, however, don't answer the question before us today: What is happening to the prices of individual generic drugs? Here again, the news is encouraging. Data reported in the Express Scripts Prescription Price Index show that generic drug prices have been halved since 2008.⁵ Thompson Reuters reported that generic dose prices in certain markets, especially in the United States,

“have gone into a downward spiral, squeezing margins for generic dose companies and often for API manufacturers as well. Contributing to this pricing pressure are an increase in the number of generic dose players, availability of

¹ GAO-12-371R Savings from Generic Drug Use <http://www.gao.gov/assets/590/588064.pdf>.

² CBO, “Effects of Using Generic Drugs on Medicare’s Prescription Drug Spending,” September 2010.

³ GPhA, Savings: An Economic Analysis of Generic Drug Usage in the U.S. (September 2011); GPhA, Savings Achieved through the Use of Generic Pharmaceuticals, 2000–2009 (July 2010); GPhA, Economic Analysis: Generic Pharmaceuticals 1999–2008—\$734 Billion in Health Care Savings (May 2009).

⁴ GPhA, Savings: An Economic Analysis of Generic Drug Usage in the U.S. (September 2011).

⁵ Express Scripts. “Express Scripts Prescription Price Index.” Drug Trend Report. (2014).

low-cost active ingredient from India and China, incumbents' desire to maintain market share."⁶

This doesn't negate the fact that the price of select number of generic drugs has gone up, in some cases substantially. This has put pressure on some pharmacies and consumers. There are concerns that it could be the start of a broader trend. But it is important to note that the prices of generic drugs are constantly fluctuating. When shortages of certain drugs or active ingredients exist, or manufacturers exit the market (leaving less competition for the sale of specific medicines) prices rise. When the maximum allowable cost limits that pharmacies agree to in their contracts don't keep pace with rising generic acquisition costs, these cost increases can squeeze pharmacies' profits. Over time, the MACs will catch up, and pharmacies often benefit when this same phenomenon works in reverse. Once prices start declining again, pharmacies benefit because higher reimbursement lags behind the lower acquisition costs. In the cases of the drugs that underwent price increases, the higher prices serve to attract additional generic competitors, and costs decline.

Indeed, some of the articles pertaining to the rising cost of some generic drugs seem to prove out this point in trying to make the opposite case, that generic prices are going up more sharply and unexpectedly than in the past. For example, the Wall Street Journal recently noted, in one such article, that pharmacies are paying more money for 37 percent of all generics than they did in the previous quarter. But that would imply that they paid the same or less for the other 63 percent of generic drugs. This would seem to follow a basic rule of thumb that, at any time, about a third of generic prices are going up, a third are staying the same, and a third are declining. This is the dynamic long observed in this highly competitive market.⁷ During an August 5th conference call to discuss financial results, CVS Health President and CEO Larry Merlo appeared to dismiss the notion that a broader generic inflation is underway.

"While the cost of goods inflation does exist on some generic items, it is not material in the context of our overall purchasing volume and again was generally within our expectations," he told investors. "On balance, the deflationary nature of the generic pharmaceutical market remains intact and overall, our pharmacy margins' increase this quarter for multiple reasons were in line with our expectations."

But recently, the cost increases appear to be larger and more frequent, attracting notice. Yet there is no data to suggest that this is part of a broader trend. In fact, as I noted, the aggregate data points to the opposite conclusion. Over any time period, there are always subsets of drugs that undergo substantial price increases as a result of many factors, often related to disruptions in raw materials. However, as I will conclude later, there is reason to be concerned that the cost of goods for generic drugs, more generally, could rise if we are not careful in how we implement some new policies. That's true even if, for now at least, it would appear that in the aggregate, brisk competition continues to hold down overall generic drug costs.

WHAT DO THE BIG PRICE HIKES TELL US?

Notwithstanding the favorable trends, some lawmakers have noted that there are examples where some generic drugs have undergone substantial price increases. A key question is whether there are common, underlying reasons for these price increases. Whether these anecdotes point to a larger failure of policy or markets?

Consider first, the 10 drugs that have been recently cited by lawmakers from both the House and Senate as examples where old generic medicines underwent substantial price increases over the last 2 years. These 10 drugs include doxycycline hyclate, albuterol sulfate, glycopyrrolate, divalproex, pravastatin, neostigmine, benzapril/hydrochlorothiazide, isuprel, nitropress, and digoxin.

Yet in looking at the circumstances surrounding the price rises, these drugs don't lend to any consistent, shared observations. In many cases, the active pharmaceutical ingredient used to manufacture a drug was in shortage because of plant closures. This was the case with doxycycline and perhaps some of the sterile, parenteral drugs included in this list. Some drugs have seen their use decline as a consequence of patient preference for other competing generic medicines in the same class. As a consequence, manufacturers have not maintained production of the less popular alternatives. This has the effect of creating temporary shortages. This appears to be the case, for example, with pravastatin sodium.

⁶Industrial Pharmacy, September 2006, Issue 11 http://thomsonreuters.com/business-unit/science/pdf/ls/pharma/challenges_generics.pdf

⁷Ed Silverman. To the moon: will rising prices for some generic drugs never end? The Wall Street Journal, November 14, 2014.

In some cases, there are temporarily fewer competitors in the market for certain generics as companies exited for business or regulatory reasons. This appears to be the case with digoxin. In the case of digoxin, as of January this year, there were two companies actively manufacturing and marketing the drug—Lannett and Impax. In January, Covis Pharmaceuticals also entered the market. One of the key events was the elimination of one of the manufactures of the API for Digoxin as a result of tightened FDA oversight of that manufacturing facility. In this case, the company (Westwood) had to curtail its supply of both API as well as its own, tableted version of the drug. It's worth noting that Digoxin is also difficult to formulate, especially at low dosage forms.⁸ Once a category is split between just two or three manufactures, it will follow that price will temporarily rise as competition declines.

How do we know this? It is well documented that significant generic drug price breaks of about 40 percent off the cost of the branded alternative are not achieved until there are at least four generic companies competing to manufacture the same drug. Prices don't fall to a sustainable and low equilibrium of about 20 percent of the cost of the branded drug until about seven manufactures enter the market. Moreover, the often-cited statistic that a generic drug is priced at just 10 percent of the cost of its branded alternative (or less) is not achieved until there are about 15 generic manufactures competing to market one particular generic medicine.⁹ It should follow suit that, if the market is competitive, these same economic principles will work in reverse. As generic manufacturers come in and out of the market for certain drugs, when competition falls, prices will rise until new firms enter the market. This is one of the principles that makes this market competitive, and self-correcting.

A critical question is whether the market for generic drugs is still self-correcting, or have other forces impeded the entry of new generic competitors into some of these categories. It has been said that generic drug mergers have reduced the number of generic manufacturers. While it's true that big generic companies have gotten larger, the market for generic drug makers is still vibrant. It is marked by literally thousands of different generic drug manufactures globally. But is the U.S. market still highly accessible to these companies? Is it still relatively straightforward, and inexpensive, to enter the market with a generic drug? In some cases, policies pursued by the U.S. have raised the cost of market entry for new generic manufacturers. This could reduce competition, and raise prices in the long run.

CONCERNS FOR THE FUTURE OF GENERIC PRICING

There are some gathering signs that the underlying cost structure in the generic drug industry is indeed rising, in a manner that could raise barriers to entry and increase the cost of goods in the long run. I believe we should focus more attention on this challenge. One factor is rising COGS in the generic drug industry. Some of this is driven by input costs. For example, commodities are part of the raw ingredient of certain drugs. On a broader scale, in most cases the single costliest input into the manufacturing of active pharmaceutical ingredients is the energy costs. As the price of energy has gone up in recent years, so will the underlying cost of the API.

Another reason is regulatory costs. In recent years, FDA has increased its oversight of generic manufacturing. The merits of FDA's oversight are beyond dispute. The balance struck between safety and access by FDA's sometimes-abrupt imposition of these new standards is beyond the scope of this discussion. But the fact remains that new standards were sometimes imposed with little notice or accommodation, leading to plant closures while facilities were remediated. Product shortages resulted. It's reasonable to ask whether, in cases where there was no imminent risk, facilities could have been remediated under close FDA supervision while they continued to produce key medicines, reducing the likelihood of shortages. This, however, has not been the policy. The bottom line is that COGS in this sector have gone up as a result. The higher manufacturing costs, and the tighter scrutiny applied to new manufacturing facilities, have increased the entry costs for new generic drugs and generic drug makers. How much costs have risen is difficult to fully quantify.

Competition is also diminished because FDA continues to be plagued by a backlog of generic applications. While generic drug user fees were intended to work this backlog off, it has actually increased. Moreover, FDA is now issuing refuse to receive

⁸<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1381504/>.

⁹U.S. Food and Drug Administration, Generic Competition and Drug Prices. <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

letters, basically telling some generic sponsors that the agency won't even file their applications because of deficiencies. In some cases, these deficiencies are largely clerical in nature. By refusing to receive certain generic applications, it could have the effect of understating the actual functional backlog of generic approvals. A key question is how many of the generic drugs being cited for taking large price increases are faced with competition that now sits in FDA's backlog?

Generic manufacturers are also facing higher costs as a result of increased product liability risks as a result of "failure to warn" claims that they are being exposed to for the first time. A new regulation FDA crafted, in part with this understanding and purpose in mind, will impose on generic manufacturers a requirement to unilaterally change their labels without FDA review and approval—which they are currently prohibited from doing. By placing this burden on generic drug makers, the effect of FDA's new regulation would expose generic firms to the same large torts that are targeted to branded drug firms. The action may undermine some of the key public health benefits that generic drugs provide by substantially raising the industry's costs, in the process reducing access to low cost generic medicines.¹⁰

The generic drug makers are also subject to user fees for the first time. These fees will help underwrite the investments needed to make sure the efficiency of FDA's generic drug approval process continues to improve. Nonetheless, the direct costs of these fees raise the barriers to generic entry, raise the cost of goods, and are ultimately passed on to consumers. These fees are not trivial. They include an application fee of \$58,730 for each ANDA, a \$29,370 fee for each new prior approval supplement (PAS) to an approved ANDA, a one time \$26,720 fee for the drug master files, a \$41,926 annual fee for domestic API Facilities, a \$56,926 annual fee for foreign generic drug API Facilities, a \$247,717 Annual fee for domestic finished dosage form facilities, and a \$262,717 annual fee for foreign FDF facilities.¹¹

In addition to these user fees, generic manufacturers face some other fees. For one thing, many generic applications are not filed under the generic ANDA pathway, which falls under 505(j); but under another pathway referred to as 505(B)2. When a generic application is filed under 505(b) it faces full, branded drug user fees (which are much higher than generic drug user fees). Moreover, these drugs are also subject to the drug fees created under the Affordable Care Act as a way to close the Medicare Part D "doughnut hole." This was the gap in drug coverage that seniors experienced as their drug costs fell in between the lower and upper boundary of coverage limits. The ACA said only that these fees would apply to drugs approved under 505B, which ends up including generic applications filed under 505(b)2.

Other, expenses are getting loaded onto the generic drug supply chain. While each may be small, they start to add up. For example, under new regulations, generic companies are required to do many more validation batches before they file ANDAs. Even shipping costs have increased. And a growing number of drugs need to be stored at more precise temperatures (an area of increased enforcement by FDA).

One of the central tenets of the generic drug framework was the idea that there would be low barriers to entry. Generic manufacturers have long faced substantially lower entry costs when compared with branded counterparts. Historically, enrolling a single patient in a BE/BA study as part of the ANDA required for a generic filing, on average, about \$1,000. Today, the average cost per subject ranges closer to \$5,000–\$6,000. In most cases, a BE/BA trial would enroll fewer than 50 patients to satisfy the requirements of the ANDA. Even that number has risen.

In addition, it had long been said that filing a generic application would cost about \$1 million, and a branded or specialty drug would become subject to generic competition once it reached \$10 million in revenue. It goes without saying that this \$10 million "rule of thumb" figure is substantially higher now. Recent data suggests that bringing a generic drug to the market can cost up to \$5 million per filing for a section viii filing, and another \$5–\$15 million for a paragraph IV filing. The amount of revenue or scripts a category must generate, before it attracts robust generic competition, has also increased beyond that \$10 million figure. That is another factor behind some of the very large price increases we have seen with a select number of older, generic drugs. For example, in 2014 the total sales of the generic doxycycline formulations that have been called into question were about \$6.9 mil-

¹⁰Scott Gottlieb, Alex Brill, and Robert W. Pollock. Proposed FDA generic drug regulation: Higher prices, no public health benefit, American Enterprise Institute Health Policy Outlook. March 12, 2014 <http://www.aei.org/publication/proposed-fda-generic-drug-regulation-higher-prices-no-public-health-benefit/>.

¹¹David Lennarz. FDA Updates Generic Drug User Fee Rates, FDA News. August 4, 2014. <http://fda-news.registrarcorp.com/2014/08/fda-generic-drug-user-fee/>.

lion.¹² These drugs, while expensive on a per pill basis, do not generate sufficient aggregate revenue to offset the investment needed to attract many competitors. That is why the market has not corrected more quickly in some of these cases.

The fact is that generic companies lose money on many of their offerings. They try and maintain a broad portfolio because it helps them contract and meet customer demand. So they continue to manufacture generic drugs even when they break even, or worse, sustain losses. But entering a category where they know they will lose money from the outset is another matter. These are not public utilities, notwithstanding the fact that they provide an important public benefit by delivering substantial value to consumers. At the end of the day, they need to remain profitable to continue to provide those benefits. Firms will take price increases in circumstances where the market will enable profits. This helps offset all of the situations where other circumstances create losses. The rising cost of entry increases the hurdle rate that must be offset for companies to enter new categories.

Consumers have an expectation in recent years that healthcare costs should start to level off or even decline. They have been promised as much in recent policy debates. And they have been conditioned to expect low prices when it comes to their old, generic medicines. So they are rightly concerned when prices on some old drugs undergo substantial increases, even if these costs aren't passed directly onto them. They don't follow the day-to-day headlines concerning supply shortages, manufacturing snafus, or the like. All they see are their bills.

The underlying cost pressures inside the generic drug industry are indeed changing. There is a risk that increased barriers to entry, increased cost of goods, and increased cost of regulatory scrutiny and manufacturing, can coalesce to lower the competition that this sector has long enjoyed, and the savings consumers have long appreciated. The anecdotal cases of substantial price increases that plague a subset of drug categories are concerning, but don't themselves point to any uniform trends. Instead, it is the underlying cost pressure that should merit our policy attention.

Dr. Gottlieb, a physician and Resident Fellow at the American Enterprise Institute, was FDA Deputy Commissioner from 2005 and 2007, and worked as a senior official at the Centers for Medicare and Medicaid Services during implementation of the Medicare Part D drug benefit. He consults for and invests in branded life science companies.

Senator SANDERS. Thank you very much.

Is Senator Warren going to introduce—is she here? Just in the nick of time. We're up to Dr. Kesselheim, and I think you want to introduce him.

Senator WARREN. Thank you very much, Mr. Chairman.

I'm very proud to be able to introduce the next witness, from Massachusetts. Dr. Aaron Kesselheim is an associate professor of medicine at Harvard Medical School and a faculty member in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital, where he directs the Program on Regulation, Therapeutics, and Law.

Dr. Kesselheim earned his bachelor's degree from Harvard University and his medical and law degrees from the University of Pennsylvania. He also earned his master's in public health from the Harvard School of Public Health, and he's certified in internal medicine and serves as a primary-care physician at the Phyllis Gen Center for Primary Care at Brigham and Women's Hospital.

Dr. Kesselheim's research focuses on the intersection of law and public health, looking in particular at how intellectual property laws and FDA regulatory policies impact drug development, the drug approval process, and the cost and availability of drugs. He's also investigated how other issues at this intersection can impact the healthcare system, including healthcare fraud, expert testimony, and malpractice cases, and insurance reimbursement practices.

¹²Gross Doxycycline Hyclate Sales by Calendar Year per IMS: 2012, \$13,105,912; 2013, \$10,975,295; 2014, \$6,937,065.

Just last week, Dr. Kesselheim addressed the issue of generic drug price increases with his colleagues at the New England Journal of Medicine.

Welcome, Dr. Kesselheim. We are very pleased to have you here today and to share your expertise.

STATEMENT OF AARON S. KESSELHEIM, M.D., J.D., M.P.H., ASSOCIATE PROFESSOR OF MEDICINE, BRIGHAM AND WOMEN'S HOSPITAL AND HARVARD MEDICAL SCHOOL, BOSTON, MA

Dr. KESSELHEIM. Thank you. Thank you very much.

Chairman Sanders, Ranking Member Burr, Senator Warren, members of the subcommittee, it's an honor to be here today to discuss the rising prices of some generic drugs.

Generic drugs are central to patient care. They're the main way that many patients afford the medications their doctors prescribe them. Inexpensive generic drugs translate to improved patient adherence and better patient outcomes. But, generic drugs are inexpensive because of competition. The cost of a generic product is closely related to the number of manufacturers producing it. So, today I want to highlight four ways that competition fails in the generic market, and six things that we can do about it.

First, limited competition may occur naturally. Take the case of Albendazole, a broad-spectrum antiparasitic medication approved by the FDA nearly 20 years ago. Perhaps because its indications are so few in the United States, it never attracted generic competitors. Recently, its rights were sold to a small company, which raised its price from about \$6 for a daily dose to over \$119 for a typical daily dose, exploiting this niche market and earning a hefty profit, despite investing no money in research and development of the drug.

Second, reduced competition can also occur because of market withdrawals. For example, the number of manufacturers producing Digoxin, used for heart failure, fell from eight to three from 2002 to 2013. During that time, the price rose by nearly 650 percent. Such contractions can be related to safety-related drug withdrawals or manufacturers deciding to pursue greater profits elsewhere.

Third, competition can be interrupted due to inappropriate anti-competitive acts, such as generic manufacturers buying out potential competitors. This is the sort of behavior policed by the Federal Trade Commission.

Finally, competition can be squeezed out by companies winning patents or new market exclusivities issued by the FDA. Thalidomide, for example, first synthesized in the 1950s, has recently been discovered useful in treating a rare type of cancer, multiple myeloma. Despite having no remaining patents on the underlying active ingredient, competing generics have remained blocked because of patents received on the drug's distribution pathway.

What can be done? I do not support wholesale changes to the current system of manufacturing or regulating generic drugs. But, when generic drug prices skyrocket, there is something wrong with the market, and the root causes need to be identified and fixed.

Now I want to turn to six possible solutions:

First, the government needs to be aware of spikes in drug prices so that it can adequately respond. Therefore, all increases in multi-source drugs of greater than 100 percent should be reported to the Secretary of HHS so that she can investigate the rationale for the increase and determine whether public intervention is necessary. Publication of price hikes should follow so that physicians and patients can be warned, as well.

Second, the FDA, under its current authorities, can fast-track potential generic drug manufacturers to permit the private market to function more efficiently. The high price in growing number of prescriptions may now attract additional entrants to the Albendazole market, which would help bring the price back down. Substantial increases in an unpatented drug's price should trigger the FDA to seek new market entrants proactively, and those responding should receive expedited reviews of their manufacturing processes and bioequivalence data. FDA user fees could be waived to further reduce the barriers to entry for potential competitors.

Third, if a vital generic drug comes to be produced by only two or three manufacturers or its price rises uncontrollably, the Federal Government may need to guarantee volume purchases, which would make companies' investments in producing these vital products more economically attractive, as it currently does in the childhood vaccine field. The government's commitment to purchase a fixed amount at a reasonable cost would encourage restoration of a competitive market.

Fourth, the FTC should ensure that price changes do not stem from anticompetitive behavior. The FTC needs greater resources to help it enforce maintenance of competitive markets.

Fifth, interventions can also come at the government payer level. The law creating Medicare Part D, for example, forbids interference with a negotiation of drug prices or institution of a price structure in this 80-billion-dollar-per-year program. If this noninterference provision could be waived for generic drugs, then CMS would be in a better position to combat exorbitant increases in drug prices.

Finally, over the long term, reforms to the patent and market exclusivity system may be warranted. There is a low bar to obtaining new patents on peripheral aspects of old unpatented drugs, such as the business method patent at issue in the Thalidomide case. Minor changes in an old drug's formulation or other limited alterations should not lead to new market exclusivity protections.

In conclusion, I want to thank this subcommittee for its attention to this important issue. Failures in this market are events we need to take seriously, because they lead to disruptions in the supplies of lifesaving drugs to patients, affecting countless lives.

As I was preparing for this hearing, I was chatting with a physician colleague of mine, who told me about a market research firm who contacted him in the last week with a survey from a manufacturer of a decades-old drug that sells for \$70 for an entire course of therapy but faces little competition in the market at present. The final question posed to my colleague was, Would you still prescribe this drug if the price was \$10,000? As a healthcare system and as a nation, we need to make sure that question is off the table for generic drugs.

[The prepared statement of Dr. Kesselheim follows:]

PREPARED STATEMENT OF AARON S. KESSELHEIM, M.D., J.D., M.P.H.

SUMMARY OF MAJOR POINTS

- Generic drugs are one of the central components of the health care system. The generic drug industry has a long history of producing high quality drugs at very reasonable prices, which saves patients money, promotes adherence, and improves clinical outcomes.
- Generic drugs are inexpensive because they can be reliably synthesized and packaged for pennies per pill and they are made by manufacturers that can make a profit charging closer to the unit cost of production because their development costs were low. Competition among these manufacturers leads prices to approach the unit cost of production.
- Competition among generic or multisource drug manufacturers can vanish for a number of reasons, including manufacturers' business decisions, fluctuations in market supply and demand, anticompetitive behavior from sellers or purchasers, and re-assertion of patent or market exclusivity rights.
- The first solution is greater transparency: all increases in multisource drug prices of greater than 100 percent should be reported to the Department of Health and Human Services, which can investigate the rationale for the increase in price and determine whether some sort of public intervention is necessary.
- The FDA Office of Generic Drugs can responsibly fast-track potential generic drug entrants into markets where high prices result from manufacturers exploiting natural monopolies, waiving the user fees to further reduce barriers to entry for potential competitors.
- The Federal Trade Commission requires increased funding to be able to intervene in the generic drug market to ensure that price changes do not stem from anticompetitive behavior.
- Interventions can also come at the government payor level. If the Medicare Part D non-interference provision was waived for multisource drugs, then the Centers for Medicare and Medicaid would be in a better position to combat exorbitant increases in drug prices.
- Over the long-term, reforms to the patent and drug market exclusivity system may be warranted to help prevent more older drugs from soaring in price.

Chairman Sanders, Ranking Member Burr, and members of the subcommittee, my name is Aaron Kesselheim. I am an internal medicine physician, lawyer, and health policy researcher in the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital in Boston and an Associate Professor of Medicine at Harvard Medical School. I lead the Program On Regulation, Therapeutics, And Law (PORTAL), an interdisciplinary research team studies the intersections between laws and regulations and the development, utilization, and affordability of drugs. It is an honor to have the opportunity to share my thoughts with you about the rising prices of some generic drugs.

Generic drugs are one of the central components of the health care system. Generic drugs become available after the expiration of the market exclusivity period for brand-name drugs, and are the main way that many patients are able to afford the medications their doctors prescribe for them. The FDA reviews them carefully for purity and bioequivalence with the brand-name, standards which are almost always met before the drug is marketed.¹ Meta-analyses I have led, including one published in the *Journal of the American Medical Association* in 2008,² found no evidence of any clinical differences in studies comparing brand-name and generic drugs, even among the small number of special "critical dose" drugs that have their effective and toxic ranges separated by relatively small differences.

Having the same effectiveness and safety as their brand-name counterparts, generic drugs can provide reliable clinical outcomes for patients. What sets them apart from brand-name drugs is their low cost. When generic manufacturers market their versions after the end of the brand-name drug's market exclusivity period, prices can over time be reduced by as much as 80–90 percent. With low-cost generic drugs currently making up about 84 percent of all prescriptions, the cost savings related to generic drug prescribing has saved U.S. patients over a trillion dollars in the last decade alone.³ Inexpensive generic drugs translate to improved patient adherence and better patient outcomes. A recent study led by Josh Gagne in my Division showed that patients initiating a low-cost cholesterol-lowering drug had better medication adherence and, as a result, an 8 percent reduction in hospitalization for acute heart disease, stroke, and death compared to patients initiating a high-cost cholesterol-lowering drug.⁴

Why are generic drugs inexpensive? They are inexpensive because most small molecule prescription drugs can be reliably synthesized and packaged for pennies per pill. Brand-name drugs sell for much more—recently, the \$1,000 per pill cost of sofosbuvir (Sovaldi) for hepatitis C virus has been widely debated—because they are protected by government-issued patents and various FDA rules that prevent competitors from making their own versions of the drug. The government provides limited periods of market exclusivity for brand-name drugs because innovative drug development is expensive. These monopoly periods permit the brand-name manufacturers to charge far above the unit cost of producing the pill to help compensate for the millions of dollars in research costs involved in clinical trials and other tests leading to the development of a new drug. After the market exclusivity period ends, competition is initiated by other manufacturers that do not have as high of development costs and can therefore still make a profit charging closer to the unit cost of production. Competition leads prices to decrease for these multisource drugs and approach the unit cost of production.

We take for granted that older drugs are inexpensive, but competition is the reason why they are reliably inexpensive. This competition can vanish for a number of reasons, including business decisions by manufacturers, fluctuations in the supply and demand of the market, anticompetitive behavior, and re-assertion of patent or market exclusivity rights. When any of these things happen, prices skyrocket.

First, generic drug prices can rise because of a confluence of business decisions and profit-seeking from manufacturers. Take the case of albendazole, a broad-spectrum anti-parasitic medication first marketed by corporate predecessors to GlaxoSmithKline (GSK) outside the United States in 1982 and approved by the FDA in 1996. Albendazole is rarely used in the United States, and the parasitic infections it treats usually only occur in poorer populations such as immigrants and refugees. Though its patents have expired, GSK remained the sole producer of the drug until the company sold its U.S. marketing rights to Amedra Pharmaceuticals, a small private firm, in October 2010. In 2011, Teva, the producer of the only potential therapeutically interchangeable competitor mebendazole (Vermox), discontinued production of its product for non-safety related reasons. In last week's *New England Journal of Medicine*, my co-authors and I reported that between late 2010 and 2013, the listed Average Wholesale Price for U.S. patients rose from about \$6 to over \$119 per typical daily dose. For a routine 6-month course of therapy, an uninsured patient therefore faces tens of thousands of dollars in costs. Insurance payors were also strongly affected, particularly Medicaid, the Federal- and State-funded health insurance program for the poor. Medicaid spending on albendazole rose from less than \$100,000 in 2008 (\$36.10/prescription) to over \$7.5 million in 2013 (\$241.30/prescription).⁵ In this case, Amedra exploited an existing monopoly on a niche drug, a tactic that was successful in part because of the exit of another manufacturer from the market. It is worth pointing out that companies in these circumstances can earn high revenues without having made much, if any, investments in research and development.

Second, competition can languish because of changes in the drug industry and manufacturing challenges. For example, the number of manufacturers producing oral digoxin tablets, used for atrial fibrillation and heart failure, fell from 8 to 3 companies from 2002 to 2013; during that time, the price of digoxin reportedly rose by 637 percent.⁵ The market contraction was thought to be related in part to safety-related drug recalls and manufacturers deciding to leave the market. The cost of a generic product is closely related to the number of generic manufacturers producing it, with the first generic manufacturer pricing its drug only slightly below the brand-name manufacturer's price, and the second pricing it at only about half the price. By the FDA's estimation, it is not until the number of generic manufacturers reaches more than 5 that the price falls to under 25 percent of the brand-name price.⁶ Shortages from reduced supply or increased demand can play a role in these circumstances. For example, hospitals like Brigham and Women's Hospital, where I see patients, have been struggling with intermittent shortages of normal saline (that's salt water) and other vital unpatented, multisource basic healthcare products due to unexpected demand and variations in supply from manufacturers with production irregularities at their plants. These changes can sometimes lead to spikes in the price of the products.

Third, competition can be interrupted due to horizontal or vertical mergers, or inappropriate anticompetitive behavior. These sorts of activities fall under the oversight of the Federal Trade Commission (FTC). When the FTC has reviewed mergers of generic drug manufacturers, it has sometimes ordered the new entity to relinquish control of certain drug products if the transaction would lead to anticompetitive effects from a decrease in the number of independent competitors in the markets at issue.⁷ A more recent case of a potentially anti-competitive business arrange-

ment supporting high prices for a very old drug occurred in the case of the 60-year-old drug ACTH, now marketed as H.P. Acthar Gel, a treatment for hard-to-manage seizures in young children, as well as severe cases of multiple sclerosis. The medication used to sell for as little as \$40 per vial until a small company called Questcor bought it in 2001. According to reports in the *New York Times*, the manufacturer raised the price immediately to \$700 per vial, and then increased it to \$23,000 per vial in 2007.⁸ When another company sought to bring a lower-cost competing drug named Synacthen into the market in 2013, Questcor bought the rights to Synacthen.⁹ Synacthen remains unapproved, while H.P. Acthar Gel cost Medicare more than \$141 million in 2012 alone¹⁰ for a drug first FDA-approved in 1952.

Finally, competition among multisource drug manufacturers can be squeezed out by companies winning patents or new market exclusivities issued by the FDA. Thalidomide, for example, is famous for its tragic role in helping modernize the FDA in the 1960's, and was later discovered to be effective in treating a rare type of cancer, multiple myeloma. However, despite the fact that there are no remaining patents on the underlying active ingredient in thalidomide, competing generic versions have remained blocked because of patents that the current manufacturer of the drug received on its distribution pathway.¹¹ In the case of the anti-gout drug colchicine, the FDA sought to bring production of generic colchicine under its regulatory umbrella. Versions of colchicine had been available in the United States since the 19th century and thus it was never formally approved by the FDA as an individual pill. It was sold by multiple manufacturers at about 9 cents per pill until the FDA formally approved one version of it in 2009 and gave that manufacturer a period of market exclusivity. After the FDA's action, this manufacturer raised the price to \$4.85 per pill.¹² Another price jump happened under similar circumstances in 2011 when the FDA approved a synthetic progestin drug called 17 alpha-hydroxyprogesterone caproate (17OHP), which is used to reduce the risk of preterm birth in pregnant women, and was available through many different compounding pharmacies at about \$300 per dose.¹³ In 2011, the FDA approved one manufacturer's version of it. When the manufacturer raised the price to \$30,000 per dose, the FDA—under pressure from legislators—announced that it would continue to permit production of the drug from compounded sources.¹⁴ With competition in the market re-established, the company could not sustain its intended exorbitant price.

So what can be done? I do not support wholesale changes to the current system of manufacturing or regulating generic drugs. The generic drug industry serves an extremely valuable function in the health care marketplace, and has a long history of producing high quality drugs at very reasonable prices, which saves patients money, promotes adherence, and improves clinical outcomes. But when generic drugs skyrocket in price, there is something wrong with those markets, and the root causes of the problems need to be identified and fixed. Failures in the generic drug market are events that legislators and policymakers need to take seriously, because they can lead to disruptions in supplies of lifesaving drugs to patients. Thus, I first suggest investment into research surveying the extent of high generic drug prices, as well as a comprehensive examination of their causes. We need a systematic approach to understanding the problem so that focused solutions can be developed. If the markups are related to other points along the drug distribution chain, such as wholesalers or pharmacies, this should be clarified.

However, because high prices for some generic drugs are already reaching critical levels, more immediate actions are necessary. It is critical for the government to be aware of spikes in drug prices so that it can adequately respond. Therefore, all increases in multisource drug prices of greater than 100 percent should be reported to the Secretary of the Department of Health and Human Services so that she can investigate the rationale for the increase in price and determine whether some sort of public intervention is necessary. Publication of these price hikes should immediately follow so that physicians and patients can be warned about the impending changes. Too often, patients are not aware of these fluctuations in price until they try to fill a drug at their pharmacy, which can lead to patients having to choose between filling their medication and other basic necessities and then to gaps in medication adherence. Physicians may be able to determine alternative inexpensive medication regimens for patients, a process that will be aided by advanced notice of these changes.

In addition to greater price transparency, there are some potential short-term options to help mitigate high prices. One option would be for the FDA Office of Generic Drugs to take a more proactive posture and fast-track potential generic drug entrants into markets where high prices result from manufacturers exploiting natural monopolies. While albendazole may not be of interest to many manufacturers at a low price, its current high price and growing number of prescriptions may now attract additional entrants, which would help bring the price back down. The FDA

should do everything in its current power to facilitate these new market entrants as quickly and as safely as possible. According to the FDA, the standard processing time for a generic manufacturer's application is about 10 months, which does not include the time it takes for the generic manufacturer to address any deficiencies in its proposal. Legislation in 2012 created new generic drug user fees that promise to reduce such wait times by providing greater funding for FDA staff. In addition, under its current legal authority, the FDA can create special pathways that permit the private market to function more efficiently. Substantial increases in an unpatented drug's prices should trigger the FDA to issue public announcements seeking other generic manufacturers of the product and that those responding to such a request should receive expedited reviews of their manufacturing processes and bioequivalence data.⁵ Generic drug user fees could be waived in these circumstances to further reduce barriers to entry for potential competitors.⁵

Ultimately, policymakers might be forced to apply a lesson from the childhood vaccine field, in which production of needed vaccines occasionally became threatened in part because manufacturers were not assured of enough profit to continue. The Federal Government intervened with guaranteed volume purchases,¹⁵ which made companies' investments in producing these vital products more economically attractive. Since the government is currently the largest single payor of drug bills in the country, we may need to consider a system that would come into play if a vital generic drug comes to be produced by only 2 or 3 manufacturers, or its price begins to rise uncontrollably. At that point, the government, perhaps through the Veterans Administration, Medicare, or Department of Defense, could issue a commitment to purchase a fixed amount of this drug at a more reasonable cost over a certain period of time, to encourage restoration of a more competitive marketplace for that product.

The Federal Trade Commission also should play an important role in intervening in the generic drug market to ensure that price changes do not stem from anti-competitive behavior. The FTC clearly has interest in this area, but needs greater resources to help it enforce the maintenance of competitive markets in the generic drug industry on behalf of both suppliers and purchasers of multisource drugs. The FTC's work would be aided by greater transparency that might alert it to the possibility of inappropriate behavior.

Interventions can also come at the government payor level. It is worth noting that Medicare currently negotiates or sets prices for basically every health care service it pays for—physician time, radiology services, laboratory services, hospital stays—but it is forbidden from negotiating the prices of prescription drugs. A clause in the statute creating the government's \$80 billion per year Medicare Part D program, for example, explicitly states that the Secretary of HHS cannot interfere with the negotiations of drug prices or institute a price structure. If this non-interference provision was waived for multisource drugs, then the Centers for Medicare and Medicaid would be in a better position to combat exorbitant increases in drug prices. Such a change would require congressional action.

Finally, over the long-term, reforms to the patent and drug market exclusivity system may be warranted to help prevent older drugs from soaring in price. Under current interpretation of basic patentability requirements, such as novelty and non-obviousness, there is a relatively low bar to obtaining new patents on peripheral aspects of old, unpatented drug products, such as the business method patent at issue in the thalidomide case. While true research or business innovations deserve patents, it may be worth clarifying the legal standards for issuing patents in the pharmaceutical market so that minor changes in an older drug's formulation or other limited alterations do not lead to new market exclusivity protections. Similarly, in the future, the FDA should be wary when its actions lead to new market exclusivity protection for old and inexpensive products, knowing that extremely high prices will inevitably result, so that the colchicine case is not repeated.

In conclusion, I want to thank this subcommittee for its attention to the very important issue of high generic drug prices, which are affecting more patients with each passing year. Without timely intervention from legislators and other government policymakers, this issue threatens to grow worse, impacting countless lives. As I was preparing for this hearing, I was chatting with a physician colleague of mine who told me about a call he received from a market research firm asking questions on behalf of a manufacturer of a decades-old drug that currently sells for \$70 for an entire course of therapy but faces little competition in the market at present. After the standard questions about his perceptions of the drug's clinical utility and side effects, the final question posed to my colleague was: "Would you still prescribe this drug if the price was \$10,000?" As a health care system and as a nation, we need to keep that question off the table for generic drugs.

REFERENCES

1. Davit BM, Nwakama PE, Buehler GJ, Conner DP, Haidar SH, Patel DT, Yang Y, Yu LX, Woodcock J. Comparing generic and innovator drugs: a review of 12 years of bioequivalence data from the United States Food and Drug Administration. *Ann Pharmacother*. 2009;43(10):1583–97.
2. Kesselheim AS, Misono AS, Lee JL, Stedman MR, Brookhart MA, Choudhry NK, Shrank WH. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. *JAMA* 2008;300(21):2514–26.
3. Government Accountability Office. Drug pricing: research on savings from generic drug use. <http://www.gao.gov/assets/590/588064.pdf>.
4. Gagne JJ, Choudhry NK, Kesselheim AS, Polinski JM, Hutchins D, Matlin OS, Brennan TA, Avorn J, Shrank WH. Comparative effectiveness of generic and brand-name statins on patient outcomes: a cohort study. *Ann Intern Med*. 2014;161(6):400–7.
5. Alpern JD, Stauffer WB, Kesselheim AS. High-cost generic drugs: implications for patients and policymakers. *New England Journal of Medicine* 2014;371(20):1859–62.
6. Food and Drug Administration. Generic competition and drug prices. March 1, 2010. Available at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.
7. Federal Trade Commission. Analysis of agreement containing consent orders to aid public comment, In the matter of Novartis AG, File No. 121–0144. July 2012. Available at: http://www.ftc.gov/sites/default/files/documents/cases/2012/07/120716_novartisanal.pdf.
8. Pollack A. Questcor finds profits, at \$28,000 per vial. *NY Times*. December 29, 2012.
9. Pollack A. Questcor pays \$135 million to acquire rights to a competitor's drug. *NY Times*. June 14, 2013.
10. Ornstein C. The obscure drug with a growing Medicare tab. *ProPublica*. Aug 4 2014. Available at: <http://www.propublica.org/article/the-obscure-drug-with-a-growing-Medicare-tab>.
11. Sarpatwari A, Avorn J, Kesselheim AS. Using a drug-safety tool to prevent competition. *New England Journal of Medicine* 2014;370:1476–78.
12. Kesselheim AS and Solomon DH. Incentives for drug development: the curious case of colchicine. *New England Journal of Medicine* 2010;362(22):2045–47.
13. Armstrong J. Unintended consequences—the cost of preventing preterm births after FDA approval of a branded version of 17OHP. *New England Journal of Medicine* 2011;364:1689–91.
14. Food and Drug Administration. FDA statement on Makena. March 30, 2011. Available at: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm249025.htm>.
15. Hinman AR, Orenstein WA, Rodewald L. Financing immunizations in the United States. *Clin Infect Dis* 2004;38:1440–47.

Senator SANDERS. Thank you very much, Dr. Kesselheim.

Let me begin by making this point, then asking a question. According to Medicare and Medicaid data, between July 2013 and July 2014, half of all generic drugs went up in price. During this time period, nearly 10 percent of all generic drugs more than doubled in price. And that's some 1,200 drugs, not a handful of drugs. And, in fact, some of these drugs went up by 500–600 percent. So, the concern here is not whatever the explanation may be for a small number of drugs—maybe low-volume drugs usually escalating in price, it is a concern that thousands of drugs may go up. Should we be worried about that? And what do we do about it?

Dr. Schondelmeyer, why don't you start.

Mr. SCHONDELMEYER. Absolutely we should be worried. That data you presented reflects my own experience. I work at the University of Minnesota, and help manage our drug benefit. And, just on Monday, we were reviewing the top prescribed drugs in our plan, and most of those are generics. And, of the generics, three-

fourths of those generics on our top-prescribed list went up in price. They were on the list of drugs that have had extraordinary high price increases.

Senator SANDERS. Significant increases in prices?

Mr. SCHONDELMEYER. Yes, sir. These aren't just isolated the low-volume drug that drug companies think they can slip by and it won't affect the market that much, people won't worry about them.

Senator SANDERS. You think that consumers all over this country should be worrying about this trend.

Mr. SCHONDELMEYER. Absolutely. And the data base we looked at in the AARP study includes data nationwide for both commercial payers and Medicare and Medicaid.

Senator SANDERS. OK.

Let me go to Mr. Frankil.

Mr. FRANKIL. Yes, I agree, we should all be concerned about this.

Initially, consumers don't feel the price right away. Oftentimes, there's a copay, and maybe not until you get into your coverage gap or your donut hole do you feel the difference. There's a delayed reaction by the public. The public does feel it eventually. I'm surprised that some of the payers haven't stepped up a little sooner—private payers and public payers—because they've eventually got to pay the bills.

I also want to mention, as Dr. Schondelmeyer said, that some of these drugs that are dramatically going up in price are not low-volume drugs. There's quite a few very high-volume drugs. Pravastatin is a top-20 drug. Levothyroxine, which has nearly doubled in price in the past 6 to 9 months, is a top-5 drug. These are high-volume drugs affecting the majority of America, and we should be concerned. I don't know what agency it is, but there should be an agency in the Federal Government that watches over this and has the power to do something about it, and also monitors the PBMs and the insurance companies to pay pharmacies appropriately. We shouldn't be put in a position to lose money.

Senator SANDERS. OK.

Ms. Riha, you are not a pharmaceutical expert, you're just an ordinary human being—

Ms. RIHA. Right.

Senator SANDERS [continuing]. Struggling economically. What do these price increases mean to you and, I think, for millions of other folks?

Ms. RIHA. As I said, I charge these on my credit card, so eventually it will have to be paid off. But, there are millions of Americans who don't have the wherewithal to do that, so they're having to make the real choices every week. Do I pay my prescription or do I let it go? Do I pay for food this week? Do I pay for gasoline? I don't have Medicare coverage or Medicaid at this point, because I'm too young, but my health insurance—and it's Obamacare, thank you very much, and I'm very pleased with it—

Senator SANDERS. Yell that to Senator Burr.

Ms. RIHA. Senator Burr, I really love my Obamacare.

[Laughter.]

Senator BURR. Listen, I'm on it, too. I don't share the cost increase quite as much as you do, but the coverage is good.

Senator SANDERS. All right, no speeches. I gave you a shout-out here, and you gave me a speech.

[Laughter.]

Ms. RIHA. There is some health insurance coverage of many of these medications, but it doesn't cover the whole cost. And, as costs go up, people can't pay the additional cost that's not covered by insurance.

Senator SANDERS. OK.

I wanted to ask Dr. Gottlieb—you mentioned low-volume drugs, but Mr. Frankil and Dr. Schondelmeyer said that it's not just low-volume drugs. Your response to that?

Dr. GOTTLIEB. It's a diverse list. A lot of it is low-volume drugs. And there's examples where there are high-volume drugs. If we want to get an accurate picture of what's happening in the market overall, you need to adjust the prices and the price increases based on script volume.

The other thing is, the list also includes parenteral drugs, and they've faced a whole other set of regulatory issues, some very specific issues addressing those. I think to really get at the root cause, we need to carve up the list a little bit more finely, because there's very discrete issues with certain categories of drugs.

Senator SANDERS. OK.

Dr. Kesselheim.

Dr. KESSELHEIM. I think these regulatory issues have been around for a really long time, and this is a new issue. I can't see how this is a regulatory problem. I think that we all want high-quality, safe drugs, and we want the FDA to be monitoring the safety of our drug supply. And it's been doing that, and it's continuing to do that. I see this as a market failure, and a bunch of individual market failures, in some cases. As Dr. Gottlieb said, I think that there are a diversity of reasons why these kinds of price jumps happen. We need to look into quantifying exactly what those are, and then take steps to specifically address those failures.

Senator SANDERS. OK, thank you.

Senator Burr.

Senator BURR. Thank you, Mr. Chairman.

Ms. Riha, since you raised the question, and just so you know it, my coverage is about the same, from the standpoint of what it covers. My premium went up \$100 a month, and I have a \$3,000 deductible, where I had zero before. My experience with the coverage has been a fantastic cost increase to me. Unfortunately, I don't have a hearing in Congress to hear my complaint.

But, I'm glad you're here. I understand your problem. And, as a Member of Congress, I'd love to see the problem fixed. I'm just not sure that it's in the power of us, as legislators.

I want to go to Dr. Kesselheim, because you raised some really great ideas. If you have a regulatory system that's responsive to it, you'd have an FDA—and I just go to your points, and if I missed one of them, let me know—the FDA should fast-track applications that create competition. We know an application is now 36 months versus 31 months. Before, we didn't have user fees. Now we've got user fees, and the application process has slowed down. You said, "Waive the user fees." If user fees are what is keeping manufacturers from putting applications in, and they want to create a generic

competitor that would help to bring costs down, let's waive the user fees for the company. If I missed another one, I'm sorry. But, if you were FDA director today, would you be proposing those actions by the FDA with what we see, as part of the solution?

Dr. KESSELHEIM. I think both are reasonable responses to try to address individual market failures in particular drugs. Currently, there is a queue for review of new generic drug applications. If we're seeing prices rise by 500 percent, 1,000 percent, because the market has contracted and we need more entrants into the market, it makes sense to me that there are going to be actual patients who are going to be affected by this who are going to stop taking their medications and have changes in their healthcare because of it. The FDA should be nimble enough to respond to that by fast-tracking the applications to try to respond to that. And if a barrier to entry might be the payment of a user fee, then, in this particular field, as we're trying to attract more competitors to it, waiving the user fee in that particular instance might be worth it. I think that Congress could step in and increase the funding to the FDA to make up for any lack of user fees that comes out because of it.

And I think that the third part of that was that government payers could also step in to try to establish a more predictable market by putting out bids for certain amounts of the drug at a certain reasonable price so that when manufacturers are coming into the market, they can know that they have a guaranteed purchaser that'll be there and it's not just going to all disappear in 3 to 6 months.

Senator BURR. Let me go to Dr. Gottlieb, if I can, for the two points that you raised which were FDA-centric.

With your experience at the FDA, does the FDA have the authority to pick and choose what they fast-track and/or choose to waive user fees under the agreements with the manufacturers?

Dr. GOTTLIEB. Not to waive user fees right now. The FDA has limited authority to change the prioritization of how they review applications. A lot of the existing regulations were put into place following the generic drug scandals in the 1980s, if some of us remember that, where FDA pulled back from doing anything to prioritize how they reviewed applications, other than first-in/first-out. We did, when I was there, promulgate a policy to prioritize first-in-class generics. FDA could promulgate policies to do more prioritization—they do some right now—of generics, where it's a critical need, where there's access problems, concerns around limited access because there's one manufacturer in the market, and there's no therapeutic substitution of a product.

There are things that the FDA could do along the lines of what Aaron suggested. I wouldn't prioritize based on price. I think that would be moving the process in the wrong direction.

Senator BURR. Dr. Gottlieb, would we find agreement between the three of us if I said the FDA is not nimble and it's not flexible?

Dr. GOTTLIEB. I think the FDA would not be as nimble under its current regulations to do what he's suggesting. They probably have more authority than they're exercising to prioritize based on access issues.

Senator BURR. OK.

Let me ask one last question, if I can. If the FDA were to finalize the generic drug labeling rule, what effect do you believe that would have on generic drug pricing? I'm not speaking to the specifics that we've used as examples, but the overall generic drug pricing.

Dr. GOTTLIEB. This is another concern that's raising the cost of goods in the industry overall, is that the industry is now going to be exposed to the same kind of product liability for alleged failure to warn cases that plagued the Brandon industry. And we see how much litigation costs are on the Brandon side. The generics are ostensibly going to be exposed to those same costs. It's going to get baked into the price of the drugs.

Senator BURR. Thank you, Mr. Chairman.

Senator SANDERS. Thank you, Senator Burr.

Senator Warren.

STATEMENT OF SENATOR WARREN

Senator WARREN. Thank you, Mr. Chairman.

And thank you all for being here today.

Dr. Gottlieb, in your testimony you say, among other things, that increasing FDA oversight of generic manufacturers is playing a role in increasing the costs of generic drugs. And you made a similar argument, back in 2011, when you testified before the Senate Finance Committee and cited increases in FDA oversight as a factor contributing to drug shortages. So, I'd like to examine that claim about the FDA's "tighter scrutiny" a little bit more closely.

One way that regulatory opponents often track FDA oversight is by looking at the number of warning letters that the agency sends out. And these letters basically tell a company to stop breaking the law, or face the consequences from that. And there has been a significant increase in FDA warning letters in the past 2 years, from about 2,000 in 2011 to nearly 7,000 in 2013. That's almost a 400-percent increase. And it would certainly be noteworthy if those letters went to drug manufacturers. Do you know how many of them did, Dr. Gottlieb?

Dr. GOTTLIEB. The warning letters went to drug manufacturers—

Senator WARREN. Yes.

Dr. GOTTLIEB [continuing]. For manufacturing violations?

Senator WARREN. Well, no—went to drug manufacturers.

Dr. GOTTLIEB. I would suspect a significant portion of those letters went to drug manufacturers.

Senator WARREN. Actually, my staff checked with the FDA this week, and it turns out that almost none of those letters went to drug manufacturers. Most of them were about tobacco regulations. In fact, in 2013 only 11 of the nearly 7,000 FDA warning letters were about generic drug manufacturing problems, and that was down from a grand total of 20 such letters in 2011.

Your testimony states that pharmacies paid about 40 percent more for generics last quarter than they did the previous quarter. So, I just want to focus on this part of it. Do you think it's reasonable to argue that such an increase, a 40-percent price increase, resulted, even in part, from the FDA issuing 11 manufacturing warning letters last year?

Dr. GOTTLIEB. It's hard to analyze that in the abstract, and I'm not sure that we're talking just about warning letters or untitled letters. But, you know, it is the case that, when you look at things like the parenteral drugs, which is what the 2011 testimony was about, I believe, fully 25 percent of the manufacturing capacity for 20—for parenteral drugs has been taken out of the market. And that's led to, not only price increases, because you don't have—

Senator WARREN. OK, but I'm—

Dr. GOTTLIEB [continuing]. As many manufacturers, but shifting—

Senator WARREN [continuing]. I'm trying to focus—

Dr. GOTTLIEB [continuing]. The compounding—OK, sorry.

Senator WARREN. I'm trying to focus on this question about the letters, because this is often one of the ways that those who oppose the regulations focus in. And I get it that there are a lot of other things going on, including other forms of regulation. But, I've actually taken a look at those, as well, and the FDA, last year, issued a grand total of five injunctions against drug companies and one seizure of product. That's fewer overall concerns. That's 11 warning letters, five injunctions, and one seizure, compared with a 40-percent price spike just this year. And so, the question is, Is it reasonable to try to tie those specifically together—we're talking about enhanced FDA enforcement—or not?

Dr. GOTTLIEB. Right. Well, I wouldn't tie warning letters to the points I was making. I would look more at the 483 findings, if you want to look at the FDA's oversight in manufacturing, and I would look at what's happened to overall manufacturing capacity or of it's a result of FDA inspections. I think that would correlate with competitiveness in the market if you were trying to find proxies for what was happening—

Senator WARREN. But, as I understand it, the forms you're talking about are down, as well, and we're seeing prices go up. So, I'm—

Dr. GOTTLIEB. When FDA does inspections, 483s are issued. You're saying inspections are down? Inspections—

Senator WARREN. Well, I'll tell—

Dr. GOTTLIEB [continuing]. Are probably up.

Senator WARREN [continuing]. We'll talk about inspections in just a minute. I wanted to stay focused on this part.

I understand that individual enforcement actions may temporarily affect the price or availability of a particular drug, but data demonstrating decreasing enforcement over manufacturers does not justify a price spike of 40 percent. The numbers just don't line up between the prices and regulatory enforcement.

Let's go to the inspections for just a minute, since you've raised that. You also suggest that if there is no imminent risk from a manufacturing violation, then manufacturing facilities should be allowed to continue to produce medications, Dr. Gottlieb. I want to think about what that would mean.

The FDA has noted that roughly 40 percent of the generic drugs in the United States are now manufactured in India. In 2012, Ranbaxy, a major Indian manufacturer, pled guilty to seven Federal criminal counts of selling adulterated drugs. And that same year, they recalled nearly half a million bottles of generic Lipitor

that could have contained tiny glass particles. In 2013, the FDA imposed an import ban on another Indian manufacturer named Wockhardt after inspectors found urine spilling over open drains a few feet from sterile manufacturing areas and found mold growing in a storage area containing raw drug materials.

Do you expect us to believe that, after 30 years of successful cost and quality control in the generic drug market, that the American public now has to choose between drugs that are much more expensive and drugs that come from dirty facilities, possibly contaminated with mold, urine, or glass?

Dr. GOTTLIEB. Certainly not. What I actually said was that, rather than issue a public 483, which forces manufacturers typically to close facilities because of liability risks that they would face, what we could do in cases where there's not an imminent risk is allow them to remediate those facilities under close FDA supervision. And that's exactly what's been done in a case, for example, under Team Biologics, with vaccine manufacturers. Now, certainly urine on the floor of a plant would qualify as something you might want to close the plant for if you're under close FDA supervision.

Senator WARREN. All right. I'm sure there are ways that we could streamline our oversight of drug manufacturers. But, let's be clear, India is producing 40 percent of our generic drugs, and the FDA's supposedly burdensome oversight team in that entire country consists of 10 full-time employees. That's 10 people to watch over the production of billions of doses of medicine to make sure that they aren't laced with broken glass or splashed with urine.

I'm sure that some generic drug manufacturers would like to blame their price increases on the FDA and its 10 full-time employees in India, but I think we need a deeper investigation into the price hikes. Frankly, I think we need more support for those FDA inspectors who are trying to keep our drugs safe.

Thank you, Mr. Chairman.

Senator SANDERS. With that, there are some votes on the floor right now.

Senator BURR. Mr. Chairman?

Senator SANDERS. Yes.

Senator BURR. Could I ask unanimous consent that my opening statement be included, as prepared?

Senator SANDERS. Of course.

Senator BURR. Thank you.

Senator SANDERS. Let me thank all of the panelists for their participation in this discussion of an enormously important issue. Thank you all very much.

The hearing is ended.

[Additional material follows.]

ADDITIONAL MATERIAL

PREPARED STATEMENT OF SENATOR BURR

While I share the concerns regarding the importance of Americans being able to access affordable health care, I am also concerned that today's hearing not interfere with the reported Federal investigation into generic drug prices. It is my hope that today's hearing will be conducted in a manner befitting of the Senate and this committee.

Over the past few years, a lot of promises about affordable health care were made, and a lot of promises have been broken. When a patient is sick and needs a prescription drug, they are understandably most concerned about whether that drug is available and if they can afford it. As we examine the reasons behind why some generic drugs have experienced price fluctuations, I hope that the committee does not lose sight of the important role prescription drugs play in delivering quality care to patients in need of these therapies. These life-saving products not only help many Americans to meet their health care needs, but also improve patients' quality of life.

While we may hear about a few specific drugs and circumstances, it is important to remember that there are over 13,000 approved generic drugs in the United States. Generic drugs play a valuable role in helping patients' access affordable medicines. The IMS Institute for Healthcare Informatics found that generics saved U.S. consumers nearly \$1.5 trillion over the past decade. In recent years the share of prescriptions filled with generic drugs has increased, lowering health care costs not just for patients, but taxpayers as well. According to the Congressional Budget Office, between 2007 and 2010 the share of prescriptions filled with generic drugs increased from 63 percent to 73 percent in Medicare Part D, and this has contributed to this program's success story. This is further affirmation that when it comes to health care choice and competition are essential. Consumers know how to leverage these forces to make the market respond to their health care needs.

Let's take a look at today's generic drug landscape. Since 2012, the Food and Drug Administration has been implementing the first Generic Drug User Fee Agreement. Since this agreement was intended to accelerate the delivery of high-quality, lower-cost generic drugs, it's worth asking if it has accomplished that goal. In 2011, the median time for generic approvals was about 31 months. Two years and hundreds of millions of dollars in generic user fees later, it is now taking longer for generic drugs to be approved by the FDA—36 months and counting.

While FDA has taken some initial actions to address the significant backlog of generic drug applications, the fact remains that thousands of generic drug products await review by the Agency. In fact, there are more generic drug applications awaiting review by the FDA today than before the generic drug user fee agreement was put in place. In other words, the regulatory burden has gone up without realizing the full potential benefit of new generic drugs entering the market to help lower costs through increased choice and competition.

The FDA has also proposed a generic drug labeling rule that undermines the core tenet of “sameness” under the Hatch-Waxman Act. This rule will increase the costs of generic drugs and lead to increased costs for patients. Obamacare’s prescription drug tax is being passed onto patients, not only raising prescription drug prices, but also increasing premiums.

Instead of cherry picking a handful of examples, we need to look at what the full picture tells us. Drug shortages remain a concern. Taxes, fees and regulatory burden are driving up the costs of doing business. When the costs of doing business go up, the market responds and adjusts.

We have thousands of generic drug applications awaiting FDA review. Ultimately, many factors, including the policies enacted by Congress and this Administration’s actions, are impacting the availability of, access to, and the price of these life-saving products.

The first rule of medicine is to do no harm. If we are going to point a finger at why health care costs are increasing we should start by pointing it at ourselves—the Federal Government—and asking if the policies that are being implemented are helping or hurting. When it comes to the health care law and FDA’s actions and inactions, we already know the answer.

So, Mr. Chairman, by all means let’s hold a hearing on drug pricing. But we are not doing right by the American people if that’s all we look at, and then proceed to ignore the fees imposed, bureaucracies created, hurdles erected, regulations unleashed, and other roadblocks constructed by this Congress and the Federal Government more broadly.

I look forward to hearing from our witnesses here today and engaging in a constructive dialog.

PREPARED STATEMENT OF SENATOR MIKULSKI

Thank you, Senator Sanders for convening this important hearing about skyrocketing prices of generic drugs. This is an issue hurting patients nationwide. I’ve already heard from Marylanders who are seeing their drug prices increase dramatically and unexpectedly. We must do something about it.

Just last week, I received a letter from my constituent, Rosanne, a Medicare beneficiary from Silver Spring, MD. She has been taking ursodiol for several years. This is a generic drug used to treat an autoimmune disease. In June, a 3-month supply cost Roseanne \$159 and in September, the same prescription cost her \$1,659. This drug is her lifeline. She must pay the 1,000 percent increase to stay healthy and live a normal life, but it’s not easy on her checkbook. And many others are simply unable to afford these price increases.

Generic drugs are supposed to provide people an affordable alternative, but for many Marylanders and for so many patients, that is no longer the case. These increases are just one more squeeze on middle class families that are already working so hard to make ends meet. They are one more squeeze on seniors like Roseanne who have fixed incomes. The American people cannot afford to lose access to lifesaving medications, but they also cannot afford astronomical, unexpected, and sudden new costs to their weekly and monthly budgets.

I've also heard from Maryland hospitals who are struggling. Johns Hopkins University faces \$3.75 million in unplanned generic drug costs this year and the University of Maryland Medical Center estimates \$1 million in unplanned costs. How can we expect our hospitals to budget properly if they are hit over and over and over with unexpected and inexplicable new drug costs that they have absolutely no way to plan for?

I want to thank Senator Sanders again for convening this hearing on an issue that is negatively impacting Marylanders. I also want to thank Representative Cummings for testifying before the committee today and for his work to investigate this issue on behalf of Maryland patients and Maryland families who are already struggling to pay the bills.

I look forward to working with my colleagues on the HELP Committee and with Representative Cummings, so that we can better understand why these prices are skyrocketing and so we can do something about it to stop these price increases.

[Whereupon, at 2:15 p.m., the hearing was adjourned.]

