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THE COMPLEX WEB OF PRESCRIPTION DRUG PRICES, PART I: PATIENTS STRUGGLING WITH RISING COSTS

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C O N T E N T S

THE COMPLEX WEB OF PRESCRIPTION DRUG PRICES, PART I: PATIENTS STRUGGLING WITH RISING COSTS

WEDNESDAY, MARCH 6, 2019

U.S. SENATE,
SPECIAL COMMITTEE ON AGING,
Washington, DC.

The Committee met, pursuant to notice, at 9:31 a.m., in Room 138, Dirksen Senate Office Building, Hon. Susan M. Collins, Chairman of the Committee, presiding.

Present: Senators Collins, Tim Scott, Rubio, Hawley, Braun, Rick Scott, Casey, Gillibrand, Blumenthal, Jones, Sinema, and Rosen.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS, CHAIRMAN

The CHAIRMAN. Good morning. The hearing will come to order.

Today the Senate Aging Committee is holding the first of three hearings focusing on the high cost of prescription drugs. These hearings build on the work we have done since 2015, which has produced new laws to encourage more competition from generic drugs and to prohibit "gag clauses" that prevented pharmacists from informing their patients about the least expensive way to purchase their medicines, but it is evident that much more work needs to be done.

We have heard the statistics:

More than half of all Americans, including 90 percent of seniors, take prescription drugs regularly. One out of four Americans has a difficult time affording their medicine, and we have seen the headlines: "Drugmakers Raise Prices on Hundreds of Medicines." "Diabetes Patients at Risk from Rising Insulin Prices."

Behind these headlines and statistics, however, are real people: Average Americans trying to make ends meet, and at a loss to understand why the cost of a drug that they need to remain active, healthy, and, in some cases alive, continues to rise to the point where it is unaffordable.

Here are some of the stories of Mainers struggling to afford their prescription drugs.

Elizabeth, a 70-year-old from MidCoast Maine, lives with a severe low blood pressure disease that makes daily activities, such as making her bed, difficult. Her neurologists have tried multiple treatments and concluded that the medicine she needs is Northera, but with a price tag in the thousands of dollars, she simply cannot afford this treatment. Instead, she takes a different medicine that she says is "just barely keeping me able to function." She told us, "I am just treading water."

Philip from Yarmouth, Maine, had his epilepsy under control for years since the 1990's. Every 3 months, he would drive to Canada to buy enough Onfi to last a quarter of the year at the price of $120. Years later, he tells us, when this same drug got approved in the United States, his monthly costs skyrocketed to $1,200, so he stopped taking it. He is now taking an alternative drug for $75 a month that does not work as well and causes a host of unpleasant side effects, from balance to mood problems.

We have talked to Vereen from Lewiston, Maine, who describes the deteriorating condition of her 34-year-old son, Mark, who cannot afford to treat his diabetes properly, and Renee from Portland, Maine, who one day found that the refill for her multiple sclerosis maintenance therapy would be $12,000. She went without, risking her life until she was able to restore coverage.

When taken as prescribed, prescription drugs can work wonders keeping blood pressure in check and seizures under control, lowering cholesterol levels and triglycerides, combating nausea and infection, and balancing hormones in the body and chemicals in the brain. For some conditions, prescription drugs represent a lifeline that allow individuals to live, breathe, eat, and sleep, but in the face of rising costs, these therapies are becoming increasingly out of reach for those who need them most. Prescription drugs do not work for those who cannot afford to take them.

On a national level, we are spending an enormous amount, while millions of Americans continue to be unable to afford the treatments they need. This year alone, Americans are expected to spend more than $360 billion on prescription drugs. Of this amount, individuals will pay about $49 billion out-of-pocket. The Federal Government will pick up another $163 billion in payments through Medicare, Medicaid, and other programs.

Americans are going to great lengths to pay for their prescription drugs—cashing in retirement accounts, working three or four jobs at retirement age, choosing medicine over food. These statistics do not capture the tribulations that Americans encounter every day because the drug they need carries a prohibitive price tag—causing them to stretch or skip doses, settle for an alternative that works poorly, or simply go without.

The entire drug supply chain is appallingly opaque. While family members and doctors are often doing everything they can to help, navigating the complex web of prescription drug prices is not easy, even for the experts. Renee summed up the problem well after getting back on her MS maintenance therapy. She said: "I am lucky. As a community advocate, I knew who the players were and how the system worked. How does the average resident manage through all of this?"

The complexity in the current system seems designed to benefit everyone except the patient.

Of course, we want new medicines to reach consumers and for companies that invest in the research and take the risks necessary to develop these drugs to see a fair return on their investment, but we must do more to ensure that these essential medicines are more affordable and their prices more transparent.

Addressing the rising costs of prescription drugs is a top priority for this Committee. Today we will hear about the impact of high prescription drugs directly from patients. Tomorrow we will focus on potential policy solutions. At a third hearing later this spring, we will hear from administration officials on their proposed solutions.

I am so grateful to each and every one of our witnesses for being willing to come here today and share their stories.

I now turn to our Ranking Member, Senator Casey, for his opening statement.

OPENING STATEMENT OF SENATOR ROBERT P. CASEY, JR., RANKING MEMBER

Senator CASEY. Thank you, Chairman Collins, for holding this hearing.

When I talk to people in Pennsylvania, whether they are families or workers or seniors, one of the main topics that keeps coming up over and over again is, "How do I make ends meet?"

We have seen unacceptably slow growth in wages over not just years but now literally decades, and certainly at least the last four decades. The cost of living continues to rise. It is more expensive to put food on the table; the amount of money families must save to pay for priorities like child care or a college education. The cost of prescription medications, of course, is at the top of that list. The cost of these prescription drugs is busting the budgets of many families across Pennsylvania and across the country. Seniors and their families are stretched to the limits. We will hear more about that today.

The costs are overwhelming. Just last week, the Senate Finance Committee heard from the companies that make the prescription medications and set the prices of these drugs. None of the executives that testified last week have difficulty making ends meet because of the cost of one of their products. I hope, we all hope, that they will watch this hearing, or at least see it after the fact, and listen to our witnesses share their personal stories and their struggles to afford needed medications.

These are the stories of patients who take only half of a dose in order to make their medication stretch, and they are the stories of families who never expected to need to decide between putting food on the table and paying for a prescription.

We will hear all of this in the testimony of Americans from Pennsylvania, Maine, Georgia, Indiana, and Florida. They are the voices of our loved ones—our parents and grandparents, our aunts and uncles, our brothers and our sisters, and the money they are spending now has a significant impact on the resources they will hurricane available for their children and our children—indeed our future.

We must heed the warning of our witnesses today. These prescription drug prices are unsustainable and for far too many families, of course, unaffordable. If we want families to have the money they need for child care or for retirement, and everything in between, we must take action on this issue, so tomorrow I look forward to a dialog about solutions after we have heard stories today from Americans who are appearing before us.

Once and for all, we must advance common-sense policies to help Americans afford the medications they need.

I want to thank each of our witnesses for being here today, and I especially want to express my gratitude to Chairman Collins for holding this important hearing. Thank you.

The CHAIRMAN. Thank you very much, Senator.

We are now going to turn to our panel of witnesses. Again, I want to thank you for courageously sharing your personal stories with us. I know that you have traveled from many different places and that testifying before Congress may not feel easy to you, but you are doing a wonderful public service by bringing your personal experience in navigating the health care system just to get your everyday prescription drugs and making that experience available to us. Your voices are powerful, and we are very grateful.

First, we will hear from one of my constituents, Michelle Dehetre, from Lewiston, Maine. Michelle is a mother and a grandmother who works full-time and is an active member of her community. She also lives with Type 1 diabetes. She will talk about her struggles in affording expensive insulin and other treatments that she needs literally to survive day to day.

I am going to have Senator Braun to introduce our second witness who hails from Indiana. Senator Braun.

Senator BRAUN. Thank you. Pam and I met yesterday, and she is from Granger, Indiana, a retired school teacher, widowed at age 40, raised three children on her salary, and now helps out with two grandchildren. Pam suffers from multiple myeloma, a form of cancer, and her co-pay for her cancer-treating drug, Revlimid, is $577 per month. I think it used to be lower, and that is where it is now. She makes too much in retirement to qualify for assistance, had to go into debt for $10,000 currently when she was 3 years from having her mortgage paid off, and now that is a 30-year commitment.

Finally, last year she was able to qualify for a grant to cover the cost of Revlimid and is now paying zero, but it was a long journey to get there, and that is part of the uncertainty on any ailment and how you access the drug that is going to help you.

In addition to Revlimid, she is taking other high-cost drugs that she pays for out of her own pocket, kind of adversely impacting her quality of life.

Pam, thank you for being here.

The CHAIRMAN. Thank you, Senator.

I will now turn to Senator Jones to introduce our witnesses from Alabama.

Senator JONES. Thank you, Chairman Collins, and I am so pleased to welcome and introduce Ms. Donnette Smith. Ms. Smith is a retired Federal worker who joins us from Huntsville, Alabama. She now serves as the president of Mended Hearts, a national nonprofit that provides support services to heart disease patients, caregivers, and their loved ones.

As both a heart disease advocate and a patient herself, she has become well acquainted with the challenges of high prescription drug costs. It is my understanding, at least in my information—and we will hear more from Ms. Smith—that her prescription drugs run upward of $6,000 per month and that she has had to spread samples from her doctor as thin as she can to make ends meet. Today she is going to share some of those challenges with us that she has faced in getting the medicine that she needs in order to live a full and healthy life.

Ms. Smith, thank you so much for joining us. Thank you for your advocacy, and I look forward to learning more about your experiences.

Thank you.

The CHAIRMAN. Our next witness is from Florida, and we are so fortunate on this Committee to have both of Florida's Senators serving on it. We will start with Senator Rubio and then turn to Senator Scott to introduce the witness.

Senator RUBIO. Thank you, and I want to thank both you and the Ranking Member for holding this hearing—I do not know of any topic we hear about more—and for giving us the opportunity to introduce Mr. Sheldon Armus, who is from my home State of Florida. He resides in Boynton Beach, where at this moment it is 70 degrees and sunny, and we still have no State income tax, and he will be able to provide important insight on high-cost drugs are financially harmful for those that rely on them to manage chronic conditions. He spent 35 years working in the health care industry, from a pharmaceutical sales representative to the owner of a medical device company, so he has a unique perspective on the industry, and I want to thank him for being here today and for sharing his story so that we are better informed when we examine policy changes that will lower the cost of prescription drugs.

The CHAIRMAN. Thank you.

Senator Scott?

Senator RICK SCOTT. Senator Rubio and I are happy to have somebody from Florida here. It is a lot warmer there. I could not believe how cold it is up here, and my wife told me, "You worked really hard to get this job to move to cold." We are honored to be joined by a fellow Floridian, Sheldon Armus, of Boynton Beach. He is on Medicare A, B, and D. During a hospital visit 2–1/2 years ago for bypass surgery, he was diagnosed with Type 2 diabetes. After 4 months on prescriptions to manage his insulin, Sheldon went to the pharmacy expecting to pay, I think, $60 for each prescription. He was hit with a bill of over $300, and we are hearing this, especially with insulin, all over the country.

Sheldon, like so many in our country, is being subjected to the rising cost of prescription drugs and is forced to pay a lot of money out-of-pocket just to get the care he needs.

On Monday, I met with, I think, six individuals in my hometown of Naples all on insulin, and it was just—their stories are just shocking, how much the cost of insulin has gone up in just a very, very, very short period of time, so whether it is insulin or other things, we have got to figure out how to drive down the cost of prescription drugs. You know, we just cannot afford it.

Thanks for being here.

The CHAIRMAN. Thank you very much, Senator Scott, and now last, but certainly not least, I will turn back again to the Ranking Member to introduce our witness from Pennsylvania.

Senator CASEY. Thank you, Madam Chair. I am honored to introduce Barbara Cisek from Rural Ridge, Allegheny County, Pennsylvania, the same county that Pittsburgh is in, but we are here to promote Rural Ridge today. Barbara is here with her son, David, and Barbara is, to say the least, a true advocate for herself and for others, and today not just her and her family, but, of course, many Americans.

She has been a caregiver to her Mom when her Mom was battling ovarian cancer and has direct experience with a lot of the challenges we are here to talk about today.

Barbara, thank you for being here and for being willing to share your story. We are going to learn a lot by listening to you today.

Thanks very much.

The CHAIRMAN. Thank you, Senator, and, Ms. Dehetre, we will start with you.

STATEMENT OF MICHELLE DEHETRE, LEWISTON, MAINE

Ms. DEHETRE. Good morning. Thank you, Chairman Collins, Ranking Member Casey, and distinguished members of the Committee for inviting me to testify before you today.

My name is Michelle Dehetre. I was diagnosed with Type 1 diabetes in 1985 as a freshman in high school. I am 48 years old, a mother of five, and I have four grandchildren. My dream is to see my 11-year-old son graduate high school.

Diabetes threatens my life. Just last week, on Thursday night, while driving my middle son home to his father's, I had low blood sugar. The paramedics came and arrived on the scene, and I was sent to the emergency room.

Unfortunately, this is not an unusual occurrence, because I cannot afford the treatment I need, paramedics end up visiting me two to four times a month. I require two types of insulin to live: a long-acting and a short-acting. I take Lantus and Humalog. I work full-time and shell out nearly $300 per month out of pocket on insulin, syringes, and test strips that keep me alive.

Ending up in the ER always scares me, not only because I know it is a close call, but because on top of my medicine, I cannot afford another medical bill. When the paramedic visit results in a ride to the hospital, it is $600 for the ride and up to $2,000 just for the ER visit.

I have tried to save costs on my treatment. I asked my doctor about using an older insulin and found an option at Walmart for $25. I picked up a vial of Humulin N and Humulin R. It is basically the same insulin that I started using in 1985, but as I have grown older, my blood sugar levels have gotten more and more unpredictable, even when I eat the same thing from day to day, so the older insulin did not work well.

I was able to successfully save money on test strips. The brand that my insurance covers cost me $99. Thankfully, I was able to get a brand from Walmart and use them, and it only cost me $51 a month, without using my insurance. I use the test strips to check my blood sugar levels at least six times a day: when I wake up in the morning, before and after every meal, when I go to bed at night, and in between.

I cannot feel when my blood sugar is going low. It tends to go too low at night. My Mom and my aunt are nurses. Even in my family of caretakers, it has proven very difficult to keep my blood sugar in check.

My doctor says that what I really need is a continuous glucose monitor and a pump. I had that in 2007, and it worked really well. When my insurance coverage changed, my costs to keep that pump running skyrocketed to $1,500 for a 3-month supply, and that is after the insurance coverage. There is no way I could afford that, so I am using syringes and test strips.

The money I am spending on diabetes treatment already is too much. In addition to buying food, paying the electric bill, and other monthly bills for my household, spending at least $300 per month for my diabetes medication is a major financial strain. I cut back on spending whenever I can. I am always looking for ways to save money on food and gas and sometimes fall short at the end of the month.

Treating my diabetes is a matter of life and death. When my body does not get the insulin it needs, it makes my blood sugar go very high, which over time can lead to diabetic complications, such as blindness, neuropathy, and even death.

Sadly, I actually know that I am better off than others. In the year 2019, I wonder how many others are also struggling to cover the cost of insulin and other diabetes medicines and supplies. How many others are trying to save costs by using insulin from 1985 to no avail?

In 2019, no one should have to go through this. I want insurance companies and pharmaceutical companies to wake up. What they think they are doing to save money is not helping people like me.

Thank you for the opportunity to testify, and I am happy to answer your questions.

The CHAIRMAN. Thank you very much for your testimony.

Ms. Holt.

STATEMENT OF PAMELA HOLT, GRANGER, INDIANA

Ms. HOLT. Hello, Chairman Collins, Ranking Member Casey, my home Senator, Senator Braun, and members of the Committee. Thank you for the invitation.

My name is Pamela Holt, and I am from Granger, Indiana. At the age of 40, I was widowed when my husband died of a heart attack; therefore, I raised my three children on my own. I was fortunate at that time to be a teacher and later an administrator with good benefits, and that set me up to have a good retirement, I thought.

That all changed, however, when I was diagnosed with multiple myeloma 3 years ago. I had been recently retired. Multiple Myeloma is an incurable but treatable blood cancer. Upon my diagnosis, I underwent a bone marrow transplant and chemotherapy. I am very grateful to be currently in remission.

To keep my cancer at bay, however, I must take the drug Revlimid. Initially, this prognosis felt good. I could live longer. I could help raise my grandchildren. I could spend summers at our favorite lake in Wisconsin. I am deeply grateful for that, but when I learned the cost of Revlimid, I was horrified and frightened.

On Medicare Part D, I went into and out of the donut hole in January—I do that every year—paying $4,950 the first month and then $640 for Revlimid every 28 days for the rest of the year. That cost was really unaffordable for me, and after just 1 year, I found myself in debt. I was completely underwater and it became necessary for me to refinance my home. That was devastating because I was only 3 years from having it paid off, and having been a single parent all those years, it was a struggle, but I look at it as a fortunate experience because I had a home that I could refinance, so I could afford the drugs. In the last year I have been fortunate to receive a grant through HealthWell for the cost of my Revlimid, but that money is not a given. At any time through the year, they can run out of funds. I just read that seven of the eight granting people that work for multiple myeloma have closed their funding, so think of all the other people out there that have not received money to cover this cost.

Also, I do not feel I should be dependent on a grant. I felt I could be comfortable in my retirement, and that is not the case. I have to keep following where there is money to help me supplement.

I spent my life doing the right things—contributing to my community, teaching in public schools, raising my children. I feel it is rather unfair that, despite my hard work and careful planning, I must face all these financial challenges along with the illness that I have no control over.

I am grateful for the additional time Revlimid has given me with my family. Having cancer is really hard enough; I should not have to lose all my savings just to stay alive.

I am encouraged by the action Congress is starting to make in the hearings over the last couple of months. I am particularly grateful to this Committee for listening to patients.

What patients need most is real change to the system and congressional action that will bring down drug prices.

For me, one solution would be the CREATES Act. It addresses a tactic the company that makes Revlimid, Celgene, uses to deny generic companies access to samples of Revlimid. There are no competing drugs for the drug I need to take, so they can charge whatever they want. I understand this year it is up to $740 rather than my $600-and-some I was paying. Celgene can set the price at whatever they want.

I came to D.C. last year to encourage Congress to pass this important piece of legislation. I was grateful when my Senator, Senator Young, agreed to cosponsor the legislation, but I was disappointed that it did not get completed, but I am excited that it is back on the table.

I am hopeful the members of this Committee will sign on to the legislation and take meaningful steps to pass it.

For myself and many other patients across the country, congressional reform would be life changing.

Thank you for taking the time to hear my story. I look forward to the action that you will take on drug prices for myself and for the many other patients across the United States.

The CHAIRMAN. Thank you very much, Mrs. Holt.

Mrs. Smith.

STATEMENT OF DONNETTE SMITH, HUNTSVILLE, ALABAMA

Ms. SMITH. Thank you. Chairman Collins, Ranking Member Casey, and members of the Committee, thank you for the opportunity to be here today to talk about the challenges I have had in getting the medication that I need. My name is Donnette Smith, and I am from Huntsville, Alabama. I have suffered from heart-related conditions from birth, and the efforts and skills of some excellent doctors along the way have enabled me to have a full, if complicated life, but today I sit before you as a person at high medical risk.

I am a retired Federal employee, and I live in Huntsville, Alabama, where I spent my career as a technical writer for the U.S. Army and NASA. I have also had the honor to be an advocate and resource for heart patients as president of Mended Hearts, a national peer-to-peer support organization for heart patients, providing hope and encouragement for over 67 years. I am also on the board of directors for Heart Valve Voice US.

My medical story began at birth, although I did not know that until much later. I was born with a heart defect that led to aortic stenosis and heart failure. After suffering from debilitating shortness of breath throughout my childhood, I finally learned the truth about my condition in my late teens, when a NASA physical revealed a severe heart murmur. I was devastated.

Just after my 40th birthday, I had open heart surgery to replace my deformed aortic valve. I did well for a number of years, but a failing valve and severe cardiovascular disease a few years later led to two more heart surgeries and five stents. After the third surgery in 2009, my doctors said it was urgent to dramatically reduce my cholesterol level, which was off the charts. I believe I tried every statin and step therapy available, but nothing worked for me. I was a stroke or a heart attack waiting to happen.

When Repatha, a new type of cholesterol-reducing drug—a PCSK9 inhibitor—became available several years ago, my cardiologist believed that it could dramatically reduce my risk.

He tried unsuccessfully to get my insurance to cover it. Without insurance, it would have cost me over $14,000 per year. The applications and appeals process were very detailed and complicated and extremely time-consuming for my doctor and his staff. Even with all his effort, it was not approved. When I spoke about my struggles at a cardiology town hall meeting in 2015, a physician there became an advocate for my case. My insurance company eventually approved 3 months of coverage in January 2018, and I began taking Repatha. The drug dramatically changed the quality of my life. My LDL cholesterol level fell from 283 to 70 in 1 month, and I felt the cloud of fear hanging over me finally lift.

The drug is very expensive, and with insurance my co-pay was $583 per month. That is not a small amount of money, but I was willing and able to pay it if necessary, and I was fortunate enough to discover a manufacturer co-pay card which sharply reduced the cost. However, the coupon only works if the prescription is covered by insurance. Unfortunately, after 3 months I received a notice from my insurer telling me that I would have to go through preauthorization again. That was 1 year ago, and I am still waiting.

I heard that the drug's price was recently reduced, which may provide better options if my doctor's latest pre-authorization request is not approved. Right now I am taking samples of Repatha that my doctor has been able to get for me, which I stretch out by not doing the injections as often as possible. He thinks that any amount I can take is better than nothing. I hope that the latest pre-authorization is approved. I have been hanging in there, but I do not know what this is doing to my health for the rest of my life.

In some ways, I consider myself lucky. I encounter many people who have not had the medical care I have had. I urge you to do something, for all of the seniors and others who cannot afford their medications.

Thank you again for the chance to share my story with you today.

The CHAIRMAN. Thank you very much, Mrs. Smith.

Mr. Armus.

STATEMENT OF SHELDON ARMUS, BOYNTON BEACH, FLORIDA

Mr. ARMUS. Chair Collins, Ranking Member Casey, and members of the Committee, thank you for having me today.

My name is Sheldon Armus. I am 71 years old and live in a senior community in Boynton Beach, Florida. I am a constituent of Senators Rick Scott and Marco Rubio, members of this Committee.

I spent the first 35 years of my career working in the health care industry. I started as a young pharmaceutical sales representative, and I worked my way up to management for several companies, including manufacturers of medical devices.

Before retiring in 2014, I owned my own medical device company and then worked as a science teacher for 10 years.

One month into retirement, I underwent a quadruple cardiac bypass operation. Surgery saved my life. However, the surgery, as well as my diabetes that they discovered when I was in the hospital, and other cardiac conditions left me taking seven different drugs each day.

All of these drugs keep me alive, and I am very thankful for their existence. However, they also have proven to be a real financial burden.

Xarelto is one of my drugs; it is a blood thinner that prevents dangerous blood clots that can lead to heart attacks. It is a new and expensive drug with a list price of more than $450 for a 30-day supply. That is one tablet a day. It is outrageous, and, yesterday, on my way to the airport to come here, my doctor's office called me and placed me on another highly advertised patented new drug called "Brilinta."

You have probably heard of Xarelto because it is heavily advertised also to consumers on TV. Janssen Pharmaceuticals makes this drug, and they have also promised to start disclosing the list price of its medications on those ads, which is more information than Janssen would like doctors to know.

Last month, I dropped a Xarelto on the bathroom floor. I guarantee you all bathroom floors are sterile when it comes to your medications, and there is no 5-second rule.

There is not a generic on the market for Xarelto. I am lucky to be on Medicare Part D, where I pay only a portion of the price, but it is still too much.

Before Congress closed the donut hole, I would fear the month that my out-of-pocket costs would spike, because of fluctuations in the list price, I never knew when I would hit the donut hole threshold. At some point I would go to the pharmacy to pick up my prescriptions and discover that they all cost much more than I expected. Sometimes I would actually have to wait several days for a Social Security check to arrive before I could afford to pay for the drug. It was always a shock to my system.

Like most middle-income folks, my wife and I live mostly on Social Security plus some savings. The deductible for the premiums for Part D equals over $1,000, and that is before filling the first prescription.

The donut hole will be closed for patients, but it does not solve the problem of high list prices. I struggle to afford my drugs with Medicare Part D coverage, but I feel even worse for those without coverage who must pay the list price. The list price of insulin these days, which has been talked about here before, which has been around for 100 years, has skyrocketed.

Patients and taxpayers still pay for a percentage of the list price. That is a very important thing to note because, therefore, it is in the best interest of the pharmaceutical companies to artificially inflate the list price.

I know because I worked in the industry; I attended meetings in which maintaining and increasing the high list prices, which back in those days were called "average wholesale prices," was discussed and encouraged. Pharmaceutical reps such as myself as well as the public are told that the high drug prices are due to the high cost of research and development. However, according to the Washington Post, nine out of ten big pharmaceutical companies spend more on marketing than on research. Being from Florida, I had to buy a new overcoat to come here today. I can assure you my 30 Xareltos cost more than my overcoat.

At one time I was proud to have worked in the pharmaceutical industry, but now, being a patient, I no longer feel that way. In fact, I am embarrassed to tell my fellow seniors of my past work experience.

I am grateful to the Committee for holding this hearing and delving into the issue of high drug prices. The issue starts at the top with high list prices set by drug companies, but it ends at the bottom, with us, patients just trying to continue to live their lives.

Thank you for your time.

The CHAIRMAN. Thank you very much for your testimony.

Mrs. Cisek.

STATEMENT OF BARBARA CISEK,
RURAL RIDGE, PENNSYLVANIA

Ms. CISEK. Chairman Collins, Ranking Member Casey, and members of the Committee, thank you for inviting me to testify today. It is an honor to be here.

My name is Barbara Cisek, and I am 72 years old and live in Rural Ridge, Allegheny County. My husband, Ed, and I were high school sweethearts, married just shy of 43 years when he passed away in 2009. We raised two sons together, David and Michael, who now have four kids between them, and my son David is here with me today.

Raising my family, keeping our hairdressing shop open, and caring for my mother as she battled chronic illnesses was hard. Like me, she had a lot of different medical issues and was sick a lot of the time, but always fought to get back on her feet. She was diagnosed with ovarian cancer at the age of 80 and lost her battle to cancer before her 83rd birthday.

I wonder what will happen if I live to be the age of my mother. With all the medical expenses I am facing on a fixed income, I am scared there will not be anything left. I pay about $500 out of my own pocket for medicine and over-the-counter items every month. If I actually take all my medications my doctor prescribes, the costs would total over $1,500 per month. That is on top of my Medicare, which is $134, and my Medicare Advantage, which is $293.

I have battled bleeding ulcers, high blood pressure, high cholesterol, and severe migraines for years and was diagnosed a year and a half ago with diabetes. I am recovering from a stroke that I suffered last November and need to get a total shoulder replacement in the next several months. I am living with chronic pain caused by a bulging disc, spinal stenosis, and sciatica. In addition to the injections for my shoulder—I pay $50 every 3 months for those injections—I use an inhaler to manage my COPD, have an oxygen concentrator at home, and will need to start using portable oxygen tanks. With ovarian cancer in the family, I get tested every year, so I feel like I am a puzzle with a piece missing.

What makes managing all these conditions worse and more stressful is never knowing what the insurance will cost from 1 year to the next and my prescription drug costs will be. The Imitrex that I take for my migraines cost $150 before it became generic. Now that it is generic, my insurance will not cover it, and I pay $45 for 27 pills. Phenergan, a medicine the doctor recommended for me for nausea is not covered, and there is no way I pay the $1,032 price. Elavil, a medicine that helps with my migraines, is no longer covered, and I have to pay $85 for a 30-day supply. I spend $100 for two ounces of cream that treats a rash that the insurance will not cover. It is hard to make the cream stretch, but I use the tiniest amount that I can to make it last. I just found out when I inquired about the shingles vaccine, it is not covered by my insurance and will cost me $420 out of pocket.

The most expensive medicine I take is Nexium, and I have to have it. Other forms of the drug, which treats my slow-bleeding ulcers, have made me sick to the point where I needed blood transfusions. I have to go through a step-by-step process every year, with my doctor sending a letter to my plan confirming that I do actually need the brand-name drug. For a 90-day supply, I pay $300. My Spiriva inhaler for my COPD is $150 a month.

When you add all these drug costs to what I pay for other supplies, like diabetic test strips and lancets, my oxygen tanks, my CPAP, an eye vitamin to delay my macular degeneration, xylimelts and special bottles of mouthwash and toothpaste to treat dry mouth and receding gums, it is a lot and it all adds up. That is why I am sharing this with you today—to help you understand what it is like for those of us senior citizens who are feeling the full weight of the costs because we make a little too much to get help from the State or the Federal Government.

My husband retired as an engineer with Westinghouse for 33 years. He worked hard, as did I, to build a good life and a good future for our family. I have lived in our home for 45 years and do not want to leave it. I want to be able to afford my medicines so that I can stay healthy and away from the nursing home. If things like this keep going up, drugs are going to cost more and more and my insurance covering less and less, and I do not know what I will do.

I came here today to speak not just for myself, but every other senior citizen who has had to stand at the pharmacy counter and leave something behind.

Thank you for the invitation to testify before this Committee. I look forward to answering your questions.

The CHAIRMAN. Thank you very much for your testimony.

All of you are coping with very serious illnesses, and I could not help but think, as I listened to your individual stories, that your illnesses are also worsened by the fact that you are coping with this anxiety and uncertainty about what your prescription drug costs are going to be from month to month, so I would like to ask each of you a question: Do you understand what you are going to be faced with when you get to the pharmaceutical counter and why you are paying what you pay? We will start with Michelle. I am sorry. We need your mic turned on. Thank you.

Ms. DEHETRE. I am unsure how to answer that question. I have asked at the pharmacy when, you know, a price has changed in my prescriptions, and it is usually because my insurance company has changed the way that they cover it.

The CHAIRMAN. Thank you.

Ms. Holt?

Ms. HOLT. I just recently had the experience of going to the pharmacy to pick up a drug that I need to offset the results from my chemo medication, and it is an antinausea/antidiarrheal that I typically paid $46 for a 3-month supply. The last time I went to the drive-through to pick up my prescription, it was $500-and-some. There was no pre-warning. I had to leave. Obviously, I was not prepared for that payment, and I asked if there was anything, you know, that had happened, anything they could do, and then I had to go back and pick it up. I was at a standstill. I cannot get by day to day without that drug, and they had me.

The CHAIRMAN. You do not have much choice.

Ms. HOLT. No.

The CHAIRMAN. Ms. Smith?

Ms. SMITH. Yes, it is a shock when you go to the pharmacy to pick up something, especially a new drug, and discover the price, and you may or may not be ready to dole out that kind of money at that point.

I take 12 different drugs, so my problems with getting the Repatha and it being so expensive, it is nothing, you know, when you add everything up together, and, honestly, I have talked with other people who are in the same boat that I am in as far as prescription drugs, and I had one lady tell me that, "Well, I picked up my drugs today, and I was going to the grocery store, but when I paid for my drugs, I cannot go to the grocery store." I mean, that is really concerning.

The CHAIRMAN. It certainly is.

Mr. Armus?

Mr. ARMUS. Well, as I mentioned in my comments, I now have a new anticoagulant that has been added to my drug regimen. I have no idea what that will cost because the prescription was just written in the last day or so.

I feel that the situation is not only out of control, it has been going out of control for the last 10 or 15 years, and we are just to the point where it is so painful that we—I think it is a bipartisan effort to really do something about it, because the pain is excruciating at this point, and there are many people—and those other people at the dais here—that pay a lot more than I do for drugs.

I do not know what I am going to pay for this. I do not know what I am going to have to sacrifice. It might be, "Leave the gun. Take the cannoli."

The CHAIRMAN. Thank you.

Mrs. Cisek?

Ms. CISEK. It is frustrating when you go to get a prescription filled that you take out a health insurance plan and they seem to change it from month to month, if you say it is going to be a $15 co-pay, and then you go and realize, "Oh, no, it is going to cost me $100." When I listened to the speeches last week about why somebody's medications do not come down that had been up for years, they said research and development. How about the cost to the patient? And that is the part, but you know, you say this amount or this amount, but I have joked when I go to get my Nexium pill, I will say, "Well, I mortgaged the house." That is how you feel with the cost of the medication, that you just do not know anytime you get something filled what it is going to cost.

The CHAIRMAN. Thank you.

Senator Casey, good timing.

Senator CASEY. Well, thanks very much. We are doing a little juggling here today.

First of all, I want to thank everyone for their testimony. This is, I think, for people here but also, I think people listening, a real exposure to real life, not some theory but how people get from day to day and week to week and month to month, and it is just a searing reminder about the challenge that we have, and I am grateful our witnesses are willing to share their personal stories. It is very difficult in any circumstance to testify in a setting like this. It is ever more so when you are testifying about your own life and your own challenges, but I want you to know that it helps us be able to convey not just the reality of this problem, but the urgency to take action.

We are hearing about real life today, and I wanted to just start with what I usually do not do, which is a very simple yes-or-no question, because I think that it highlights what many of you are facing and what we have got to try to do to react and to take action in light of your testimony, so I just want to ask some basic questions.

The first one is: Do you believe Medicare should be able to use its purchasing power to negotiate drug prices? I will just start from left to right. Michelle, I will start with you. Just give a yes-or-no answer to that question.

Ms. DEHETRE. I fully do not understand the question, so that one is hard for me to answer.

Senator CASEY. Okay. Pamela?

Ms. HOLT. Yes for me.

Ms. SMITH. Yes for me.

Mr. ARMUS. Definitely.

Senator CASEY. Barbara?

Ms. CISEK. Absolutely

Senator CASEY. The second question is: Do you believe the United States should be able to safely import medications from other countries where they—meaning the drugs—are more affordable in countries like Canada? I will start again with Michelle. Yes, the question is: Do you believe the United States should safely import medications from other countries where they are more affordable, like, for example, Canada?

Ms. DEHETRE. While I think it is sad that we would have to do that in order to bring more affordable costs to us, the people that live here, I would have to say yes to that, but it is sad that we have to do that to take away from our local pharmaceutical companies.

Senator CASEY. Pamela?

Ms. HOLT. Vehemently, yes, if it would cause competition and cause drug prices to go down.

Ms. SMITH. I agree also if it can be done safely.

Mr. ARMUS. I agree. There are people in my community that are already sending for drugs from Canada.

Senator CASEY. Barbara?

Ms. CISEK. Yes, and I know of ones that do.

Senator CASEY. Thank you, and I appreciate your answers to those. None of them are necessarily easy questions.

It is my hope that Congress can act upon the recommendations that we hear from folks either testifying today or otherwise. One bill that I am particularly interested in is Senator Stabenow's bill which she has introduced and which I support to allow Medicare to negotiate for lower prices. That is one.

I have another bill on the other issue that we raised with Senator Sanders to allow for the safe importation of prescription drugs, in this case from Canada, maybe down the road other countries as well, so we are grateful for the testimony you provided.

I will wait for my second round to ask a question of Barbara so that we can keep the hearing moving. Thanks very much.

The CHAIRMAN. Thank you, Senator.

Senator Braun?

Senator BRAUN. Thank you, and thank you for convening a discussion like this. It is so important. This has been a passion of mine for years. I took on the health insurance companies in my own business 10 years ago, and you do have recruits and reinforcements on both sides of the spectrum here that enough is enough.

I was tired of the litany of every year you are lucky it is only going up 5 to 10 percent. That started when I had a company of just a few employees, and I did not have anything I could do about it until I hit 300, which was 10 years ago, and I could tell what a looming issue this was going to be and did what most companies did not do, did not have the nerve to do, and that is, take on the status quo.

This is going to give you hope because I have got three bills I just dropped yesterday, and there are a few of us, whether you are looking at maybe Government getting more involved, which I do not blame that because the industry has done such a poor job of providing a product and a service at a value, embarrassed by the fact that 30 other nations have a better ranking when it comes to cost and total measurement of value along with it. We have got to do better.

In a nutshell, I made my system consumer-driven, and I can tell from the testimony it is so opaque, it is so confusing, that it is hard to participate as a consumer. I forced it into the system, encouraged that to be done, did things like pay 100 percent of wellness so we are preventing rather than remediating, and to make a long story short, actually lowered costs out of the gate by 50 percent and have not had a premium increase now in 9 years for my employees. It is unbelievable what, if you really tackle the system by changing all the things we have come to just accept—and that is that you spend this much money, you never ask how much it costs because you are frustrated that you would not get an answer and an easy way to do it. That is going to change.

I did drop three bills that address things to me more comprehensively. There needs to be a general bill of transparency. If you are in the business of health care at any level, you publish your prices in print or on the Web so people can see it, so it is not that confusing to access it.

Just recently there was a ruling on PBMs to take this whole gimmick of rebates. There is nothing like that in any other industry. The reason we have it here is because there is so much profit margin there. You have a whole other middleman that operates off these artificial rebates. They carve up most of the profits between themselves and the insurance companies and it never gets down to the individual.

I have got a bill that wants to do that for private insurance, not just through Government.

I have got another bill, safely importing drugs. All these rules, not being able to get insurance across State lines, all the things that have been embedded into our health care system like not being able to pool or associate, that needs to change.

I have got a bill that is going to fast-track good drugs that work elsewhere, get them into this country, and it is sad that we cannot do that here on our own.

Another gimmick, when it comes to brand names transitioning to generics, there are things like citizen petitions, which you would think would help us. It is actually a tool the insurance companies use to thwart the process of generics coming onstream.

I want to give you hope that this is now an issue both sides of the spectrum are serious about, and you cannot blame some for wanting Government to do more when an industry has been so dysfunctional. I will leave it at that because I do want to ask a couple questions.

I know just from the testimony it is difficult finding comparison. I know when I was in between being CEO of my company and my company's insurance, I had to actually call to find a prescription. I called two places. It is a generic, and I figured it would be easy, quick, and they would be within a few bucks of one another. I called one place; it is $34.50. It took them 2 minutes. They fumbled around to give me a price. I said I had no insurance, and that was true. I was in between. I called—and I am going to mention the name—Walmart. They gave me an answer within 10 seconds, 10 bucks, and I could pick it up within 15 minutes. You should not have that type of discrepancy between one or the other.

Would you folks, as you are looking for better ways to compare prices—either one or two of you real quick because I am running out of time. Would you engage as consumers if the information was there to shop around? Because I think that is the key to bringing prices down. Pam, let us start with you.

Ms. HOLT. I definitely would when it came to $46 versus $100 or $500-and-some. That was cause me to do quite a bit of phone shopping before I could have a prescription——

Senator BRAUN. Great example. Anyone else?

Mr. ARMUS. I think the time has come for prices to actually be fixed, because if we continue to work on percentages of list, the list prices are just going to go sky-higher and sky-higher, and the way that insurance is structured actually increases the cost of drugs because when I worked as a young pharmaceutical rep years ago, the average price of the pills that I sold wholesale to pharmacies was about a dime a pill, and as soon as there was a Medicare Part D, the prices skyrocketed because now they were getting—the pharmaceutical companies were getting the money from the Government.

Senator BRAUN. Thank you for your testimony. It was great. I am out of time, so I yield.

The CHAIRMAN. Thank you.

Senator Jones?

Senator JONES. Thank you, Chairman Collins.

Unfortunately, it seems like from all of you—and I appreciate everyone's testimony and being here today—it is all too familiar stories that we are hearing today.

Ms. Smith, I want to just kind of focus on you for a moment if you do not mind. It sounds like you had to jump through a lot of hoops with your insurance company, which is also not uncommon, and I am sure that that had some impact.

Before I ask about the impact, what was it that they hesitated—what did the insurance company tell you when they were denying you coverage, and also then when they approved you for only 3 months? I mean, it is not like that this drug was going to cure you, but they only approved you for 3 months. Why was that? Or what did they tell you?

Ms. SMITH. They did not give me a reason. I just assumed, when I finally after 2 years got approved for the drug and actually got it, that, you know, it was good for a year. I did not know that it was only for 3 months, so at the end of 3 months, I got a letter from the insurance company that said you will have to go through pre-authorization again, which took me 2 years to get done in the first place, and now I am a year later still trying to get it.

Senator JONES. Tell me about that 2-year period. What were you doing during this period? What all did you have to do during that time? And how did that impact your care?

Ms. SMITH. Oh, my goodness. Well, first of all, I could not take a statin because side effects were just—I mean, I was almost to the point of being in a wheelchair. I could not walk, and so my cardiologist said stop taking it, so I did, so I was without any protection whatsoever with an extremely high cholesterol, which was dangerous because I have had so many heart surgeries and have cardiovascular disease as well.

We would send in an appeal. It would be denied. We have to start all over again, so that went on and on over and over, and finally, as I said in my statement, a physician who heard my story decided to help me, and he got on board and was doing a lot of actually shaming the insurance company that they were not doing something to help me, and he actually got it approved, but then it was only for 3 months, and we had to start all over again, so we are back in the appeal process.

Senator JONES. Is it twice that you have gotten it for 3 months each or just——

Ms. SMITH. No. Just once.

Senator JONES. Just the one time for 3 months.

Ms. SMITH. For 3 months. Now I am getting samples from my doctor, and instead of two injections a month, I am doing one, and sometimes one every other month just so I will have some of it my system.

Senator JONES. During this time did the insurance company ever give you any explanation of why they were denying you coverage for this drug?

Ms. SMITH. No.

Senator JONES. None at all?

Ms. SMITH. No.

Senator JONES. Your doctor is having to continue to do the appeals to work with you?

Ms. SMITH. Correct.

Senator JONES. How long has that appeal process been going on now?

Ms. SMITH. Three years total.

Senator JONES. So you are an advocate here. You are an advocate for patients like you. What do you tell patients when they face these kind of hurdles? How do they manage this? Because it is not only the hurdle of managing—-trying the appeals and trying to get these drugs, but they have still got to manage their health care during this time. What advice do you give folks like that?

Ms. SMITH. That is true. I really encourage them to be their own advocate and to speak out and do not give up, and I have done everything and even jokingly said that I would chain myself to the door of the insurance company until they gave this old lady the drugs that she needed, but you just really have to be your own voice and speak up and say this is just not working and do something. People are not willing to do that, so you know, I encourage them, and I work alongside of them to get them to do that. They just have to be their own advocate.

Senator JONES. Well, I think that is real critical, and I am glad you said that, because people just cannot give up.

Ms. SMITH. Right.

Senator JONES. You know, you have got to pester these folks.

Ms. SMITH. Exactly.

Senator JONES. Just continue to stay on it, because it makes no sense to me. Look, I am a lawyer. I am not a doctor. I am not a pharmacist, but it makes no sense to me that someone would, one, just approve you just for 3 months.

Ms. SMITH. Correct.

Senator JONES. Then make you go through all these hoops. You have the same illness. It is the same issues. It is the same drug, so they have got to just stay at it. They have just got to pester these people.

Ms. SMITH. They have got to stay at it, absolutely, and talk with their physician, because, you know, they do have the samples that they can help you with, and as my doctor said, some is better than nothing, so just keep at it.

Senator JONES. Okay. Well, I am going to yield back my time on that. I think that is an important message for everyone, that we just cannot take no for an answer when it comes to your health, so thank you so much for being here. I appreciate it, and thank you all for being here and sharing your stories.

Thank you, Madam Chairman.

The CHAIRMAN. Thank you.

Senator Scott?

Senator RICK SCOTT. First off, thanks to each of you for coming here. I think others have said this. First off, I want to thank Senators Collins and Casey for putting this together, but I think there is a time now that I think there is a lot of interest up here to figure this out, so I think that is real positive, because these stories are ridiculous, not being able to take care of yourselves.

First, Ms. Dehetre, I wanted to ask you a question. How often do you end up in the hospital a year?

Ms. DEHETRE. If I actually went with the ambulance, I would be in the hospital three to four times a month.

Senator RICK SCOTT. So your insurance company has to pay for that.

Ms. DEHETRE. Actually, the insurance company does not get billed if they just show up and I do not go with them. It is the part that I have to pay that I cannot afford, so if they tell me I do not have to go with them, I do not go.

Senator RICK SCOTT. The amount that you are not being able to afford for your insulin easily should be covered by the fact that your health gets worse and the insurance company in theory is responsible for the hospitalization side, right?

Ms. DEHETRE. That is what I said when they do not want to cover my pump supplies until I meet my $6,000 deductible.

Senator RICK SCOTT. What is their answer?

Ms. DEHETRE. Their answer is they designate my pump supplies and my blood glucose monitor supplies as “durable medical equipment,” Senator RICK SCOTT. It seems like it is a foolish economic decision for them.

Ms. DEHETRE. It seems that way to me, too, having been there and having to keep calling them, you know, calling and getting the paramedics and the police and all that fun stuff that have to come over every time my blood sugar goes low where they have to get calls.

Senator RICK SCOTT. All of you have—all of you that are on Medicare, you have a supplemental policy? Everybody has one? When you sign up, do they tell you what drugs are covered and what you co-payment is going to be? They do not tell you? So you have no idea.

Ms. HOLT. There are categories, and you can look up drugs in those categories, and you are given—like mine, there are tiers. There is Tier 1, Tier 2, Tier 3. My cancer drug is a Tier 3. They do not give you prices. They just tell you it is in the highest category.

Senator RICK SCOTT. Then they change what you have to pay whenever they want to during the year?

Ms. HOLT. It is totally opaque.

Senator RICK SCOTT. No one else, you have no idea we you get your plan?

Ms. SMITH. If I could, she is absolutely right about the tier, and even when the drug companies reduce the prices of their drugs, it depends on—it does not filter down to the consumer because it gets caught up in that tier. If they do not move it from the highest-priced tier, then you are still going to pay the price, even though the insurance company has lowered the price.

Senator RICK SCOTT. Okay. If you are sitting in our position and we have the ability to pass legislation, what legislation would you pass? I think the CREATES Act is one thing that makes all the sense in the world, but what else would you—I mean, I think Senator Casey asked a variety of questions, which is potential legislation, and Senator Braun did something similar. Is there anything else you would do? At this point are you just fed up? Are you just saying, look, the Government ought to set the price?

Ms. CISEK. It gets to the point where, when you do call and they say we will change the tier, which has happened to me, then you turn around and they have not changed it, and they keep it at the same price. They tell you there will be a certain co-pay, but when you go the pharmacy, it is not what is in your plan, so what do you do? Do you pay for the medicine? Or do you go home and call? Then they tell you the same thing, but they do not tell you why, and even in my case, with Nexium that I take, I went to the pharmacy to get it filled, and the pharmacist said, "Barbara, they will not cover the Nexium brand." I was on the generic, so each year I have to go through a pre-authorization with my doctor on a yearly basis in order to get that, because the generic does not work for me. I have a letter from my previous doctor that stated all the medicines I had been on for my ulcers. They did not work, and I thank God I saved that letter because that was dated in 2004, but you do not know what to expect from refill to refill, even though your plan says, "This is what we will pay." They do not stick to it, so if you call them, they tell you, “We will change it.” They do not, so it is not like you do not inquire.

Senator RICK SCOTT. Right.

Mr. ARMUS. There are different co-pays for generic drugs and for brand-name drugs, and my understanding is if there is a generic, they will not pay for the brand name.

Now, also in the State of Florida, there is a generic drug law where they are required to fill with a generic drug if one exists. Even if the doctor writes for the brand name and there is a generic, the pharmacist is required to fill with the generic. You do not know what you are getting half the time. You do not know what percentage. You do not what the list price is that you are paying a percentage of, and you do not know when you are going to go into the price gap or the donut hole until you get there, and not only is it that drug that threw you into the donut hole, you are paying the highest prices or donut hole prices for all the drugs you take at that point until you reach another threshold, which is much higher—you may never reach that. I have never reached it.

Senator RICK SCOTT. Yes?

Ms. HOLT. My Revlimid tablets I understand cost $1 to manufacture, yet they charge me $740 a pill, so I think something needs to go back to Celgene to say, “You cannot do that.”

There was a lawsuit that they lost last year in regard to a different drug, and there was a public article—I believe it was in the Washington Post—that they would just raise the cost of their flagship drug, which is Revlimid, to cover the lawsuit costs, so that drug has gone up and up and up just because they can, and I do not—I am not a policymaker. I am not a legislator, but I wish there was something to be able to control that.

Senator RICK SCOTT. Thank you.

The CHAIRMAN. Thank you.

Senator ROSEN.

Senator ROSEN. Thank you. I want to thank you, first of all, for bringing this hearing and for your willingness to come here and advocate and share your stories, because there are so many who cannot advocate for themselves. It is not that they are not willing. They are just not able because of their disease, because of their lack of access or understanding of technology and ability to communicate or potential disability, so you are acting on behalf of so many people, you will never know, and we really appreciate that.

You know, before coming to Congress, I stepped back from my career to be a caregiver for my parents and in-laws. I went from everything from cancer to Alzheimer’s, and I was in every rehab and nursing home and through many courses of diseases with many of my friends, so I know all too well on a personal basis how difficult this web is to maneuver, and so in 2018, six States, Nevada being one of them, have passed drug-pricing transparency laws. We talk about you do not know—you cannot even predict what is going on, and I do not care if you are the biggest technologist in the world; you cannot find it, and so these drug-pricing transparency laws, they require disclosure from drug manufacturers and insurers to help lawmakers and the public better understand how drugs are priced and how those prices not only affect you but affect insurance premiums and everything else.

I just want to ask you, in your own words, how do you think a predictable monthly cap on out-of-pocket prescription drug costs would help you and how would it change your life? Please.

Ms. CISEK. I think if you knew what you were going to pay each month and amortize that over the year, that might be a help, but what if it is the month that you have that high medication and say every 90 days you might——

Senator ROSEN. Putting a cap on prescription drug costs per month for a family or an individual would be more helpful?

Ms. CISEK. It would be.

Mr. ARMUS. Well, putting a cap, a dollar amount, not a percentage——

Senator ROSEN. Yes.

Mr. ARMUS [continuing]. would be very helpful, but also it must be affordable.

Ms. SMITH. I agree. I think that would be a great start in helping folks like us to afford drugs if we only knew, because, I mean, at our age we are pretty much on a fixed income, and you know, one of the things I tell my children and my grandchildren, you know, be prepared for when you get older. You might just be in your early 20's, but, you know, old age is coming, and you really do not know what to expect. You cannot plan for it, so you know, if you had a cap on drugs and you actually knew what you were going to be able to pay, I think it would help you in the long run to be able to plan for that each month and maybe do something that could help you afford your drugs rather than just being surprised when you go to the drugstore.

Senator ROSEN. Well, I think not just for people who are a bit older. It affects families, too. Kids have chronic disease, born with severe illness, and so it would help everyone, no matter what stage you are in, trying to plan for that.

Ms. SMITH. That is so true, and also, Mended Hearts works with children born with congenital heart defects, and those families can be devastated because usually one of the family members, the mother or the father—usually the mother—has to quite their job and take care of the child. It is really devastating for those families, so I agree.

Senator ROSEN. Thank you. Ma'am?

Ms. HOLT. I also totally agree. I think there needs to be a cap, and I think it would be helpful to know before we got to where we were going what our costs would be.

Senator ROSEN. Thank you.

Ms. DEHETRE. I also think it is beneficial to have a cap because, like all the other witnesses here, if you know what that cap is, you know that you are not going to pay more than that for your monthly supply.

Senator ROSEN. Thank you, and again, I really appreciate your willingness to advocate for those who cannot be here and do not have a voice. You are going to make a real difference.

Thank you. I yield back.

The CHAIRMAN. Thank you very much.

Senator Hawley?

Senator HAWLEY. Thank you so much, Madam Chair and Ranking Member. Thank you for calling this important hearing and dealing with this extremely important and pressing subject. I know that in my home State of Missouri there is no topic that I hear about more from folks than the astronomical, out-of-control, unpredictable costs of prescription drugs, and so I am so glad that you are all here. Thank you for taking the time to be here and for telling your stories. I have read your testimony. I got to hear pieces of some of your testimony as you delivered it here, and I know it takes a lot of courage to be here and to testify, and of course, you have taken time out from your own work and jobs and lives, so thank you so much for that.

I wanted to share briefly a story I know you all can relate to from my home State. There is no shortage of stories of Missourians struggling with the same thing that you have helped inform us about today, but just yesterday—just yesterday—I heard from a gentleman who gave me permission to share this story. His name is Jamal Horton. He is with the National Multiple Sclerosis society, and of course, MS medication has gotten astronomically expensive, and so a lot of folks, as you have been describing, stretch their dosages to try and control the costs, but then that makes it less effective, and it starts a terrible cycle

Here is Jamal in his own words. He says: “Due to the debilitating effects of MS, I lost my high-paying IT job. As a result, access to the medication I needed became financially impossible, and then I lost almost everything. Due to the fatigue and cognitive issues, I lost my job, I lost some friends, my marriage. I even lost my dignity, because I lost my job, I could no longer afford the MS medication that was stabilizing my disease, and because of this, my condition worsened and worsened, and now I am living with more progressed disability. This is particularly difficult because I was an aspiring athlete, and now I have lost my ability to even walk very easily.”

I know that you can relate to this, as you shared today, with your own struggles.

Can I just ask, Mr. Armus, you have a unique perspective as someone who has seen the pharmaceutical industry up close and personal, and I noticed in your written testimony you mentioned the difference between the relative amounts of money that the pharmaceutical industry spends on research and development versus marketing. I thought that was such an interesting point. Could you say something more about that?

Mr. ARMUS. Well, there are two kinds of marketing. There is market toward the industry so that might be print advertisements in journals, and then, of course, they spend an enormous amount of money on a sales force, which I once was part of, and I would like to point out also, because I have given it some thought, and the 10 to 15 years that I was actually in sales, we never discussed price with doctors, and that is when the price of pharmaceuticals was relatively low, and even more interesting to me, not once in those, let us say, 13 or 14 years, not once did a doctor ask me how much the drugs cost, and so I never told them. It was not in my best interest to talk about price. I was there to talk about the features and benefits of the product.

To this day—now I see doctors a lot for my own personal benefit, not just as a marketing person, and doctors still do not know the prices. I just spoke with my cardiologist actually this week, and I told him that I was coming up here, and well, I happened to see two doctors. One of them did not know anything about pricing, and the other one apparently did. He was a family doctor, and he said, "Those pharmaceutical companies are criminal." That is the word he used.

I mean, I did not want to use that in my statement, but the more I listen to my fellow witnesses here, I think it is appropriate.

Senator HAWLEY. Thank you so much for sharing that. Let me just ask all of you, insurance companies often portray themselves as shielding the consumer, you know, standing in between the consumer and the efforts of health care providers or drug producers to drive up prices, and so they say, you know, they are really on the side of the patients. Can I just ask you, in your experience, has that been the case? Have you found that these insurance companies—do you feel like they are on your side and really advocating for your interests? Go ahead, Ms. Smith.

Ms. SMITH. I would love to answer that. No, they are not in the business to protect the patient. They are not. In fact, when I was trying to get my PCSK9 inhibitor approved, I discovered that the insurance company, even though my doctor would send in the prescription with the reasoning why, there has to be a peer-to-peer review, a peer review, so some other doctor somewhere out there in IT land would review my case who has never seen me before and deny that I needed the drug. That makes absolutely no sense to me.

I also found out that it depended on where you live. I am in the South. Alabama, Louisiana, Mississippi, they are all notorious for denying this drug. We could go north and get it approved, but in the South, because there is one insurance company that dominates in that area, they can charge whatever the heck they want, so no, they do not care about the patient.

Senator HAWLEY. Well, thank you so much for sharing that, and I see that my time has expired. I just want to say, you mentioned one insurance carrier. I noticed that in our present health care system there seem to be some people who are doing really well and then others who are not. The people who are not doing very well are the patients. The people who doing really well are the insurance companies and the drug companies, and to my mind, that is a big, big problem. Thank you all so much for being here.

Thank you, Madam Chair.

The CHAIRMAN. Thank you.

Senator Sinema?

Senator SINEMA. Thank you so much, Chairman Collins and Ranking Member Casey, for holding the first of two hearings dedicated to rising prescription drug costs, and thank you to all of our witnesses who are here today and to those in Arizona who have shared their deeply personal stories with us.

The issue I hear about most back home is the cost of health care. There is a gentleman in Mesa, Arizona, who is lucky enough to be insured, but he has seen the price of his medication to treat a serious lung condition increase nearly five times in just 1 year. He has looked, but there are no generics available that could offer him any financial relief.

A woman from Glendale, Arizona, worries about her husband who has a serious heart condition, but his medication costs more than $500 out-of-pocket for a 3-month supply, so he refuses to fill his prescription because he is worried about how it will impact their family financially.

Another Arizona woman struggles to afford her specialty cancer medication. Even though her medication is a generic, she still has to pay thousands of dollars out-of-pocket and often spends hours on the phone just to understand the unexpected cost increases and to research payment assistance options, and this, of course, is unacceptable.

We can and must come together to increase competition and innovation, drive down costs, and improve the quality and accessibility of health care, so I would like to ask our witnesses today about the complex calculations that you all or those you know must make in order to refill their medication, so do you have to ask yourself is there a more affordable generic for my condition? How much will my insurance cover this month, if any? What kind of payment assistance options are available to me?

What I would like to hear from you is a little bit how this burden falls on you or those that you know to figure it out, and what is the impact that that has on your well-being, on your financial health, and on your family stress?

Ms. CISEK. In my case, having had problems with stomach ulcers, I took the generic, and it ended up that I landed in the hospital and had to have a blood transfusion, so that is what the generic did to me, so that is why I insisted I go back on the brand, but I do have to say my doctor very willingly has contacted the insurance and gotten the approval. Now, mine is for 1 year, but with a lot of the generics, though, you do not have the same regulation. It is supposed to be a 5 milligram pill. It can either be 4 milligrams or 6 milligrams, and what fillers did they use?

My husband worked for Westinghouse Electric for 33 years, had the most fantastic insurance. The medication was—I do not want to say “next to nothing,” but compared to what it is now, how much I miss that, but upon his retirement, we were paying $741 as a Westinghouse retiree, so when you have had really good insurance and then you go paying what you are paying now, it hurts.

Ms. SMITH. I cannot help but think, you know, I am 71. I am not as sharp in some things as I used to be, obviously, and I think about patients who are much older. My Mom is 92. She cannot even comprehend the prices of her drugs. It depends on me or my sister to do that for her, so I am thinking, as I get older and I cannot advocate for myself, who is going to do that for me?

That is really something that really concerns me, and I think that is probably something that concerns a lot of caregivers that are caring for our elderly parents or such, but it is a concern and something that I think we need to really look at.

Ms. HOLT. With my Revlimid drug, which I take to remain remission for my multiple myeloma, no generics are allowed. Through manipulation of Celgene, they have kept any and all generics off the market. Revlimid is the drug that my doctors choose for me to be on this. With this disease, my symptoms will come back, and there are only very limited drugs that are effective, so when you are on a drug, they do not want you to switch.

I am totally dependent on this drug to keep myself in remission at this time. To have some type of generic would be wonderful just to bring the market a little bit more affordable, but at this point they have manipulated the system.

Senator SINEMA. Thank you. Madam Chair, my time has expired. Thank you.

The CHAIRMAN. Thank you.

Senator Gillibrand?

Senator GILLIBRAND. Thank you, Madam Chairwoman and Mr. Ranking Member. This is such a crucial hearing.

I have traveled across my State to talk to people about this crisis. Your stories are heartbreaking. The stories of my constituents across New York are heartbreaking, and there seems no end in sight, and so the fact that this hearing is taking place and that we are shining a light on the abuses in this industry and how it is affecting people's lives is important.

I talked to an advocate who lost one of her patients. He was diagnosed with a cancer, and his medication was $5,000 a month, and they only had $60,000 in savings, and he did not want to leave his wife without anything, so he chose not to take the medicine and he died. That is the real choices that people are making every day because this industry is unwilling to protect people's lives. They are more interested in profits than people, and that is wrong. That is not who we are as Americans. That is not what we represent.

Ms. Holt, thank you for sharing your powerful story. As a single Mom with three kids, I admire your strength and resilience. In your written testimony, you discussed having to refinance your home just to deal with the debt brought on by prescription drugs. How else has this impossible choice between life-saving medicine and essential expenses impacted your life? How is it impacting your children's lives?

Ms. HOLT. Well, I obviously am not going to leave them any inheritance, which may or may not be a good thing. My car is 13 years old, because I have a grant this year to pay for my co-pay, I have to stay under $60,000 income, so even the savings I do have, which is minimal, I cannot use because it raises my income to the point that I will no longer qualify for this grant, so I cannot take vacations. I cannot do what I would normally do, which I would like to do because this illness is going to come back and my life span is limited, but I am in this strange place where I am like status quo, so that is what is impacting me.

Senator GILLIBRAND. Ms. Smith, I appreciate you sharing your story as well, and I read how you have to get creative with the ways you pay for your drugs because of the difficulties with insurance companies covering the cost of your heart medication, and now you are forced to ration out samples from your doctor. That to me is absolutely unacceptable and shows a huge failure in our health care system.

What if the insurance company decides not to cover your drugs this year? What if you are no longer able to access samples from your doctor? What will you have to do? What choices do you think will be in front of you?

Ms. SMITH. Well, I would have two options. I certainly could not pay for it, not in retirement. I would either have to go back on the statins, which were totally debilitating, or just not take them at all and take my chances, and that is what I have been doing for the last 3 years on and off, except for the 3 months that I did get access to the drug.

I mean, it is risk a heart attack or a stroke or take a drug that makes me unable to walk. Those are the choices, and I might add, too, I am a civil service retiree, so I have a civil service retirement benefit that I get each month, but I am 71 so I get Social Security. My Social Security check that I get was cut because I have a civil service retirement, so I would not have enough money from my Social Security to pay for just one of my drugs, let alone all 12 of them.

Senator GILLIBRAND. Ms. Dehetre, thank you for sharing your story. In your testimony, you discuss the struggles with the climbing cost of diabetes treatment, among other health care costs, that have left you scrambling to balance your finances each month. Fifteen years ago, if you needed a vial of insulin, it would cost about $175. Today the same vial costs $1,500, a reality of the prescription drug gouging that we all know too well.

Is there anything in your experience dealing with prescription drug costs that suggests that pharmaceutical companies will stop taking advantage of their patients in this way? And what else should Congress do to hold these bad actors accountable?

Ms. DEHETRE. I do not see an end to it at this point. That is why I was so willing to come and testify today, because of this bill and what Ms. Collins is trying to do, not only for myself but I am friends with other diabetics. I am friends with somebody with MS, so speaking with them, I have been exposed to a lot of people going through the same thing, so until there are changes made and they force them to make them, I do not think that anything will change for us, the consumer.

Senator GILLIBRAND. Thank you, Madam Chairwoman. Thank you, Mr. Ranking Member.

The CHAIRMAN. Thank you very much, Senator Gillibrand.

Ms. Dehetre, I want to followup with the conversation that you started with Senator Scott. I received a letter from Dr. Irwin Brodsky, who is the medical director of diabetes at the Maine Medical Center, in which he said that approximately 40 percent of people with Type 1 diabetes, the kind of diabetes that you have had since high school, will have a severe low blood sugar reaction over the course of the year, and you have talked about how often that has happened to you, and that when it does result—first of all, it endangers your life, and you talked about one that happened when you were driving your son, which is scary.

Ms. DEHETRE. I actually had two of my sons in the car at the time, and it is very scary when you start to become aware and you realize that you could have killed your children.

The CHAIRMAN. That has just got to be so frightening and devastating.

Ms. DEHETRE. It is not—yes.

The CHAIRMAN. If you go to the hospital, it is going to cost a minimum of $2,600, so for the life of me, I cannot understand why your insurance company will not cover a continuous glucose monitor and a pump for you which would give you so much better control over your diabetes, and it sounded like for a time you did have that several years ago.

Ms. DEHETRE. The actual pump and glucose monitor was something new. I got it in 2015, and I was able to use it for about 4 months because that is when the supplies ran out for it, and then when I called to get new pump supplies and realized how much it was going to be and I could not afford it, I went back to shots, but while I was on it, I did not go to the hospital even once.

The CHAIRMAN. Wow, so what a difference that made.

Ms. DEHETRE. Right. Well, it alarms you when your sugar is going either high or low so that you can take care of it.

The CHAIRMAN. Of course, we have had even further advances with essentially an artificial pancreas with a closed loop system, which is so exciting, but it is ironic that not only is your health being endangered, but also if you are being hospitalized more often, the insurer is ending up paying more money, except for, as you said, when you refused to go because you are worried about your co-pay, but that is not a great solution for you either.

Ms. DEHETRE. No.

The CHAIRMAN. I am wondering, has your physician tried to get coverage from the insurance company?

Ms. DEHETRE. My physician has tried two or three times to contact my insurance company and petition with that company about approving it, and to no avail, which is frustrating. It is frustrating for me.

The CHAIRMAN. It is frustrating, and it is just plain wrong.

Ms. DEHETRE. It is. It is very wrong, and like I said, I am friends with other diabetics as well as other people with medical conditions that there is no cure for, and it is frustrating to see that. My friend with MS, she sometimes does not get her shots because they are too expensive.

The CHAIRMAN. That is why it is so important that we hear from your experience to help us shape some of the solutions. Some of us have introduced bills already. We are working on other proposals.

Mr. Armus, I want to ask you a question because of your experience in the industry. I have just introduced a bill to try to do some reforms of the patent system, because we have seen some real gaming of the patent system by some pharmaceutical companies. I want to ask, in your experience, do you believe that the increases in prices that we see on some of these drugs that are tied to changes in perhaps their packaging or how they are released into the body—and I realize you do not have inside information to evaluate each of those, but could you give us your experience on whether you think these changes justify what are often enormous price increases? Or are they just an attempt to game the patent system and block generics from coming in as competitors?

Mr. ARMUS. The patent system is there for a manufacturer's exclusivity. In most cases, they get 17 years of patent protection, which they start from the day that they start researching it, so if they take 3 to 5 years to come out on the market, they lose that amount of time as far as their patent is concerned, but let us say they lost 5 years, they still have 12 years of exclusivity to charge whatever they want. Nobody is telling them what they can charge. The list price is one of the key—it is not the only key factor, obviously, but it is one of the key factors.

You know, I was thinking while I was sitting here, because I said it myself, they tell us that research and development is one of the reasons for the high cost of drugs. They get tax credits and tax deductions for research and development, and yet they still charge us for research and development on the retail end. You know, I had a business of my own. I took deductions for any research and development that I had, and so, actually, they are getting double the value on the research and development.

The TV advertising is totally unnecessary. They may have a necessity if they are going to advertise to doctors because they want doctors to know what the product is, but they are advertising to the consumer, who cannot write a prescription. All he could do is beg his doctor for it. I did that one time. It put me into the donut hole so fast. I said, “Why did you prescribe that for me?” He said, “Because you asked me for it.” That was his simple answer.

You know, and that one was like $150 a month. I said, “Is there anything else that you could prescribe?” He said, “Oh, yes.” Now I have one that costs me $3 a month. That is how little they care about prices and costs.

I do not want to take up anybody else’s time. I could talk forever.

The CHAIRMAN. Mrs. Smith, let me just end with you before yielding to my colleague, who is being very patient. I was struck when in October Amgen, which is the maker of Repatha, announced that it was going to cut the list price for that drug by 60 percent. Now, cutting the list price does not necessarily mean that the patient is going to see a 60-percent reduction, so we always have to remember that.

Here is the startling part of his or her announcement, the CEO noted that an estimated 75 percent—75 percent—of Medicare patients prescribed a PCSK9 inhibitor never actually fill the prescription because of the high out-of-pocket cost, so here we have this essential drug, which has been vital for you, but 75 percent of people cannot afford to use it. Would you like to comment on that?

Ms. SMITH. Yes, I would. Thank you. Definitely, and that is a true statement; people just—they go to the pharmacy. They find our how much their co-pay is, and they do not fill it. I have talked with several. I have one friend who the same thing happened to. Finally, after months and months and months, she finally got the drug approved by her insurance company. She went to the pharmacy. It was over $500, almost $600 for the prescription, and she said, “I cannot afford it.” She did not get it filled.

That story, it goes on and on and on. I hear it so much. I was pretty much the same way when I first found out how much it was going to cost, and I thought, “I cannot afford that every month, so I just will not get it filled.” Then I thought, Okay, you know, I mean, there has got to be—there is a fight in here somewhere. We have got to figure this out.

I started on this journey of trying to get it approved, and one of the things that I have discovered with it was the co-pay card that is available through the company, if you have private insurance, then you are eligible for that, but if you are on Medicare and your supplement is a Government-sponsored supplement, you cannot get that, and to me, those are the ones who really need it the most, and they are not—that $5 co-pay card is not accessible to them.

You know, it is kind of a Catch–22, but you are absolutely right. People go to the pharmacy; they do not—and not just this drug but others. They do not get it filled because they cannot afford it.

The CHAIRMAN. Thank you.

Senator Casey?

Senator CASEY. Thank you, Madam Chair.

I just have one question directed to Barbara. I meant to get to this question earlier. Barbara, I went through your testimony, and you cannot see it from where you are, but I checked off all of the things that you listed that you are battling or that you have suffered through. I do not want to remind you of all that, but it is quite a long list, and as I said before, this is a testament to real life.

I wanted to ask you about another challenge that you had, but I think a challenge you willingly accepted, and that is being a caregiver for your Mom when she was battling ovarian cancer. Not all Americans have someone like you who is both a close relative and also willing to be a strong advocate and to be able to speak up. Many do, but many do not as well, and your Mom was blessed to have that help, I am sure.

I guess I wanted to ask you, having gone through that experience, what would you say about the kind of support that you believe that most people would need to both navigate the insurance issues as well as the prescription drug issues? What would you tell us about that?

Ms. CISEK. Well, I know in my mother's case, my father died at a young age. I was 15 at the time she was 45. I had a supportive family. My husband was helpful. My son, David, very helpful. Some of the medicines that she was going through, thank God she had PACE. One of the medications she was taking was Zofran. For a 1-month supply—now, it has been 20 years since my mother died, so within that time span of the 3 years, that was $1,500 then for a 1-month supply, so the doctor would give the prescription. I would take it to the pharmacy. He would call the doctor. Then, of course, it had to go through the State, but once hospice was in the last 15 months, everything was taken care of by them.

My promise always to my mother was that she would not end up in a home, and I was glad we were able to do that, but I think if you can get hospice and maybe more financial support for the families—my mother and I were both hairdressers, so I could juggle my schedule so that I could be with her, take her to the hospital, take her for her radiation, but then it made it very hectic at home, but, you know, the good days were good and the bad days were bad.

Thank God one thing with hospice was they did the compounding as far as medication, so everything fell under that umbrella, but any durable medical equipment, everything was covered, but I think so many families just do not have the family support and the financial support, and you find—and I dealt with my mother-in-law being in a nursing home 2 months after my mother died, so you see it from that angle, but it makes me wonder sometimes, so many end up on Medicaid, you wonder why some of that cannot be directed to the family so someone could work part-time. The medicines, if someone is not on PACE, as my mother was——

Senator CASEY. PACE meaning the State prescription drug——

Ms. CISEK. Through the State, yes, because of the income. After my father died, there was not savings. There was no pension, but I think there has to be the willingness to do that, but if people like that can get their medication at a lesser amount, pretty much as we have talked about here, if that money could be directed toward the families, maybe you would not have people having to juggle. You know, I have a full-time job or the husband has, and you cannot work together to keep your family together. In that case. my mother was living with us the last 3 years, but she was with us quite often. If she had a stroke, she would be with us for 8 months. She would have a procedure; it would be another few months, but like I say, she always did fight to get back on her feet, so she was a strong individual that way.

If there could be more financial help within the home, maybe it could be better afforded if they did not have to go into a nursing home, and the care that you would receive from your family, or at least hopefully, would be much better than what you would have with the nursing home, but as far as medication, I do have to say my mother had excellent Blue Cross and Blue Shield, and that covered her expenses quite well that way, but once she was able to get on the PACE program, that was fantastic because when my mother died, she was getting $530 a month Social Security. That was it, and that was in 1999 when she died.

Senator CASEY. Barbara, thanks very much.

Ms. CISEK. Thank you.

The CHAIRMAN. Thank you, Senator Casey.

I want thank all of our witnesses for appearing today and sharing your very personal stories with the Committee. Oftentimes when we have hearings in Congress on the cost of prescription drugs, the witnesses are the pharmaceutical companies, the pharmacy benefit managers, the insurers, the hospitals, some health care providers, and today I feel that we heard from the most important voices of all, and that is the patients, and it is really important that we start from that perspective as we work to solve what is an increasingly difficult and onerous burden of high and ever rising prescription drug prices.

We have seen increasingly that cost is such a barrier to following a doctor's orders. It is a barrier to remaining healthy. It is a barrier to getting well, and that should just not be. No one should have to choose between paying the rent or the mortgage and purchasing much-needed prescription drugs. Nobody should have to choose to go deeply into debt or refinance a home in order to afford drugs that are necessary to keep that individual alive. No one should have to face the choice of being cold and hungry in order to afford prescription drugs.

I believe that there has been a wake-up call in Congress that this is an issue we must address. We want to make sure that we do not discourage innovation and the development of important new medicines, but we also need to make sure that the system is not being gamed and people are not being treated unfairly.

I know that this is a bipartisan cause, as you could see today by the number of Senators from both sides of the aisle who attended our hearing, and many of us have introduced bills, either together or separately. I mentioned the patent bill that I introduced earlier this week. I know Senator Casey has a dashboard bill to increase availability of information, and I am a cosponsor of the CREATES bill that Mrs. Holt mentioned, and we did have some success in the last Congress in getting bills all the way to the President's desk and signed into law, but, clearly, our job is not done, and that is why this is the first in a three-part series on the cost of prescription drugs. Tomorrow we are going to hear from experts in the field to help us untangle this web and understand exactly what we can do to make the system more affordable and more transparent, and then our third hearing we will hear from the administration on its proposals which deal with such issues as rebates and whether or not they are reaching the patient rather than enriching those along the supply line.

I want to thank not only our witnesses, who are terrific, but our great staff who have worked very hard on this issue.

Senator Casey, if you have any closing remarks, I would be delighted to yield to you.

Senator CASEY. Madam Chair, thanks very much. I want to add that that was a really good statement, and I will submit a statement for the record.

Senator CASEY. I just want to thank our witnesses for being here and for bringing us your stories and the reality of your lives that will help inform tomorrow's hearing and future debates on solutions, and I just want to thank you again.

The CHAIRMAN. Thank you very much.

This hearing is adjourned. We will reconvene at 9:30 a.m. tomorrow in this very hearing room, 138 Dirksen, to continue this series of hearings. Thank you again.

[Whereupon, at 11:27 a.m., the Committee was adjourned.]

APPENDIX

Prepared Witness Statements

Testimony Submitted by Michelle Dehetre to the U.S. Senate Special Committee on Aging
March 6, 2019

Good morning. Thank you Chairman Collins, Ranking Member Casey, and distinguished Members of the Committee for inviting me to testify before you today.

My name is Michelle Dehetre. I was diagnosed with Type I Diabetes in 1985 as a freshman in high school. I am 48 years old. I am a mother of five. My dream is to see my 11-year old son graduate high school.

Diabetes threatens my life. Just last week, on Thursday night, while I was driving my son home, I passed out at the wheel. Soon the paramedics arrived on the scene, and I got sent to the emergency room.

Unfortunately, this is not an unusual occurrence. Because I cannot afford the treatment I need, paramedics end up visiting me two to four times a month. I require two types of insulin to live: a long-acting and short-acting version. I take Lantus and Humalog. I work full time, and shell out nearly $300 per month out of pocket on the insulin, syringes, and test strips that keep me alive.

Ending up in the ER always scares me, not only because I know it’s a close call, but because on top of my medicine, I cannot afford another medical bill. When the paramedic visit results in a ride to the hospital, it costs $600 and the hospital cost is usually about $2,000.

I have tried to save costs on my treatment. I asked my doctor about using an older insulin, and found an option at Walmart for $25. I picked up a vial of Humulin NPH and another of Humulin Regular. It is basically the same insulin that I used to take in 1985. But as I have grown older, my blood sugar levels have gotten more and more unpredictable, even when I eat the same thing from one day to the next. So the older insulin didn’t work well.

I was able to successfully save money on test strips. The brand that my insurance covers cost me $99 out of pocket per month. Thankfully, I was able to get another brand from Walmart for $51 per month, without using my insurance. I use test strips to check my blood sugar levels at least six times a day: when I wake up in the morning, before and after every meal, when I go to bed at night, and in between.

But I can’t feel when my sugar level is plummeting, it tends to go too low at night. My mom and aunt are nurses. Even in my family of caretakers, it has proven very difficult to keep my blood sugar in check.

My doctor says that what I really need is a continuous glucose monitor and pump. I had that in 2007 and it worked really well. When my insurance coverage changed, my costs to keep the pump running skyrocketed to $1,500 for a three-month supply. There is no way I could afford that. So I am using syringes and test strips.

The money I am spending on diabetes treatment already is too much. In addition to buying food, paying the electric bill, and other monthly bills for my household, spending at least $300 per month for my diabetes medicine is a major financial strain. I cut back on spending whenever I can. I am always looking for ways to save money on food and gas, and sometimes fall short at the end of the month.

Treating my diabetes is a matter of life and death. When my body doesn't get the insulin it needs, it makes my blood sugars go very high, which over time can lead to diabetic complications, such as blindness, neuropathy, and even death.

Sadly, I actually know that I am better off than others. In the year 2019, I wonder how many others are also struggling to cover the cost of insulin, and other diabetes medicines and supplies. How many others are trying to save costs by using insulin from 1985 to no avail? In 2019, no one should have to go through this. I want insurance companies and pharmaceutical companies to wake up. What they think they are doing to save money is not helping people like me.

Thank you for the opportunity to testify, and I am happy to answer your questions.

Testimony Submitted by Pamela Holt
U.S. Senate Special Committee on Aging
March 6, 2019

Chair Collins, Ranking member Casey, my home Senator, Senator Braun, and members of the committee — thank you for inviting me.

My name is Pamela Holt, and I am from Granger, Indiana. At the age of 40, I was widowed when my husband died from a heart attack, so I raised three children on my own. I was fortunate to be a teacher and administrator with good benefits that set me up to have a good retirement.

That all changed, however, when I was diagnosed with Multiple Myeloma 3 years ago.

Multiple Myeloma is an incurable but treatable blood cancer. Upon my diagnosis, I underwent a bone marrow transplant and chemotherapy. I am lucky to be in remission today.

However, to keep my cancer at bay, I must take the drug Revlimid. Initially, this prognosis felt good — I would get to live longer, help raise my grandchildren, and spend summer at our favorite lake in Wisconsin. And I am deeply grateful for that time. But when I learned the cost of Revlimid — I was horrified.

The price of Revlimid is over $250,000 per year.

On Medicare Part D, I went into and out of the donut hole in January — paying $4,950 the first month and then $640 for Revlimid every 28 days for the rest of the year. That cost was unaffordable for me and after just one year, it sent me into debt quickly. I was entirely underwater, and I made the heartbreaking decision to refinance my house.

It was 3 years from being paid off entirely. Now I have to start all over.

In the last year I have been fortunate to receive a grant for the cost of my Revlimid, but such money can always fall through. I should not be dependent on grants to afford a medication I need to survive.

I spent my life doing all the right things — contributing to my community, teaching in public schools, raising my children — it is unfair that despite my hard work and careful planning, I must face financial challenges because of cancer I have no control over.

I am grateful for the additional time Revlimid has given me with my family. But having cancer is hard enough, I shouldn’t have to lose my savings to stay alive.

I am encouraged by the action Congress is starting to take in the hearings over the last couple of months, and I am particularly grateful to this committee for listening to patients.

But what patients need most is real change to the system and Congressional action that will bring down drug prices.

For me, one solution would be the CREATES Act. CREATES addresses a tactic the company that makes Revlimid, Celgene, uses to deny generic companies access to samples to Revlimid. This prevents generic competitors from coming to market and allows Celgene to set the price of Revlimid high.

I came to DC last year to encourage Congress to pass this importation piece of legislation — I was grateful when my Senator, Senator Young, agreed to cosponsor the legislation. But I was disappointed that it didn't get over the finish line.

I am hopeful the members of this committee will sign on to the legislation and take meaningful steps to pass it.

For myself and patients across the country, Congressional reform would be life changing.

Thank you for taking the time to hear my story. I look forward to the action you will take on drug prices for myself and other patients across the US.

STATEMENT OF DONNETTE SMITH
Before the US Senate Special Committee on Aging
March 6, 2019

Chairman Collins, Ranking Member Casey, and members of the Committee – thank you for the opportunity to be here today to talk about the challenges I have had in getting the medication I need. My name is Donnette Smith and I am from Huntsville, Alabama. I have suffered from heart-related conditions from birth, and the efforts and skills of some excellent doctors along the way have enabled me to have a full, if complicated life. But today, I sit before you as a person at high medical risk.

I am a retired federal employee and I live in Huntsville, Alabama, where I spent my career as a technical writer for the U.S. Army and working for NASA. I have also had the honor to be an advocate and resource for heart patients as President of Mended Hearts, a national peer-to-peer support organization for heart patients, providing hope and encouragement for 67 years

My medical story began at birth, although I did not know that until much later. I was born with a heart defect that led to aortic stenosis and heart failure. After suffering from debilitating shortness of breath throughout my childhood, I finally learned the truth about my condition in my late teens, when a NASA physical revealed a severe heart murmur. I was devastated!

Just after my 40th birthday I had open heart surgery to replace my deformed aortic valve. I did well for a number of years, but a failing valve and severe cardiovascular disease a few years later led to two more heart surgeries and five stents. After the third surgery in 2009, my doctors said it was urgent to dramatically reduce my cholesterol level, which was off the charts. I believe I tried every statin and step therapy available but nothing worked for me. I was a stroke or heart attack waiting to happen.

When Repatha, a new type of cholesterol-reducing drug (a PCSK9 inhibitor), became available several years ago, my cardiologist believed that it could dramatically reduce my risk.

He tried unsuccessfully to get my insurance to cover it. Without insurance, it would have cost me over $14,000 per year. The applications and appeals process were very detailed and complicated and extremely time-consuming for my doctor and his staff. Even with all his effort, it was not approved. When I spoke about my struggles at a cardiology town hall meeting in 2015, a physician there became an advocate for my case. My insurance company eventually approved three months' of coverage in January 2018 and I began taking Repatha. The drug dramatically changed the quality of my life. My LDL cholesterol level fell from 283 to 70 in one month, and I felt the cloud of fear hanging over me finally lift!

The drug is very expensive and with insurance my copay was $583 per month. That isn't a small amount of money but I was willing and able to pay it if necessary. And I was fortunate enough to discover a manufacturer copay card which sharply reduced the cost. However, the coupon only works if the prescription is covered by insurance. Unfortunately, after three months I received a notice from my insurer telling me that I would have to go through pre-authorization again. That was one year ago and I am still waiting. I heard that the drug's price was recently reduced, which may provide better options if my doctor's latest pre-authorization request isn't approved. Right now I am taking samples of Repatha that my doctor has been able to get for me, which I stretch out by not doing the injections as often as prescribed. He thinks that any amount I can take is better than nothing. I hope that the latest pre-authorization is approved. I have been hanging in there, but I don't know what this is doing to my health for the rest of my life.

In some ways, I consider myself lucky. I encounter many people who have not had the medical care I have had. I urge you to do something, for all of the seniors and others who cannot afford their medications. Thank you again for the chance to share my story with you today.

Testimony Submitted by Sheldon Armus
U.S. Senate Special Committee on Aging
March 6, 2019

Chair Collins, Ranking member Casey, and members of the committee — thank you for having me.

My name is Sheldon Armus. I'm 71 years old and live in a senior community in Boynton Beach Florida. I am a constituent of Senators Rick Scott and Marco Rubio, members of this committee.

I spent the first 35 years of my career working in the health care industry. I started as a young pharmaceutical sales representative, and I worked my way up to management for several companies, including manufacturers of medical devices.

Before retiring in 2014, I owned my own medical device company and worked as a science teacher for 10 years.

One month into retirement, I underwent a quadruple cardiac bypass operation — a surgery that saved my life. However, the surgery, as well as my diabetes and cardiac conditions left me taking seven different drugs each day.

All of these drugs keep me alive, and I'm very thankful for their existence.

However, they also have proven to be a real financial burden.

Xarelto is one of my drugs; it is a blood-thinner that prevents dangerous blood clots that can lead to heart attacks. It is a new and expensive drug with a list price of more than $450 for a 30 day supply! It is outrageous.

You've probably heard of Xarelto because it is heavily advertised to consumers on TV. Janssen Pharmaceuticals, the company that makes Xarelto has promised to start disclosing the list price of its medications on those ads.

But that wouldn't make a difference for patients like me. There isn't a generic on the market I could turn to instead.

I am lucky to be on Medicare Part D, where I pay only a portion of that price. But it is still too much.

Before Congress closed the donut hole, I would fear the month my out of pocket costs would spike. Because of fluctuations of the list price, I never knew when I would hit the donut hole threshold. At some point I would go to the pharmacy to pick up my prescriptions and discover that they all cost more than the month before.

Sometimes I would have to wait a few days until my Social Security check arrived in order to be able to afford it.

It was always a shock to my system.

Something must be done. Drug prices are out of control — I am grateful that the donut hole has been closed for patients, but it doesn't solve the problem of high list prices. I struggle to afford my drugs with Medicare Part D coverage but I feel even worse for those without coverage who must pay list prices directly.

Patients and taxpayers still pay for a percentage of the list price; therefore, it is in the best interest of the pharmaceutical companies to inflate the list price.

I know because when I worked in the industry, I attended meetings in which maintaining and increasing high list prices was discussed and encouraged.

Pharmaceutical Reps as well as the public are told that the high drug prices are due to the high cost of research and development. However, according to the Washington Post[1], 9 out of 10 big pharmaceutical companies spend more on marketing than on research.

At one time, I was proud to have worked in the pharmaceutical industry. But now, being a patient, I no longer feel that way. In fact, I'm embarrassed to tell my fellow seniors of my past work experience.

I am grateful to the Committee for holding this hearing and delving into the issue of high drug prices. The issue starts at the top with high list prices set by drug companies, but it ends at the bottom, with us, patients just trying to continue to live our lives.

Thank you for your time.

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[1] https://www.washingtonpost.com/news/wonk/wp/2015/02/11/big-pharmaceutical-companies-are-spending-far-more-on-marketing-than-research/?utm_term=.c7e754c8211c

Barbara Cisek
Testimony before the
United States Senate Special Committee on Aging
March 6, 2019

Chairman Collins, Ranking Member Casey, and Members of the Committee, thank you for inviting me to testify today. It is an honor to be here.

My name is Barbara Cisek. I am 72 years old and live in Rural Ridge, Allegheny County. My husband Ed and I were high school sweethearts, married for just shy of 43 years when he passed away in 2009. We raised two sons together, David and Michael, who now have four kids between them. My son David is here with me today.

Raising my family, keeping our hairdressing shop open, and caring for my Mom as she battled chronic illnesses was hard. Like me, she had a lot of different medical issues and was sick a lot, but always fought to get back on her feet. She was diagnosed with ovarian cancer at age 80 and lived with us the last three years of her life.

I wonder what will happen if I live to be my Mother's age. With all the medical expenses I'm facing, on a fixed income, I'm scared there won't be anything left. I pay about $500 out of my own pocket for medicine and over-the-counter items every month. If I actually took all of the medications my doctors prescribe, the costs would total well over $1,500 every month. That's on top of my Medicare Part B premium of $134 per month and the $293 I pay for a Medicare Advantage plan.

I have battled bleeding ulcers, high blood pressure, high cholesterol, and severe migraine headaches for years, and was diagnosed a year and a half ago with diabetes. I am recovering from a stroke that I suffered last November and need to get a total shoulder replacement in the next several months. I'm living with chronic pain caused by a bulging disc, spinal stenosis, and sciatica. In addition to injections for my shoulder that cost $50 every 3 months, I use an inhaler to manage my COPD, have an oxygen concentrator at home, and need to start using portable oxygen tanks when I go out. With ovarian cancer in the family, I get tested every year. Sometimes I feel like I'm the puzzle with the piece missing.

What makes managing all these conditions worse and more stressful is never knowing what my insurance will cover from year to year and what my prescription drug costs will be. The Imitrex I took for the migraines cost $150 before it became generic. Now that it is generic, my insurance won't cover it and I pay $45 for 27 pills. Phenergan, a medicine my doctor recommended to help with my nausea isn't covered, and there is no way I can afford the $1,032 price. Elavil, a medicine that helps with my migraines, is no longer covered and I have to pay $85 for a 30-day supply. I spend $100 for two ounces of cream to treat skin rashes that insurance won't cover. It's hard to make the cream stretch, but I use the tiniest amount that I can to make it last. I just found out my shingles vaccine is not covered and will cost $420 out of pocket.

The most expensive medicine I take is Nexium, and I have to have it. Other forms of the drug, which treats my slow-bleeding stomach ulcers, have made me sick to the point where I needed blood transfusions. I go through the step therapy process every year, with my doctor sending a letter to my plan confirming that I do actually need the brand-name drug. For a 90-day supply, I pay $300. My Spiriva inhaler for the COPD is $150 each month.

When you add these drug costs to what I pay for other supplies, like diabetic test strips and lancets, my oxygen tanks, my CPAP, an eye vitamin to prevent cataracts, xylimelts and special bottles of mouthwash and toothpaste to treat dry mouth and receding gums, it's a lot. It all adds up. That's why I'm sharing my story with you today—to help you understand what it's like for us senior citizens who are feeling the full weight of these costs because we make a little too much to get help from the state or the federal government.

My husband worked as an engineering aide at Westinghouse in nuclear fuels for nearly 40 years. He worked hard, as I did, to build a good life and a good future for our family. I've lived in our home for 45 years and I don't want to leave it. I want to be able to afford my medicines so I can stay healthy and away from the nursing home. If things keep going like they are, with drugs costing more and more, and my insurance covering less and less, I don't know what I'll do.

I came here today to speak not just for myself, but for every other senior citizen who has had to stand at the pharmacy counter and leave something behind.

Thank you for the invitation to testify before the Committee. I look forward to answering your questions.

Statements for the Record

Closing Statement of Robert P. Casey, Jr., Ranking Member

In a country as prosperous as ours, we should be able to do better. No one should be forced to choose between affording their medication and putting food on the table. No one should be asked to deplete their life savings in order to stay healthy, and no one should need to split a pill or skip a dose in order to make a prescription last longer.

As our witnesses told us, that is not always the case.

We can and must do better.

To our witnesses, thank you and we heard you.

Your experiences will be front of mind as we sit in these same chairs tomorrow, listening to experts suggest solutions to address the rising costs of prescription drugs.

Again, Chairman Collins, thank you for bringing these patient voices to the conversation.

Association for Accessible Medicines
Statement for the Record
Senate Special Committee on Aging
Hearing on "The Complex Web of Prescription Drug Prices"
March 6, 2019

Introduction

The Association for Accessible Medicines (AAM) applauds Chairman Collins, Ranking Member Casey, and the Senate Aging Committee for its leadership in holding today's hearing on the rising cost of prescription drugs.

Patients continue to struggle to afford the high cost of certain medications. High launch prices on new brand biologics and annual price increases on existing brand-name drugs, combined with an increasing trend of anti-competitive tactics designed to delay or prevent competition from more affordable biosimilars and generics, are pushing access to medicines out of reach for too many patients.

That's why lowering prescription drug prices continues to be the top health care priority for America's patients. In the latest Politico/Harvard poll, respondents ranked lowering the cost of prescription drugs as the number one priority – with 94 percent of Democrats and 89 percent of Republicans saying "it is extremely important" for Congress to act.[1]

As the Senate Aging Committee examines the affordability challenges of high-priced prescription drugs, it is essential to understand the differences between the brand-name and generic drug markets and how the different pharmaceutical supply chains operate. Not only is the Food and Drug Administration's (FDA) approval process different for generics and brand-name drugs, but their respective markets and the path by which they reach patients diverge significantly, with important policy implications. These differences lead to different outcomes for patients, differences in the amount of spending funded by taxpayers, and differences in what consumers pay for health care coverage.

Independent research and data, however, demonstrates one undeniable conclusion: Brand-name drug prices continue to rise, while generic drug prices continue to fall. Brand-name drugs comprise only 10 percent of prescriptions filled annually by patients, but now constitute 77 percent of all spending on prescription drugs.[2] In contrast, the amount spent on generic medicines has declined for the last 30 consecutive months.[3]

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[1] Politico-Harvard, "Americans' Health and Education Priorities for the New Congress in 2019," January 2019.
[2] AAM, "Generic Drug Access & Savings Report," July 2018.
[3] Morgan Stanley, Monthly YOY Generic Prescription Drug Sales, January 2019.

These trends present public policy challenges and necessitate meaningful action by Congress and the Administration to lower the cost of prescription drugs for patients.

The Generic Drug Market Is Fundamentally Different Than the Brand Drug Market

The pharmaceutical industry in the United States is predicated on a balance between innovation and access. Brand-name drug companies are rewarded for inventing and developing new treatments and cures. In return for the innovation, current law provides brand-name drug companies with 12 years of guaranteed market exclusivity (i.e., a monopoly) for biologics and 20 years for each patent. There is also extra monopoly time provided to incentivize pediatric and orphan drug development. During the period of patent and marketing exclusivity, brand-name drugs are priced and sold free from competition and discounts or rebates are negotiated with others in the supply chain, such as pharmacy benefit managers (PBM), wholesalers and pharmacies.

Once the exclusivity period expires and the brand-name drug is off-patent, generic manufacturers and the newly developing biosimilars market are provided with an opportunity to make the same medicine, with the same clinical benefit, for patients. The introduction of competition into the market significantly reduces the price of medicine, and patients benefit from greater, more affordable access to FDA-approved drugs. Experience shows prescription drug prices decline by more than half the first-year generics enter the market.[4]

Generic drugs consequently play an integral role in health care. The expiration of patents and the introduction of multiple generic manufacturers competing against each other on price results in significant savings for the health care system. Over the last 10 years, generic manufacturers delivered savings of nearly $1.8 trillion – including $265 billion in 2017 – to patients and the health care system.[5]

But the manner in which the generic drug market operates differs in meaningful ways from the one for brand-name drugs. These differences between brand-name drugs and generics drugs lead to different financial incentives for other stakeholders in the supply chain.

While brand-name drugs operate in a market where there is no direct price competition due to government-awarded exclusivities and patent protections, generic drugs compete within a multi-competitor model with drug prices decreasing as more competitors enter the market. In fact, today there are more than 200 manufacturers supplying generic drugs to the U.S. market.

While brand-name drug companies maximize revenue through price rather than volume and negotiate discounts or rebates with other stakeholders in the supply chain, generic

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[4] IMS Institute for Healthcare Informatics, Price Declines after Branded Medicines Lose Exclusivity in the U.S., January 2016.
[5] Ibid., AAM.

drug manufacturers compete solely on the basis of price and the ability to supply. As a result, brand-name drug companies retain 76 percent of all revenue, while other stakeholders in the supply chain capture 24 percent.[6] In contrast, generic drug manufacturers retain 36 percent, while other stakeholders capture 64 percent of all revenue.[7]

In the brand-name drug market, brand-name drug companies use their leverage in the supply chain to negotiate formulary placement through rebate agreements with PBMs and health insurers. There is little room for wholesalers and pharmacies to capture large margins due to their relative lack of negotiating power. And pharmacy reimbursement for brand-name drugs is tied to the reported price and there is only one product available.

For the generic drug market, wholesalers, through collaborative purchasing agreements with pharmacies across the country, and group purchasing organizations exert leverage through their purchasing power and the robust competition among multiple generic manufacturers who are making identical products. Today, generic drug manufacturers compete for the business of three consolidated wholesaler-pharmacy groups who now control more than 90 percent of all generic drug sales.[8] This competition results in significant savings for patients but leaves generic drugs vulnerable to drug shortages and easily impacted by increased operational costs.

Brand-Name Drugs Increase Costs, Generic Medicines Drive Savings

The differences between the brand-name drug and the generic drug markets lead to different results for patients. Patients thrive with access to generic medicines, both in terms of health outcomes and financial savings. Insured patients benefit from an average copay for generics of only $6.06, while paying more than $40 for brand-name drugs.[9] In fact, over 90 percent of generic prescriptions are filled for $20 or less out-of-pocket.[10] That is in comparison to just 39 percent for brand-name drugs at that price.[11]

Experience also shows that patients are far less likely to fill a prescription for a high-priced brand-name drug. Brand-name drugs account for 40 percent of all abandoned claims for new patients, while constituting only 20 percent of approved claims.[12] In contrast, new patient abandonment rates for generics are three times lower than those for brand-name drugs.[13] Prescription drug abandonment has a serious effect on patient health – leading to hospitalizations, death, and extensive health care costs.

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[6] USC Schaeffer, “The Flow of Money Through the Pharmaceutical Distribution System,” June 2017.
[7] Ibid.
[8] Fein, Adam, “The 2018-19 Economic Report on Pharmaceutical Wholesalers and Specialty Distributors,” October 2018.
[9] Ibid., AAM.
[10] Ibid.
[11] Ibid.
[12] Ibid.
[13] Ibid.

With brand-name drugs accounting for 77 percent of total spending on prescription drugs in 2017, the high cost of many prescriptions is often out of reach for patients.[14] One of out every 10 prescriptions filled in the U.S. is for brand-name drugs.[15] In other words, 10 percent of prescriptions comprise 77 percent of the costs. And specialty medicines (including brand biologics) are rapidly approaching half of all spending despite being used by fewer than 3 percent of patients.[16]

Annual price increases of less than 10 percent on brand-name drugs and the cumulative impact of such price increases translates into hundreds, if not thousands, of dollars in higher prescription drug spending. AARP, for example, found 94 percent (133 of 142) of brand-name drugs more than doubled in price between 2005 and 2017.[17] And the Office of Inspector General at the Department of Health and Human Services (HHS) found that "reimbursement for brand-name drugs in Part D still increased 62 percent from 2011 to 2015" after accounting for rebates.[18]

Higher spending on prescription drugs impacts everyone – directly in the form of higher premiums and out-of-pocket costs and as taxpayers to cover the costs of Medicare, Medicaid, and other federal health care programs. Prescription drugs now account for $0.23 out of every premium dollar and the average co-pay for brand-name drugs was $40.30 in 2017.[19] [20] Moreover, in the latest National Health Expenditures report from the Centers for Medicare and Medicaid Services, Medicare spending on prescription drugs increased 36 percent, Medicaid spending increased 50 percent, and CHIP spending increased 35 percent over the last five years.[21]

In contrast, nine out of every 10 prescriptions filled in the U.S. are for generic drugs and spending on generic drugs accounted for only 23 percent of total prescription drug spending.[22] Continued growth in the use of generic drugs and declining generic drug prices led to savings of $265 billion in 2017 – an average of $1,952 for every Medicare and $568 for every Medicaid enrollee.[23]

Savings, however, often go unrealized. HHS found "incompletely aligned incentives for generic substitution leave significant savings uncaptured."[24] Seniors and the Medicare Part D program would have saved $3 billion in 2016 if generics had been dispensed rather the brand-name drug.[25] Last year, the FDA reported that patients could have

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[14] Ibid.
[15] Ibid.
[16] IQVIA, "Medicine Use and Spending in the U.S.," April 2018.
[17] AARP, "Trends in Retail Prices of Brand Name Prescription Drugs," September 2018.
[18] HHS OIG, "Increases in Reimbursement for Brand-Name Drugs in Part D," June 2018.
[19] America's Health Insurance Plans (AHIP), "Where Does Your Health Care Dollar Go?," May 2018.
[20] Ibid., AAM.
[21] CMS, National Health Expenditure Data 2017, December 2018.
[22] Ibid., AAM.
[23] Ibid.
[24] HHS, "Savings Available Under Full Generic Substitution of Multiple Source Brand Drugs in Medicare Part D," January 2018.
[25] Ibid.

saved “more than $4.5 billion in 2017” if they had the ability to purchase FDA-approved biosimilars.[26]

Moreover, new analysis from Avalere shows generic drugs are increasingly being placed on higher formulary tiers for seniors with Medicare Part D coverage. From 2011 to 2019, the number of generic drugs on Tier 1 (Preferred Generic) has declined from 71 percent to 14 percent. [27] Generic drugs are now placed on Tier 3 (Preferred Brand) 18 percent of the time and Tier 4 (Non-Preferred Drug) 25 percent of the time.[28] As a result, patients are shouldering more of the out-of-pocket costs for the same drugs at the same price. Avalere found “patient cost-sharing would have been $15.7 billion lower” over the last four years if generic medicines were placed only on generic formulary tiers. [29]

In recent years, the Assistant Secretary for Planning and Evaluation (ASPE) at HHS and the Government Accountability Office (GAO) examined trends in the prices of generic drugs. Due to the relatively-low cost of generic medicines, minor price changes can result in significant percentage increases. GAO, for example, cited the price of hydrocortisone increasing from $0.16 per tablet in 2012 to $0.41 per tablet in 2013 – an increase of 160 percent.[30] Correspondingly, the HHS ASPE report concluded, “Our review of the evidence strongly supports the conclusion that generic drug prices are not an important part of the drug cost problem facing the nation.”[31]

Nowhere is the need for lower-priced alternatives, and the challenges facing them, more real than among high-price brand biologics. Biologics, many of which are specialty medicines, are the most rapidly growing segment of increasing brand-name prescription drug costs in the U.S. Many brand biologics cost tens of thousands of dollars per year per patient – some more than $200,000.

Biosimilar medicines represent a key step forward in reducing high drug prices. Biosimilars are safe, effective and more affordable versions of costly brand biologics. By the year 2025, over 70 percent of drug approvals are expected to be biological products.[32] Experts estimate that FDA-approved biosimilars could save more than $54 billion over the next 10 years.[33] In doing so, biosimilars will mean greater access to lifesaving cures for an estimated 1.2 million patients.[34] Research shows women, low-

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[26] FDA, Remarks from FDA Commissioner Scott Gottlieb, M.D., FDA’s Biosimilars Action Plan, September 2018.
[27] Avalere, “Effect of Potential Policy Change to Part D Generic Tiers on Patient Cost Sharing and Part D Plan Costs,” February 2019.
[28] Ibid.
[29] Ibid.
[30] GAO, “Generic Drugs Under Medicare,” August 2016.
[31] HHS, “Understanding Recent Trends in Generic Drug Prices,” January 2016.
[32] U.S. Pharmacist, “Biosimilars: Current Approvals and Pipeline Agents,” October 2016.
[33] RAND, “Biosimilars Cost Savings in the United States,” October 2017.
[34] The Biosimilars Council, “Biosimilars in the United States: Providing More Patients Greater Access to Lifesaving Medicines,” August 2017.

income families, and elderly patients would particularly benefit from access to biosimilar medicines.[35]

Unfortunately, the ability of biosimilars to fulfill their potential is threatened by market abuses by brand-name drug companies and misguided policies that block access to lower-cost medicines. Seventeen biosimilars are now approved in the U.S., yet only seven are on the market and available to patients.[36] In comparison, more than 50 biosimilars are available to patients in Europe.

It is sobering to consider what America's patients would face if there no FDA-approved generic or biosimilar medicines to provide reliable access to affordable treatments. Generics do not only deliver the most medicine at the lowest cost and the greatest savings. Generic medicines also cushion the significant impact dealt to patients and the health care system by high brand-name drug prices every day.

Put another way, the availability of low-cost generics offsets the impact of high brand-name drug prices.

Conclusion

Understanding the differences among brand-name drug, brand-name biologics, generic drugs, and biosimilars; how each market functions; and, the different incentives stakeholders have throughout the supply chain is essential when considering solutions to address the rising costs of prescription drugs and to ensuring that the policies that are adopted result in meaningful savings to patients at the pharmacy counter.

AAM is available to help explain how the prescription drug markets work, help identify opportunities for improvement, and discuss solutions that lower the cost of prescriptions for patients. We appreciate the Aging Committee's hearing today and look forward to working with the Chairman, Ranking Member, and members of the Committee to address this public health challenge.

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[35] Ibid.

[36] FDA, FDA-Approved Biosimilar Products, January 2019.

PREMIER TRANSFORMING HEALTHCARE TOGETHER®

Statement for the Record

Submitted by

The Premier Inc. healthcare alliance

The Complex Web of Prescription Drug Prices

Senate Special Committee on Aging

March 6-7, 2019

The Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Special Committee on Aging hearings titled "*The Complex Web of Prescription Drug Prices"* scheduled for March 6-7, 2019. We applaud the leadership of Chairman Collins, Ranking Member Casey and members of the Committee for holding this hearing to scrutinize prescription drug pricing and consider policy solutions that promote competition to lower costs for American patients. ***Premier is committed to addressing the rising cost of pharmaceuticals and strongly supports the creation of a competitive marketplace to lower prescription drug prices.*** A competitive marketplace allows market forces to work as intended to naturally lower drug prices for consumers, providers and the government. The key to this is enacting policies to remove barriers to competition, making it easier to develop generics, streamline the drug approval process and promote biosimilars, and to accelerate the movement to value-based care.

Premier is a leading healthcare improvement company, uniting an alliance of more than 4,000 U.S. hospitals and health systems and approximately 165,000 other providers and organizations to transform healthcare. With integrated data and analytics, data-driven collaboratives, supply chain solutions, consulting and other services, Premier enables better care and outcomes at a lower cost.

Premier aggregates and works with healthcare providers to drive maximum market competition. We put manufacturers in head-to-head competition, assess the product's value and create market-leading contracts that may be used by healthcare providers. For our services we charge a flat percentage of the negotiated, discounted price. The fees are not varied within product categories so as to maintain a level playing field. We see every day the power of competition. By aggregating the buying power of U.S. hospitals, ***Premier's drug portfolio prices have grown less than half the rate of the industry average inflation rate***. Premier is saving our members millions of dollars by driving economies of scale, creating transparency around pricing and quality and applying competitive pressure to the marketplace.

Premier constantly scans the market and works closely with high-quality manufacturers to encourage them to bring products to the market where only one or two suppliers exist. This alleviates price spikes and drug shortages. These efforts have met with great success in lowering prices for consumers, providers and the government. For example, in 2015, isoproterenol HCl injection and sodium nitroprusside – two very old, established off-patent drugs - were sold to another manufacturer. Being the only manufacturer in the market with a de facto monopoly, this company dramatically increased the price to $14,000 for these products, a nearly 500 percent increase. Premier immediately reached out to alternative suppliers to encourage them to file Abbreviated New Drug Applications (ANDAs) with the FDA, and supported these companies through the approval process through advocacy with the FDA, encouraging accelerated review of these applications. Once the new drug makers were approved and entered the market, the costs dramatically dropped, taking the prices back to their historic levels. Specifically, Nitroprusside went from a high of $650 back down to approximately $20 and Isoproterenol went from a high of more than $14,000 in January 2017, back down to less than $2000 (the 2013 price point) in January 2019.

Premier is a solution to the rising cost of drugs. We need, however, policy changes for us to continue to succeed in our work to reduce healthcare spending. We have developed policy solutions that are attainable, practical, and sustainable.[1] As the Committee begins to examine the rising cost of drugs and develop policy solutions to help lower costs for Americans, Premier urges the Committee to focus on the following as overarching principles:

- ***Solutions that use competitive forces to lower drug prices and increase the availability of generic medications and biosimilars in the marketplace*** - A wealth of research and Premier analytics show that competition in the pharmaceutical marketplace brings down prices. Competition from generic drugs has saved the U.S. healthcare system $1.46 trillion from 2005 to 2015.[2] According to the Food and Drug Administration (FDA), drug prices drop to roughly 52 percent of brand-name drug prices with two manufacturers producing a generic product, 44 percent with three manufacturers and 13 percent with 15 manufacturers.[3] This dynamic is reflected in the fact that 88 percent of dispensed prescriptions are for generic drugs, yet they account for only 28 percent of total drug spending.[4]

  The reverse is also true. When manufacturers of drugs leave the market, drugs can experience significant price spikes due to the lack of competition. Extreme price jumps can put life-saving drugs out of reach for patients. For example:

  - Neostigmine, a Drug Efficacy Study Implementation (DESI) drug, was priced at $33 (for 10 vials of 10mg/mL) in 2009. The new “brand” Bloxiverz, approved by FDA in the same package size, jumped to $150 in 2013 and continued to experience price increases up to $938.12 by 2015 when other manufacturers of these older unapproved drugs exited the market. While not anywhere near where it was prior to the removal of other manufacturers in the market, the price dropped to $580.90 in 2015 with two other manufacturers entering the market.

  - Epinephrine, another DESI drug, was $69.16 for a vial in 2015 and jumped 352 percent to $312.50 in 2016 when other manufacturers were required to leave the market by FDA. The price continued to rise another 20 percent in 2017 on a drug that has long been on the market with no “new” indications or therapy improvement.

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[1] Premier previously provided detailed comments in response to the “HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs” request for information. Available at: https://www.premierinc.com/wpdm-package/premiers-response-trump-administrations-rfi-drug-pricing/

[2] Generic Drug Access & Savings in the U.S. 2017. Available at: https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf

[3] IMS Health, Price Declines after Branded Medicines Lose Exclusivity in the U.S. January 2016. Available at: https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/price-declines-after-branded-medicines-lose-exclusivity-in-the-us.pdf

[4] *Id.*

  - Potassium Chloride, another DESI drug, in 2014 sold for $40.86 for 20MEQ/15ML and when other manufacturers were required to leave the market, the price jumped to $236.93 in 2016. This price increase sent a shock wave through the health community for a drug that has long been deemed safe and effective with no research and development cost attached to the product.

  But in order to increase the competitive forces, more players are needed. ***Therefore, solutions to address drug prices should focus on lowering the barriers to entry to bring additional generic and biosimilar competition to the market.***

- ***Sustainable solutions to address drug shortages that decrease barriers to entry, namely the time and cost to enter the marketplace, while maintaining the quality and safety of the product*** – Drug shortages continue to plague the healthcare system and have grown in both number and intensity in the past two years.[5] Drug shortages are a major driver of skyrocketing costs contributing to over half a billion dollars in increased healthcare expenditures annually. A recent study found that prices for drugs under shortage increased more than twice as quickly as they would in the absence of a shortage adding $230 million a year to U.S. drug costs.[6] Another recent study found that the price of fluphenazine tablets in 2016 increased by over 2000% during a shortage.[7]

  In addition to the increase in drug prices, drug shortages cause a multitude of downstream impacts to the healthcare system that increase healthcare expenditures such as:

  - Increased labor costs associated with managing drug shortages, estimated to be $216 million annually.[8]

  - Increased potential for adverse events, and consequently increased costs to the healthcare system such as increased hospital days, due to the unavailability of a critical medication. For example, a shortage of norepinephrine was significantly associated with increased mortality amongst patients with septic shock.[9] The FDA estimates that the norepinephrine shortage resulted in $13.7 billion of projected losses to the U.S. healthcare system.[10]

  Over the past 15 years Premier has implemented innovative strategies enabling us to reliably supply our members with 92 National Drug Codes (NDCs) that are on the drug shortage list. We have also embarked on an expanded partnership strategy with suppliers we expect will extend this progress. This work, therefore, is not done, and we will not stop until we have

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[5] FDA Public Hearing Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions. Available at: https://healthpolicy.duke.edu/events/drug-shortage-task-force

[6] Hernandez I, Sampathkumar S, Good CB, Kesselheim AS, Shrank WH. Changes in Drug Pricing After Drug Shortages in the United States. Ann Intern Med; 170:74–76. doi: 10.7326/M18-1137

[7] Fox E. R., Tyler L. S. (2017). Potential association between drug shortages and high-cost medications. Pharmacotherapy 37, 36–42. 10.1002/phar.1861

[8] “Impact of drug shortages on U.S. health systems” (American Journal of Health-System Pharmacy, October 2011). https://www.ncbi.nlm.nih.gov/pubmed/21930639

[9] Vail, Emily, Gershengorn, Hayley, Hua, May, Walkey, Allan, Rubenfeld, Gordon & Wunsch, Hannah. (2017). Association Between US Norepinephrine Shortage and Mortality Among Patients With Septic Shock. JAMA. 317.DOI: 10.1001/jama.2017.2841.

[10] FDA Public Hearing Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions. Available at: https://healthpolicy.duke.edu/events/drug-shortage-task-force

eliminated drug shortages. ***Therefore, solutions to address drug prices should focus on eliminating drug shortages to prevent the subsequent price increases that occur during a shortage.***

In closing, the Premier healthcare alliance appreciates the opportunity to submit a statement for the record on the Senate Special Committee on Aging's hearings on drug pricing. As an established leader in using competitive forces to lower drug prices and working towards eliminating drug shortages, Premier is available as a resource and looks forward to working with Congress as it considers policy options to address this very important issue.

If you have any questions regarding our comments or need more information, please contact Soumi Saha, Senior Director of Advocacy, at soumi_saha@premierinc.com or 202-879-8005.