

INSULIN ACCESS AND AFFORDABILITY: THE RISING COST OF TREATMENT

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INSULIN ACCESS AND AFFORDABILITY: THE RISING COST OF TREATMENT

TUESDAY, MAY 8, 2018

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

The Committee met, pursuant to notice, at 10:04 a.m., in room SD-562, Dirksen Senate Office Building, Hon. Susan M. Collins (Chairman of the Committee) presiding.

Present: Senators Collins, Tillis, Fischer, Casey, Gillibrand, Blumenthal, Donnelly, Warren, Cortez Masto, and Jones.

Also present: Senator Shaheen.

OPENING STATEMENT OF SENATOR SUSAN M. COLLINS, CHAIRMAN

The CHAIRMAN. The hearing will come to order.

Good morning. When a team of three scientists at the University of Toronto discovered insulin in 1921, they revolutionized the treatment for diabetes, transforming it from a debilitating and ultimately fatal disease, to a manageable chronic condition. The scientists sold the patent for \$1 each to the university, a move intended to ensure that those in need would always have affordable access. They explicitly stated that profit was not their goal.

Yet the cost of insulin has soared in recent years. In 2013, more was spent on insulin than on all other diabetes medications combined. In a new report to be released today, the American Diabetes Association notes that between 2002 and 2013, the average price of insulin nearly tripled.

More than 30 million Americans live with diabetes, including one out of four seniors. In Maine, there are more than 137,000 people living with this condition—roughly 11 percent of our population.

Untreated, diabetes can lead to vision problems, nerve damage, kidney failure, heart disease, stroke, and ultimately death. Since 2015, diabetes has remained the seventh leading cause of death in the United States, claiming nearly 80,000 lives last year.

Fortunately, diabetes is treatable. Improving diabetes treatment has long been one of my top priorities since I founded the Senate Diabetes Caucus in 1997, and I have invited my co-Chair, Senator Jeanne Shaheen, to join us here today, and she will be here shortly.

For those living with type 1 diabetes, in which the body loses its ability to produce insulin, treatment requires life-long insulin administration. Five percent of adults diagnosed with diabetes have type 1, and in children and youth with diabetes, this type accounts

for the majority of cases. Those with type 1 diabetes depend on insulin to survive and manage their disease. Insulin is also critical for many older Americans with type 2 diabetes.

For some people with type 2, lifestyle changes and non-insulin medications can allow them to manage their diabetes; however, approximately a third of those with type 2 require insulin.

Medical costs for Americans with diabetes are more than double those incurred by individuals without diabetes. The disease costs our Nation a total of \$327 billion per year; one out of three Medicare dollars goes to treating people with diabetes.

Insulin is one of the most expensive categories of drugs purchased by private payers and government health care payers. People with diabetes who use insulin, particularly those with type 1, need this medication every day in order to live. It is a matter of life or death.

The rising cost of insulin presents a barrier to care for a growing number of Americans with diabetes. We have heard stories from people across the country who have had to ration or skip doses altogether to make their insulin supply last longer. Some have sought medication from other countries, while others have turned to the black market. Still others have raised funds for their insulin using the Internet. These measures can result in major risks that can compromise health and even life.

While the prescription drug market, and the insulin market specifically, is opaque to virtually everyone involved, one fact is clear: The patients are not getting the best deal. The price for a vial of Humalog increased from \$21 in 1996, to \$35 in 2001, to \$234 in 2015, to \$275 in 2017. Today we will hear testimony from one of my constituents who paid more than \$320, out-of-pocket, for the same product last year. And that was even after using a coupon. This chart, which my staff compiled using publicly available price data, illustrates this disturbing trend.

[The chart can be found in the Additional Statements for the Record, page 59.]

As list prices have increased, so too have out-of-pocket costs. For Medicare Part D beneficiaries, out-of-pocket costs increased by 10 percent per year between 2006 and 2013, outpacing overall inflation, medical care service costs, and spending on prescription drugs in general. For those without insurance, the costs are untenable. The cost of a single vial can be more than \$300, and some patients need more than one vial per month to effectively manage their disease.

Insulin products have changed since 1921. Early versions of insulin were produced from purified animal extracts, and scientists worked to improve duration and purity. In the late 1970's, the discovery of recombinant technology led to the approval of the first synthetic human insulin in 1982, which better mimicked human insulin and reduced allergic reactions. Continued improvements through the use of recombinant technology resulted in the development of insulin analogues with modified chemical structures and improved physiological effects.

Insulin analogues have provided greater flexibility in administration and have allowed many patients to better manage their conditions, especially those with type 1 diabetes and those prone to hav-

ing low blood sugar. However, as more products entered the market, prices began to increase significantly, even for the older versions of the insulin. The use of higher-priced analogues has grown, while the use of lower-priced human insulins has declined, even though for many patients, clinical efficacy among the various products is not markedly different.

I have previously expressed my concern with a practice called “evergreening.” This means when pharmaceutical companies obtain patents based on small innovations to extend the exclusivity of a product after its initial patent expires. For insulin, a careful look is warranted to determine if minor modifications were used to just extend the patent protections and discourage competitors.

In the face of skyrocketing costs of newer versions of a time-tested therapy, too many consumers find themselves without affordable alternatives and find that they are paying more each year.

Last Congress, this Committee conducted a bipartisan investigation into the sudden, dramatic price increases of certain decades-old prescription drugs. At the end of our investigation, we published a report documenting cases in which companies that had not invested a dollar in the research and development of a drug nevertheless hiked its price to unconscionable levels.

In February, this Committee examined why prices have soared for drugs used to treat rheumatoid arthritis. Today we continue our study of drug pricing as we examine why the price continues to climb for insulin, a life-saving drug for so many Americans.

Far too many individuals and families are familiar with the devastating toll diabetes has taken on people of every age, race, and nationality. The cost of a drug that is approaching its 100th birthday should not add to that burden.

I now would like to turn to our Ranking Member, Senator Casey, for his opening statement and express my appreciation to the members who have joined us today.

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

Senator CASEY. Chairman Collins, thank you very much for holding this hearing today. I am pleased that we were able to invite your co-Chair of the Diabetes Caucus, Senator Shaheen, to participate in our hearing. And we are grateful to be examining this subject today.

An estimated 30.3 million Americans are living with diabetes. Also, eighty-six million Americans have prediabetes, and that number that have that circumstance do not even know they have it in many instances.

In my home State of Pennsylvania, 12.8 percent, or 1.4 million people, just in Pennsylvania—and that is of the adult population—have a diagnosis of diabetes as of 2014.

We know there are many complications associated with it, including heart disease, stroke, kidney disease, blindness, and even death.

In Pennsylvania alone, diabetes and prediabetes cost an estimated \$13.4 billion a year. One state, \$13.4 billion. That includes the cost of physician visits, hospital care, and, yes, the cost of prescription medication like insulin.

Indeed, even with advancements in medication and technology, treatments can oftentimes be out of reach for our loved ones. That is unacceptable. No senior should have to go without life-saving medication.

I am pleased to say that Congress did take steps to make coverage more affordable through the Affordable Care Act—by expanding Medicaid, by closing the Medicare prescription drug coverage gap—known as the “donut hole”—and by providing preventative care at no cost. We must continue to protect and strengthen the Affordable Care Act. And we must keep the promise that Congress made to the American people that Medicare and Medicaid will be there, always will be there, when they need it.

But our work is not done. As we hear from our witnesses today, there is not one policy that will address the rising cost of prescription drugs, especially in the context of seniors. The price of insulin has tripled between 2002 and 2013, just 11 years. There is more we can and should be doing to shield patients from sky-high costs.

It is for this reason that I am so pleased that we are having this hearing today and that Chairman Collins and I had the chance to participate in hearings in the Health, Education, Labor, and Pensions Committee. We have aired issues and policy recommendations, but now we must act to address the cost of prescription drugs.

The President will soon speak on this topic. He has indicated that he, too, recognizes that more needs to be done. The time is now for both bold leadership and bipartisanship. Access to affordable prescriptions, like insulin, is a matter for so many Americans of literally life and death.

I look forward to our discussion today. Thank you, Chairman Collins.

The CHAIRMAN. Thank you very much, Senator Casey. We will now turn to our panel of witnesses.

First we will hear from Dr. William Cefalu, the chief scientific, medical, and mission officer of the American Diabetes Association. Dr. Cefalu served as the chair of the working group convened by the ADA to conduct a comprehensive study of the insulin affordability problem and to provide the ADA and policymakers with advice and guidance. Today he will announce the release of that report.

Next we will hear from Paul Grant, a father from New Gloucester, Maine, whose son Solomon was diagnosed with type 1 diabetes at the age of 9. Paul will discuss his experience caring for a son with diabetes and the challenges that he faces affording the insulin that his son requires.

I will now turn to our Ranking Member to introduce our witness from Pennsylvania.

Senator CASEY. Thank you, Chairman Collins. We are grateful to all of our witnesses. I have the pleasure to introduce Lois Ondik from Blandon, Pennsylvania. Ms. Ondik is a grandmother, a mother, and has a foster dog named “Murfee.” I have not seen Murfee yet, but I am sure we will have a chance to meet.

Five years after a diagnosis of diabetes, Lois found herself struggling to manage her condition. By happenstance, she saw an advertisement for a diabetes self-management program at her local gro-

cery store. The rest is history. She will tell us about the class she took through her local Area Agency on Aging. Lois is joined today by Martha Sitler, one of the instructors from her diabetes self-management class. That class has saved her thousands of dollars in medication costs. Not only that, I understand that Lois and Murfee are now exercising every day and walking two and a half miles every single day. By all accounts, her class has been life-changing, as Lois will share.

So, Lois, we are grateful you are here. Thanks for making the trip from Pennsylvania.

The CHAIRMAN. And, finally, I am pleased to introduce Dr. Jeremy Greene. Dr. Greene is a professor of medicine and the history of medicine at Johns Hopkins University. He treats patients at a community health center in Baltimore as well. Dr. Greene will discuss his experience treating patients with diabetes as well as his research on the history of insulin and competition in the market.

We welcome all of you for joining us, and we are going to start with Dr. Cefalu.

STATEMENT OF WILLIAM T. CEFALU, M.D., CHIEF SCIENTIFIC, MEDICAL AND MISSION OFFICER, AMERICAN DIABETES ASSOCIATION

Dr. CEFALU. Good morning. Thank you, Chairman Collins, Ranking Member Casey, and distinguished members of the Senate Special Committee on Aging for the opportunity to discuss insulin affordability. As you know, more than 30 million Americans have diabetes, and approximately 7.4 million of them rely on insulin. For millions of people with diabetes—including everyone with type 1 diabetes—access to insulin is a matter of life and death. There is no medication that can be substituted for insulin. As the leading organization whose mission is to prevent and cure diabetes and improve the lives of all of those affected by diabetes, the American Diabetes Association believes that no individual in need of insulin should ever go without it due to prohibitive costs.

In 1921, Canadian scientists Frederick Banting and Charles Best discovered insulin, revolutionizing diabetes care and making it possible for patients to live with the disease. Along with their partner, James Collip, Banting and Best sold the patent to the University of Toronto for \$3 to ensure affordable insulin for all who needed it. Further discoveries have resulted in new formulations of insulin, advancing from the animal insulin to the human insulin, and in the 1990's to the human analogues. In recent years there have been fewer advancements in insulin formulations, yet the prices continue to rise, even for the off-patent insulins.

Between 2002 and 2013, the average price of insulin nearly tripled, causing patients' out-of-pocket costs to rise and creating a tremendous financial burden for many with diabetes who need insulin.

In November 2016, the ADA Board of Directors unanimously passed a resolution calling on all entities in the insulin supply chain, including manufacturers, wholesalers, PBMs, insurers, and pharmacies, to substantially increase transparency in pricing associated with the delivery of insulin and ensure that no person with diabetes is denied affordable access to insulin. The resolution also

called upon Congress to hold hearings with all entities in the supply chain to identify the reasons for the dramatic increases in insulin prices and ensure that all people who use insulin have affordable access to the insulin they need.

In concert with the board resolution, the ADA initiated a grass-roots petition calling for the same actions. Over 311,000 people have signed this petition, making it the largest collection of signatures on an ADA petition to date. The ADA has also collected 800 stories of people with diabetes, caregivers, and health care providers who are directly burdened by the increasing costs of insulin.

For example, we heard from Michael, who reported paying over \$700 a month for the insulin he needs to stay alive. That cost is 59 percent above his monthly mortgage payment and 143 percent above his monthly insurance premium, a substantial financial burden for him or, for that matter, for many Americans.

As a physician and a clinician scientist, I have witnessed firsthand how the incredible research advances and the innovative therapies resulting from investment in biomedical research have dramatically improved the lives of those with diabetes. However, I have also observed that the incredible innovation may not benefit those who are not able to access and afford such treatments. This became even more apparent to me when I joined the ADA as the chief scientific, medical, and mission officer in February of last year, where I have had the vantage point to appreciate more fully the daily struggles of individuals with diabetes through their stories.

In the spring of 2017, the ADA Board of Directors established an Insulin Access and Affordability Working Group to ascertain the full scope of the problem and to advise the ADA on the execution of strategies to lower the cost of insulin. Throughout 2017 and into 2018, the working group held discussions with over 20 stakeholders throughout the supply chain to discuss how this complex and complicated system impacts the out-of-pocket costs for individuals with diabetes. The final product is a white paper which will be released online today outlining what we have learned from existing public information and our interview process.

The conclusions and recommendations of the working group, to be released today, are only a starting point. Beginning with increased transparency within the supply chain, every stakeholder must work toward a common goal, and that goal is to ensure affordable insulin is within reach for all who need it.

Again, thank you, Chairman Collins, Ranking Member Casey, and all the members of the Committee for convening such a hearing on this critical issue today. The ADA looks forward to working with you and every stakeholder in the insulin supply chain on strategies to lower the rising costs of insulin.

The CHAIRMAN. Thank you very much, Doctor.

Mr. Grant, welcome.

**STATEMENT OF PAUL GRANT, FATHER OF SON WITH TYPE 1
DIABETES, NEW GLOUCESTER, MAINE**

Mr. GRANT. Good morning. Thank you, Senator Collins, Ranking Member Casey, and members of the Senate Aging Committee. It is a privilege and an honor to be here to testify today.

My name is Paul Grant. I am a father of four children: Oliver, 18 years old; Jordan, 16; Solomon, 13; and Levi, 11. We live in the small community of Gray-New Gloucester, Maine, and I would describe us as an active family. We play a lot of sports: basketball, baseball, soccer, football, lacrosse, softball. We are usually on a field or in a gymnasium most days. My children mean the world to me, and I love coaching them and watching them play.

At the end of January in 2014, my son Solomon became very ill. For at least a week, he laid on the couch with flu-like symptoms. He was very lethargic, had stomach pain, grayish pale color, noticeably thinner, and he had glossed-over eyes. His mother had taken him to the doctor's, but we were told he had the flu and it would just run its course. We treated him with ibuprofen and Tylenol and made sure he drank lots of fluids. But Sol's condition did not improve. In fact, it only appeared to only get worse.

I was coaching youth basketball the day I got a call from Solomon's mother, and she was sad and upset. Sol was still very ill, and she decided that she would take him to the ER at St. Mary's Hospital in Lewiston, Maine.

My other three kids and I left basketball. We met her at the ER. And when I arrived, Sol was on a gurney, hooked up to an IV, surrounded by nurses. And the on-call doctor eventually came in and looked at us and said, "Your son has type 1 diabetes." His blood sugar that day was over 800. This was more than 4 years ago now, but I can remember this day like it was yesterday. You can imagine the feelings his mother and I experienced when we heard the words, "Your son has type 1 diabetes."

Our son has a disease. We experienced feelings of sadness, confusion, fear, astonishment, and bewilderment, just to name a few. The three of us spent that weekend in the ICU, and our lives were forever changed.

Today Sol is 13 years old and a seventh grade student at Gray-New Gloucester Middle School. At his school there are several students that share that same disease of diabetes, and the school system does really a pretty good job at helping these students manage their disease. Besides going to the nurse's office several times a day to check his blood sugar and carrying around a diabetes bag, things are pretty normal for my 13-year-old boy. He has a good group of friends, he has great teachers, and he loves playing basketball. As long as he has insulin and checks his blood sugar regularly, he manages it pretty well.

I work for a small general contracting company, Wally J. Staples Builders, Incorporated, in Brunswick, Maine. and we build new homes, additions, and garages. And we complete many interior and exterior renovations, anything to do with construction. My job is I am a project estimator. I absolutely love my job, and I have had the opportunity to work on thousands of construction projects over the years. Unfortunately, like many small businesses, my employer does not provide health insurance, so I purchase it for myself and my children through the marketplace, which is very expensive and very complicated. I pay a high deductible to keep my monthly premium lower. So, consequently, I end up paying a lot out-of-pocket for necessary supplies for Solomon, approximately \$2,500.00 last

year just on insulin supplies and diabetic supplies, and I will have spent close to \$15,000 for health care for 2017.

Solomon needs two types of insulin: Humalog and Lantus. In 2017, I would typically pay \$300 for a 90-day supply of Humalog through Express Scripts and \$150 for a 90-day supply of Lantus. This seemed like a lot—until this past January when I called to refill Solomon's Humalog prescription, and it was going to be \$900 for a 90-day supply. Nearly \$1,000 for medicine that Solomon absolutely needs to be alive and about three times more than what I had been paying. So I kind of went into panic mode as I was low on Humalog, and I needed to get it as soon as possible. I tried to get answers from my insurance company, and it was difficult, hard to get any help with that. I do not think they understand our health plan. I know I do not.

I ended up purchasing a 30-day supply at Walmart to get me by until I could figure things out. That 30-day supply cost me \$322, and that included a coupon. But I had no choice. I had to have insulin for my son.

No father ever wants to see what would happen if you run out of insulin for your child with type 1. I remember Sol's state in the week that he was first diagnosed, when his body first stopped producing insulin on its own, and I know I have to do whatever to make sure he has insulin. I have purchased it on a credit card. I have borrowed insulin from friends.

So when I saw that the price had hiked to nearly \$1,000 for a 90-day supply, I knew it was something I could not afford. And I spent several hours and days reaching out to friends in the diabetic community looking for an affordable option. Ultimately, I found a pharmacy in Canada where I could purchase a 90-day supply of Humalog for \$294, and that included a \$50 shipping fee. And this is with no contribution from my insurance company. That was January 22d, and I just refilled that prescription the beginning of April with the same pharmacy in Canada. Last week, I checked with Express Scripts to see how much a 90-day prescription would be for Solomon's Humalog, and it would cost me \$1,489, and that is with my insurance.

As I mentioned, I help people build houses for a living. I am good at my job. I can tell you very accurately how much it would cost to build a new home or put an addition on your home. But I cannot tell you how much it is going to cost from month to month to buy insulin, which I need to keep my son healthy.

I just do not understand why insulin for children with type 1 diabetes is so expensive and why I can purchase it in Canada for so much less. We are just talking about the cost of insulin today, but there are many other things like insulin pumps and glucose monitors out there that would make children's lives and parents' lives so much easier if they were more affordable.

Thank you again for the opportunity to appear before you today to share our story. I would be happy to answer questions.

The CHAIRMAN. Thank you very much, Mr. Grant, for sharing your experience.

Ms. Ondik

**STATEMENT OF LOIS ONDIK, RETIREE,
BLANDON, PENNSYLVANIA**

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

My name is Lois Ondik. I am 73 years old and a resident of Blandon, Pennsylvania. I have three children and two grandchildren. I am a retired school bus driver for the Berks County Intermediate Unit.

Five years ago, my doctor diagnosed me with type 2 diabetes. At that time my doctor wanted me to start on medication to help manage my blood sugar and A1C. A1C measures the amount of hemoglobin in the blood that has glucose attached to it, and an A1C level of 5.7 percent is considered normal. An A1C of 5.7 to 6.4 is pre-diabetes and 6.5 and over is type 2 diabetes. Five generations of my family have been diagnosed with diabetes, myself being the fifth generation, and now my daughter has just been diagnosed with pre-diabetes, making her the sixth generation. I understand the toll that it can take on both your body and finances, and I was concerned about the side effects of medications, and I knew that the cost of medication would likely eat into my budget and my savings. So I insisted on trying to manage my condition on my own, without medication. And for a while, I was able to do so.

During a recent visit with my doctor, I was again told that my blood sugar and A1C levels would soon require me to begin taking medication. And so, again, I thought to myself that there had to be another option.

Then I saw an advertisement for a diabetes self-management program through Berks Encore, my local Area Agency on Aging, hanging on the bulletin board at my local grocery store. I ended up registering for the diabetes self-management class. I did not know what the class would be about when I signed up, but knew that I needed to manage my diabetes better or face the bills and side effects associated with medication.

The class was a blessing. We met once a week for two and a half hours for 6 weeks, and it was run by two trained leaders, and one of my leaders, Martha Sitler, joins me here today.

My classmates were at different levels in their disease, including those with a new diagnosis, people managing with metformin medication, and people on insulin. I met a woman who used an insulin pump and another who was struggling to manage her blood sugar, even with insulin. Meeting them, learning about the side effects, and knowing how costly the medications can be affirmed my resolve to manage my diabetes on my own for as long as possible.

The class is evidence-based, so I know that I learned about techniques to deal with the symptoms of diabetes that really work. We discussed how to deal with emotions and stress management and also talked about foot care, exercise, healthy eating, and many other topics, especially how to talk to our doctors.

Before these classes, I did not regularly test my blood sugar, but I started to once I joined the diabetes self-management program. I also tracked everything I ate and learned how food and exercise affected my blood sugar. The class helped me understand the

amount of food I need per day, including how to balance protein, carbohydrates, and fats to better control my blood sugar.

At the end of every session, each individual created an action plan, something they wanted to accomplish before the next class. For example, I wanted to start exercising. My plan was to start low and slow, to exercise 15 minutes per day, 3 days a week. The following week we were accountable to our classmates and had to report on how we did. Sometimes it is hard to accomplish every goal you set, but being accountable to my classmates helped me reach my goal. I found the peer-to-peer support to be very important. The class was eye-opening, to say the least.

After my diabetes self-management program ended, I joined a free walking class entitled "Walk with Ease," sponsored by the Arthritis Foundation of Berks County. The program is presented by Martha Sitler and Kathy Roberts of Berks Encore, my local Area Agency on Aging. Today my foster dog, Murfee, and I walk every day, and I use two pedometers to track my activity. I went from zero exercise to more than 2.5 miles per day. I think of the walking class as an extension of the diabetes self-management program because of how important exercise is in managing my disease.

I am pleased to say that since starting my class, I lost 13 pounds and lowered my A1C two-tenths of a point. In fact, the doctor told me that had my A1C moved two-tenths of a point in the opposite direction, she would have insisted I start taking medication. That is when it all fell into perspective. I knew I had the ability to manage my diabetes on my own; I just needed the right tools.

The diabetes self-management program did just that. It gave me the tools I need to manage my diabetes, and now I use those tools to live a healthy life. I even told my doctor about the course and recommended that she tell her patients about it. I am now able to manage my disease through lifestyle changes instead of having to purchase expensive medications and supplies like insulin.

I believe it is important for people to have access to supports to prevent or better manage their diabetes, and that can help them avoid paying for high-cost medications. I am concerned about the rising cost of medications across the board because it puts treatment out of the reach of some people.

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

The CHAIRMAN. Thank you very much. I congratulate you for what you have been able to do. Your situation is, of course, different from someone who has type 1 diabetes who has no choice but to use insulin, no matter how healthy a lifestyle they may have, or that one-third of adults with type 2 are insulin-dependent. But I certainly congratulate you for the steps you have taken.

Ms. ONDIK. Thank you.

The CHAIRMAN. Dr. Greene.

STATEMENT OF JEREMY A. GREENE, M.D., PH.D., PROFESSOR OF MEDICINE AND THE HISTORY OF MEDICINE, JOHNS HOPKINS UNIVERSITY

Dr. GREENE. Thank you. Chairman Collins and Ranking Member Casey, thank you so much for calling attention to this vital matter. And if I may for a moment, I would also like to thank Mr. Grant

and Ms. Ondik for being willing to share your personal testimonies as both patients and caregivers.

I speak as an individual and not on behalf of Johns Hopkins University, but the affordability of life-saving medicines has been a subject of central concern to my own career, both as a historian of the pharmaceutical industry and an internist in an inner-city community health center in East Baltimore. No single issue exposes the tragedy and absurdity of our inability to provide 20th century cures to patients in the 21st century as does the increasing unaffordability of insulin for Americans living with diabetes today.

As you know, diabetes affects more than 9 percent of the U.S. population, more than 30 million Americans as of 2015. For the million or so Americans with type 1 diabetes, insulin is an absolute requirement for survival. Since their bodies no longer produce this vital hormone, without access to a pharmaceutical version they die preventable deaths. Of the larger proportion of Americans living with type 2 diabetes whose bodies are no longer responsive to the insulin they do produce, some can manage their illness with lifestyle measures such as dietary change, exercise, and weight loss. Most, however, require treatment with one or more oral medications in order to prevent the many serious long-term complications that type 2 diabetes brings: blindness, stroke, heart disease, kidney failure, loss of limbs, coma, and death. For many of these patients, oral medications are not enough. Roughly one out of every four patients with type 2 diabetes—and, Madam Chairman, the new statistic of one out of every three will require insulin. For more than 7 million Americans, this drug is a necessary tool to avoid preventable loss of life and limb.

Controlling diabetes with insulin is not easy. There are a number of social, biological, economic, psychological, and structural factors that complicate the ability of individual patients to manage their diabetes. Yet until recently, the cost of insulin—a drug first patented in 1923—was not considered to be part of that problem. But over the past decade in my clinic, when I have asked my patients why they are not taking their insulin as prescribed, I increasingly heard the cost of medicine itself was becoming prohibitive. I thought perhaps the problem was that I was prescribing the wrong insulin, the expensive newer versions, when really I should prescribe the cheaper older generic versions. And I was surprised to learn that this thing, “generic insulin,” simply did not exist. All insulin for sale in the United States in 2015 came from one of three brand-name manufacturers—Eli Lilly, Sanofi-Aventis, and Novo Nordisk—who control 99 percent of the nearly \$27 billion global insulin market by volume, even though none of the main agents used are protected by patents anymore.

In a recent survey, more than one out of four type 1 diabetics admitted to rationing insulin at least once due to cost in the past year. More than half of them had rationed insulin monthly, weekly, or even daily. A colleague of mine found the same proportion for her type 2 diabetes clinic. One in four rationed or withheld insulin the past year due to cost.

By some reports, the price of insulin products have increased more than 270 percent in the past decade. Eli Lilly’s Humalog was \$21 a vial when first introduced in 1996, but by 2017 cost \$275 for

a month's supply. And these dramatic increases, as we have heard, have real consequences for Americans living with diabetes who face increasingly untenable choices between insulin and other necessary expenses of daily life.

Now, I do not mean to suggest that the short-acting agent Humalog or the long-acting agent Lantus do not represent true innovations compared to the original pork or beef insulins of the 1920's. No doubt for many patients these innovations are worth the added price. What is surprising, however, is that the trailing edge of old insulin products has not become a market for generic competition, instead becoming a set of obsolete products that have been removed from the market.

On the whole, it is hard to say that a patient in 2018 who cannot afford their insulin, let alone the array of patent-protected glucometers and test strips or pumps used to titrate it, is better served by having the option—only having the option of marginally more effective agents compared to the quite effective versions that could have been generically available as of 1968 or 1988 or 2008 had a cheaper generic competitive market appeared when patents expired.

Preserving access to insulin is not a Democratic or a Republican issue. But we will make no progress unless we can understand why the insulin market is still limited to only three players, how insulin prices are actually determined. Congress alone holds the power to illuminate how the hidden pieces in the puzzle of drug pricing actually fit together. Only Congress has the power to follow the molecule through all the steps from production to consumption and understand where exactly this market is being distorted to provide evidence that will lead to a true and lasting solution.

As this Special Committee did just a few years ago when confronted with the problem of rising prices of off-patent drugs, I urge you to find continued space for bipartisan investigation into this issue affecting millions of Americans.

Thank you for the opportunity to speak today.

The CHAIRMAN. Thank you very much, Dr. Greene.

Mr. Grant, I want to start with you. I was really struck by your comparison of the fact that when you are on a job, you give a concrete estimate to your customers of how much the cost is going to be of the project. But when you go to fill a prescription for insulin for your son, you have no idea what it is going to be. It just keeps going up and up and up.

You testified that ultimately you switched to an alternative method of obtaining Humalog because you just could not afford to pay nearly \$1,000 every 90 days for a therapy that your son is going to need for the rest of his life. And you are now purchasing it from Canada. Could you tell us what the cost comparison is between the same insulin that you are getting from Canada versus what you were paying in this country?

Mr. GRANT. Yes, so to get the same exact medicine, the Humalog in a KwikPen form, a 90-day supply, in January it was \$294. That was still true at the beginning of April when I ordered my second—when I refilled the prescription. And so the crazy thing was in January, when I tried to get it through Express Scripts through my insurance company, it was \$900. And then just as a little test, last

week I called Express Scripts just to check again, you know, what this would be if I was to buy it today. And so even from January to last week, it had gone up from \$900 to \$1,489. We are talking about the same medicine. As Dr. Greene mentioned, there are only three people that make insulin. So it would be great if there was something, you know, more available right here in our own country.

The CHAIRMAN. And when you buy it from Canada, does it count toward your deductible for your insurance?

Mr. GRANT. No.

The CHAIRMAN. So that is another problem for you, too, isn't it?

Mr. GRANT. Right. So not being able to pay down my deductible, it kind of hurts there as well.

The CHAIRMAN. Dr. Cefalu, I want to put up a chart that was in your report that looks at the supply chain. And if it looks complicated and obtuse, it is because it is. It just seems unacceptable that a drug first discovered in 1921, despite the improvements in duration and purity, has increased in price so significantly in recent years and that the price continues to climb.

[The chart can be found in the Additional Statements for the Record, page 41.]

But when we look at the insulin supply chain—and, Dr. Greene, I am going to ask you to comment on this as well—we see this intricate web of transactions that move medicines and money from manufacturers, wholesalers, distributors, pharmacy benefit managers, insurance providers, private payers, government payers, finally to the consumer. And when we wrote to the three manufacturers, they all claim that they are not really benefiting from the increase in price, that their net price is approximately the same. Yet we see this enormous tripling, on average, according to the ADA, increase in the cost of this essential insulin.

So what is going on here? Who is making the money that is causing these enormous price increases? And are the manufacturers correct when they say, “We are not the ones. Our net price is relatively stable over time”? Dr. Cefalu first and then Dr. Greene.

Dr. CEFALU. Thank you, Senator. You are absolutely correct. When we went into this exercise, we wanted to get clarity on the situation. What we found, when you look at the chart, it is complex and complicated. What we are finding is a system of opaque negotiations where there is a flow of money that we do not quite understand. We really do not understand where the profits lie. We think there are incentives at every level of the supply chain that facilitate or even encourage a high list price from the manufacturers to the wholesalers to the PBMs to the health plans.

The problem is that none of these savings and profits are flowing back to the vulnerable patient, and particularly when you talk about the list price going up, the person who is really exposed is the uninsured patient. He has to pay the list price. But our understanding, or lack of understanding, of the system is that negotiations are private. We do not understand what goes on between a manufacturer and a PBM. We do not understand the level of the rebate. We do not understand from the PBM to the health plan where this rebate goes. And for that matter, again, at the point of sale, this is the problem, that the patient, particularly the under-

insured and the most vulnerable patient are the ones that are subsidizing this system.

The CHAIRMAN. I would say the uninsured plus those with high deductibles.

Dr. CEFALU. Absolutely.

The CHAIRMAN. Dr. Greene, I know my time has expired, but if you could quickly comment on that as well.

Dr. GREENE. Certainly. Thank you for this question, Senator. I think there are two ways of approaching this question, and one has to do with why did the chart get to be as complex as it is. As a historian, I can tell you that the chart did not get so complex in countries in Europe, for example, that had national health services as single payers that negotiated with the companies that produced insulin to actually produce more affordable products.

The reason that the chart got so complex is the way that we have chosen to keep prices down involved the genesis of the PBM industry comes as an attempt to find a different solution to keeping drug prices down, and yet the product over time has been an involuted system in which attempts to look under the hood and figure out what part needs to be replaced or changed or tweaked leads to a form of stasis.

The second part of the answer is to say in the present day actors, it is to everyone's advantage, to the pharmaceutical manufacturers, to the PBMs, to the insurers, to actually point at each other while list prices remain high. It is ultimately the patient, certainly the uninsured patient, many of whom I see in my clinic, and the taxpayer who ultimately is harmed by such a system. Actually exposing where the prices are increased, none of these individual actors are going to willingly actually provide this transparency.

The CHAIRMAN. It is so opaque. It really is. Thank you.

Senator Casey?

Senator CASEY. Thank you, Chairman Collins.

I will start with Ms. Ondik and then go to Dr. Greene. Ms. Ondik, you mentioned in your testimony that after your diabetes diagnosis, type 2 diabetes, you wanted to manage your condition on your own because you were concerned both about cost and side effects, and we are, of course, pleased that you had success with that self-management.

The Diabetes Association estimates that health care costs for Americans with diabetes are 2.3 times greater than those without, and from what you have heard today, what we have all heard, we know that insulin is very expensive for those, as Dr. Greene testified, 1.25 million Americans with type 1 diabetes.

What would it mean to you if you had to pay anywhere between 150 to 250 bucks extra per month for medication like insulin?

Ms. ONDIK. Well, I am a single person, and I receive Social Security and a pension. If I had to pay the high price for insulin, I could not do it. I would have to work with my doctor to try to find another way to help me out.

But I would say that Medicare, right now the price—I did look up one of them. I think it was NovoLog. And I think the retail price would have been \$125 under the Medicare program, but my out-of-pocket cost would have been \$95. And no offense to the two doctors that we have here today, but when you go to them and they

write a prescription for you for the pharmacy, they have no idea how much you are going to actually pay when you get there. They know the product or the drug is going to help you in managing your disease, but they really do not have any idea, because everybody's insurance is different.

Like I said, Medicare would be \$95, and then Mr. Grant, what he is paying for the insulin for his son, even under his insurance, which is different than what I have, that is exorbitant. You know, it is really tough for those that have to put that out.

But I would do like many other ones do. I would cheat. But, of course, on insulin you cannot do that. But I did have some medications already that were high-priced, and I cheated. I took them every other day.

Senator CASEY. Thank you.

Dr. Greene, the American Diabetes Association report indicates that people on Medicaid, those who are lower-income, can access insulin with a cost of \$1 to \$5 out-of-pocket. I live in a state where the Governor signed legislation to expand Medicaid, thankfully. Seven hundred thousand people, more than 700,000, have affordable coverage because of that act.

This population, lower-income folks, is at greater risk for developing diabetes. We also know that 18 states have not expanded Medicaid. I imagine in your practice you have seen patients that have many barriers to accessing affordable health coverage and medications.

Can you speak to how Medicaid specifically can take the cost out of the equation and remove barriers to receiving affordable and appropriate treatment?

Dr. GREENE. Thank you, Senator, for this question. It is extremely important to attend to this question of Medicaid expansion and also disparities in increased risk of diabetes and its complications in lower-income populations.

I have certainly seen this firsthand in my clinic. The expansion of coverage has greatly potentiated the ability of practitioners like me who often treat underinsured patients, patients at or around the margin of the poverty line, the ability to reduce the out-of-pocket costs—and it is hard to overemphasize how a seemingly trivial cost, like a \$20 cost a month or even a \$5 cost a month for a prescription, can be an extraordinary barrier for someone living at the edge of poverty. But when we have conversations about insulin affordability, it is important for us not to assume a middle-class insured norm for the American population.

And, conversely, reducing the amount of those who are insured through expanded forms of coverage will have disastrous effects in the ability of practitioners like myself to help manage populations of patients with diabetes. The sensitivity to that out-of-pocket cost for the insulin-dependent patient is extraordinarily important.

So I think moving in both ways, the public health benefit of Medicaid expansion and the real risks of reduced coverage and increasing amounts of uninsured Americans, is something that I view with significant concern.

Senator CASEY. Thank you, Doctor.

The CHAIRMAN. Senator Tillis.

Senator TILLIS. Thank you, Madam Chairman. I thank you all for being here.

One question that I have really relates to state Medicaid programs. In your view, is there any view about states that are doing it particularly well in terms of treating the diabetes population that we can learn from? I am a management consultant. I am always looking for best practices. So one thing I am looking for is programs out there that we should be learning more about and trying to promote as part of a national sort of de facto standard.

Dr. CEFALU. Senator, I do not know of any specific programs, but from the association we could look into that. We do know that Medicaid in general, just the access and affordability of insulin, has made a huge change, a huge improvement. So the Medicaid expansion as far as just access for those with diabetes has made a huge change. We would be happy after the hearing to look specifically into those state programs from the association to see which ones we could recommend.

Senator TILLIS. I think it would be helpful. I am also curious about—you know, I had a father-in-law who died ultimately from complications related to diabetes, and he was in a position to where he had the resources. He had a health care plan, but he just had chronic compliance issues, whether it was diet or any number of other things.

What is the data on the base of people who have diabetes where the challenges are really related to just a personal choice or some other factor that is not letting them take advantage of the resources they have available?

Dr. CEFALU. So when we talk about adherence and compliance, it is a very complicated issue. Most individuals who start on a medication, be it a hypertension medication or cholesterol medication, generally across the disease state, you may find that as much as fifty percent may quit taking that medication or reduce the medication within 6 to 12 months. Again, there are a number of factors, socioeconomic factors, and other determinants for that type behavior.

For insulin, it is different. We are also seeing that cost sharing, the amount of money a person puts out for the insulin, will actually affect adherence. For a person with type 1, adherence is a real issue. Adherence is—they cannot go without the insulin. So what they do is they start rationing the insulin, or they will skip a few doses, and that will cause them acute complications—again, acute complications of blood sugar elevation, they may get dehydrated, if it is severe enough, a condition referred to as “diabetic ketoacidosis,” which requires hospitalization.

If they do this over the chronic period and they do not maintain their A1C, as Lois has done, then in that situation it may lead to an increased chance of blindness and amputations and heart disease.

So the adherence and compliance issue from cost sharing is a huge problem. But adherence and compliance issues in medication in general is an issue. It is just that there are unique needs of those with type 1 and for those with insulin, and that adherence is based on financial considerations, which is important and not a trivial matter.

Senator TILLIS. In terms of the future of treatment, are there any particularly expensive treatments, expensive at least on the face, that the science would suggest if you took a look at the fully burdened cost, it actually would save money over time because it is more likely to improve compliance or adherence? I am asking this question because I was with doctors on a completely different subject matter earlier this year, and there are very clearly treatments where either because the time between administrations of the drug are longer, so you improve compliance, is there anything on the horizon for the diabetes population that we should be aware of?

Dr. CEFALU. We have a number—it is an exciting time for diabetes. We have a number of injectable medications that can be taken per week or longer, and this certainly improves adherence. But to improve adherence and reduce complications for an individual with diabetes, you have to give them the tools. And the tools are high-quality, low-cost insulin. They have to have access to technology to get the job done. And that would reduce the long-term complications. We know how to reduce complications. We have unbelievable medications. We have unbelievable technology that can get the job done.

As I said in my opening statement, that technology, we have seen the recent advances and what it has done to morbidity and mortality to a lot of individuals in this country. But if you cannot access the innovation, then that population does not really benefit, and that is really the situation we talk about today. All the wonderful advances are fantastic, but if they are not in the hands of the person who can implement that technology or that medication, it is an issue.

Again, Senator, we know what it takes to reduce the complications. We know what it takes. But not all individuals are at that point where financially they are able to access those medications.

Senator TILLIS. Thank you all.

The CHAIRMAN. Thank you.

Senator Cortez Masto?

Senator CORTEZ MASTO. Thank you. Thank you, Madam Chair and Ranking Member, for this important hearing. And thank you all for being here today.

Dr. Cefalu, I could not agree with you more, your last statement. I never understood why we work so hard, we spend a lot of money to create a cure for acute diseases for individuals to save lives and then we price it out of their hands. The very people that we are creating the cure for, they cannot get the drug. That makes no sense to me. And so that is why my fight has been to address the high cost of prescription drugs in general and how we put them in the hands of individuals who actually need them and can afford them.

In Nevada, we recently passed a diabetes drug transparency bill. It was passed last year, and it requires drug manufacturers to explain each factor that contributed to increases in the price of diabetes drugs, the percentage of the total increase attributed to each factor, and an explanation of the role of each factor in the increase. The bill would also require PBMs to disclose rebates negotiated with drug manufacturers and what rebates are distributed to insurers.

Dr. Greene, I am curious what your reaction is to this transparency law, and Dr. Cefalu as well. And do you think that a national drug price transparency law similar to the one that Nevada has would help us understand why drug prices have become so high?

Dr. GREENE. Thank you for that question, Senator. I have been following with great interest the activity in the Nevada Legislature and also states across the country that have tried to understand where the state government can take up the cause of off-patent drug affordability and prescription drug affordability in general.

In the State of Maryland, the Attorney General proposed a bill that became law last year making price gouging, unconscionable price hikes in off-patent prescription drugs, illegal and actionable. This was the law in the State of Maryland until just a few weeks ago when an appellate court in the Fourth Circuit ruled under the dormant commerce clause that it was unconstitutional, which is to say that the extent to which the state can successfully act to defend the interest of its consumers in not paying unconscionably high prices for prescription drugs, was limited to the scope of Federal activity.

Now, that is being appealed by the Attorney General, and personally—it was a 2-to-1 vote. I actually think there is a really credible legal argument for that ruling to be overturned and for the law to be reinstated. But I am not a lawyer. I am a physician, and I think that right now it is the law of the land suggesting that this is an arena in which only the Federal Government—only Congress, really, can take the proper actions to help ensure a more transparent system and understanding why prices are increasing.

I had high hopes for State initiatives, and I still do for the Nevada initiative. But the finding of this recent Fourth Circuit ruling has caused me to consider even more the importance of Congress taking up this issue.

Senator CORTEZ MASTO. I agree, and let me just say that the Nevada law as well is being challenged by the pharmaceutical industry, and it will go through the courts right now, and it will be in the Ninth Circuit. But it is a clear example of where the states are taking action to protect their residents and their individuals, because there is an issue that I think we all hear every time we go to our state, high-cost prescription drugs. Something has to be done to address this.

I think that transparency in general, to shine a light on what is happening and why the costs are there and what is causing these high costs is so important to address the issue. So I appreciate your comments.

Yes, Dr. Cefalu?

Dr. CEFALU. So I appreciate that. We also believe, again, from this exercise, that it is transparency throughout the supply chain, not just one or two stakeholders. The entire stakeholder issue is opaque. It is complicated. And so we would support transparency throughout the chain, first and foremost.

Transparency is not going to get the job done. That will shed a light on what the problems are, and then we can address long-term solutions.

So, again, transparency all the way through the supply chain so we understand the flow of money, who is profiting, who is not profiting. But once again, at the end of the day, it is the patient at the point of sale who is not benefiting. I think that is the important thing to consider here.

Senator CORTEZ MASTO. I agree with you. Thank you.

I notice my time is almost up. Thank you all again for this important discussion today. I appreciate it.

The CHAIRMAN. Thank you very much. The law in your state sounds very interesting and worth pursuing.

Senator JONES?

Senator JONES. Thank you, Madam Chairman, and thank you for having this hearing, and to all the witnesses who came here. I come from a state where diabetes is especially acute in Alabama—9.4 percent of the population have that—but in Alabama it is over 15 percent, with another 37 percent with pre-diabetes.

Unfortunately, I also come from a state that did not expand Medicaid, you know, which to me has always been penny-wise and extremely pound-foolish. But it is what it is down there.

I was struck by a couple things. I want to go back to that chart that we showed a few minutes ago with that complicated web. There are a lot of drugs that people take on a daily basis. Do any of you know if there are any drugs—statins, beta blockers, or whatever—in which a similar chart would be done? Is this unique to insulin and diabetes drugs? Or is that common in the industry?

Dr. CEFALU. Senator, I think we can say that this exercise and complicated pattern may apply across the drug-pricing industry. Specifically, we related it to insulin because of some of the aspects of the transactions that are unique to insulin which we wanted to focus on. But I could say in general some of the principles or many of the principles can be applied to drug pricing in general. It is many of the same players and mostly the opaque negotiations are still going on, but I still think it is acutely insulin, given the life-sustaining nature of the drug and the fact that we have heard stories at the American Diabetes Association that we had to focus specifically on insulin for this exercise. But you are absolutely right. A lot of the transactions could be applicable to other drugs.

Dr. GREENE. And, Senator, I would add that while this is the first time I am seeing this chart, and it is slightly behind me and to the left and so I cannot verify exactly, I could say you can draw almost exactly the same chart for most classes of pharmaceuticals. The recent report of the National Academies of Science, Engineering, and Medicine titled “Making Medicines Affordable,” draws a very similar chart generalized across fields of pharmaceuticals on patent and off patent in trying to understand all the many places in which the real problems of where drug price increases are happening remain obscure to the American taxpayer and to actually anyone. Pharmaco-economists, my colleagues who are trying to study drug prices, are really limited in their ability to do scientific analyses of what is happening in drug prices by the inability to see the true discounts and net prices that occur in these arrows.

Senator JONES. All right. Well, thank you for that.

I want to follow-up, again, Dr. Greene, with something that you testified to about in your practice that you would prescribe drugs

and they were sometimes the higher-priced drugs. Is that an education—and the reason I say that is because having been a lawyer and I have seen in private practice somehow pharmaceutical reps are all the time calling on doctors, and rightly so—I am not criticizing them for doing that. But there is only a limited amount of education that a doctor can do in a practice.

So how much of that is pharmaceutical marketing that is keeping—because I am really struck by the fact that there is no generic market for these drugs. And how much of that is based on the marketing that the pharmaceutical companies are doing? Or what are other causes for the lack of generic markets that have not developed with regard to diabetes drugs?

Dr. GREENE. Thank you for those questions, Senator. They are all worth attending to. And I do not take it personally. Certainly, my profession is making substantial efforts, the medical profession in America, to increase the vetting of the ways in which continuing medical education happens free of specific bias. That was not true for a substantial chunk of the 20th century. And if you look historically, the role that the pharmaceutical industry took, pharmaceutical marketers, sales representatives in particular, in the job of educating physicians about the practice of medicine really became striking. Certainly in the 1980's, when these recombinant insulins were first introduced, I could show you historical advertisements that show children, and it is aiming to physicians, saying, "He is 5 years old and already he is living in the past." In other words, convincing physicians without particular data that switching wholesale on to the newer products was necessary, even though the older products credibly could work just as well.

So I think that is part of why generic markets have not formed for insulin in the way that they have in other drugs, that what has happened is, unlike penicillin, where I will still prescribe penicillin for strep throat or for syphilis, but there still is generic penicillin in the market. Doctors and patients still feel it is valuable. The insulins that were available in the 1960's are simply not being prescribed at all today.

Senator JONES. All right. Thank you all. My time is up, but thank you all for coming, and particularly, Ms. Ondik, I would like to invite you to come down to be a life coach down in Alabama for our citizens. They could use a lot of coaching from someone like you. So thank you, and Mr. Grant also, for your stories. Thank you very much.

The CHAIRMAN. Thank you, Senator.

Senator Donnelly?

Senator DONNELLY. Thank you, Madam Chair.

I just want to start by mentioning I have a family member who deals with diabetes, and they came out to visit and left one of their nonprescription components home. And when I went to the local retail pharmacy to pick it up, it was multiples higher than the very same product online. Multiples higher. And you look and you go this is the same box, same product, but you have to have it now, and so that is—this is a chart that is extraordinarily important because I think, Madam Chair, our Committee can help unwind that chart, because one of the other things—and I want to ask you about this—is we have set up a perverse system where the higher

the retail price, the higher the rebate is for the people who determine what product it is; that when they determine this, their rebate is a percentage of whatever that price is.

And so if you have one of the low—and I am going to ask you, Dr. Cefalu, about this, and anybody else. So if a manufacturer has a much lower price, then when it is prescribed, whoever does the prescribing in that process that gets a rebate gets a much lower rebate than they would have if they had prescribed the higher-cost medicine. And we have set up a completely reverse incentive system as to what product gets prescribed. Dr. Cefalu?

Dr. CEFALU. Senator, you are absolutely correct, and, again, as we mentioned, there are incentives throughout the supply chain that facilitate or encourage. Again, the manufacturers set the list price, and from some of the data we had in the working group, it is the rebate that seems to be the key. The list price is going up, the greater the rebate. Well, where is that rebate going? Some of the evidence we got from the public information——

Senator DONNELLY. And if that price is lower and you have two competitive, then whoever gets the rebate gets a lower amount of funds.

Dr. CEFALU. So the question would be—so we look at the net prices, and the argument would be that the list price is increasing. But what is coming to the manufacturer. Maybe it is much less. We know that. But we also know that they give a rebate to a physician for formulary at the PBM level. So that is one of the incentives to provide a higher rebate for formulary so that the drug is even used at the PBM level. The rebate at the wholesale level, you are absolutely right, the higher the list price, the greater the percentage, and there is an incentive for higher list price based on the processing at the wholesaler. PBM, the same thing, higher fees. Even if they retain 4 to 10 percent, as we were told, that is 4 to 10 percent on a higher list price, and then that rebate to the health plan supposedly most of that is going to reduce premiums. But, again, a reduced premium is not going to help a person with diabetes with a high-deductible plan.

So those incentives need to be understood throughout the supply chain, and, once again, it is not one stakeholders. It is the stakeholder throughout this opaque system. And I am glad, Senator Collins, you like this complicated chart. We did not put it up there as a Snellen chart for eye vision, but it is quite complicated.

Senator DONNELLY. Dr. Greene, how important is transparency in unwinding this?

Dr. GREENE. Senator, thank you for that question. I think transparency is crucial and you are hitting the nail on the head in terms of why this issue has not made any progress. Because on the one hand, as many pharmaceutical manufacturers have stated, they are not making an increased profit off of these increased prices because the net remains the same. You would think it would be an incentive to actually favor a program that explains their contributions and the fairness of their pricing to the American people. Conversely, if the pharmacy benefit managers were actually helping save money for American consumers, you would think they would also like to open this up and show what is happening.

So both parties insisting that this remains a trade secret suggests that this discounting and this elevated list price actually is a system which benefits both of those parties and hurts taxpayers and hurts patients.

Senator DONNELLY. Well, I think that we have a terrific team on this Committee, and I think we can really be part of unlocking what is causing this, because at the end of the day, you have people who struggle with diabetes and wonder how they are going to make ends meet, how they are going to—and you cannot miss your medicine.

And so I really appreciate you having this hearing, Madam Chair, and I am very hopeful that with folks like these, and then we have the manufacturers and others come in, that we can unlock this for the American people so that they are the winners at the end of the day. Thank you.

The CHAIRMAN. Thank you, Senator.

Senator Warren?

Senator WARREN. Thank you, Madam Chair.

You know, I am glad we are taking a look at the rising cost of insulin. It is a problem that affects millions of people with diabetes who have seen the cost of their life-saving medication rise. And I am grateful to you and to the Ranking Member for holding this hearing today.

So my view on this is that when it comes to keeping prices low for consumers, nothing beats a competitive market. In the prescription drug market, the Government hands drug companies a monopoly on their product that lasts a certain number of years, depending on the type of drug. But when that monopoly runs out, market forces are supposed to kick in. Other companies are free to produce generic versions, lowering the cost for patients.

On the surface, insulin seems like an obvious candidate for exactly this kind of healthy competition. It has been around for almost a hundred years, it is in high demand by millions of patients, and there are multiple companies that make it. So I want to dig into why are prices going up instead of down.

Dr. Greene, you have studied the insulin market. How many generic insulin products are available on the market today?

Dr. GREENE. I would say there are no true generic insulins in America today.

Senator WARREN. The answer is, after a hundred years, zero.

Dr. GREENE. Yes.

Senator WARREN. Right? That is amazing. So I note biosimilars are more complex to produce than traditional generics, but that cannot be the whole story. The drug companies that make insulin have also kept releasing new versions of their product that make small improvements over the old versions. And these incremental changes deliver benefits to patients that can afford brand-name drugs, but also allow companies to extend their monopolies and keep competitors out of the market.

So just let me ask you, Dr. Greene, are patients being well served by an insulin market with a product that is only marginally more effective than a few decades ago, but at a significantly higher and higher price?

Dr. GREENE. So thank you for that question, Senator. I would say that for many patients who benefit from insulin analogues that can point to the specific benefits they have received in their own management, their ability to titrate on a finer or closer basis their insulins, and yet for the patient who cannot afford their insulin, these advances provide no benefit.

Senator WARREN. Yes. Look, I am all for more innovative products that help people. I think that is great. But we cannot mistake this market for a competitive market. What the drug companies are doing has effects that are similar to a practice called "evergreening," strategies to help keep a monopoly nice and fresh year after year, long after it otherwise would have expired. And it is not the only thing that is driving down competition. Today three of the largest insulin producers in the country are under investigation for price fixing, raising their prices by similar amounts at the same point in time. It is not just anticompetitive. It is against the law.

Now, Mr. Grant, the U.S. market for insulin is so broken that you actually turned to a pharmacy in Canada to get insulin for your son. Is that right, sir?

Mr. GRANT. That is correct.

Senator WARREN. You know, I appreciate your sharing this with the Committee and coming here to testify about this. Drug companies talk a lot about market-based solutions to tackle the drug-pricing problem. But I do not think the drug companies actually want to see these markets work. I see an industry that is doing everything it can to throw sand in the gears of the insulin market so they can keep their monopolies and keep raking in the cash on the backs of patients.

Drug companies do not like proposals like requiring them to negotiate prices with the Federal Government or importing drugs from Canada. But I think it is time we look into policy solutions that would actually make a difference for patients, whether the drug companies like it or not.

Thank you. Thank you, Madam Chair.

Mr. GRANT. Thank you.

The CHAIRMAN. Thank you.

Senator Shaheen, I want to welcome you today. I mentioned you in my opening statement. You have been the Chair of the Diabetes Caucus, and I really appreciate all the work we have done together.

Senator SHAHEEN. Well, thank you very much, Madam Chair, and I especially appreciate your and Senator Casey's inviting me today to crash this hearing.

As I am sure Senator Collins said, I have had the honor of serving as co-Chair of the Diabetes Caucus, and she is really the one who has provided leadership for so many years here in the Senate. But I am pleased to be able to join her and very much appreciate the willingness of each of you to testify today about what is happening.

Like she may have said, I actually have a granddaughter who has type 1 diabetes, so, Mr. Grant, I have seen very directly the impact on a family of what that diagnosis does to a child and what that means for the entire family. And to have added to that the fact that the cost of insulin is now becoming prohibitive for so

many families who need that to stay alive is hard to justify in any way.

So I want to ask each of you, several of us on this Committee serve on the Appropriations Committee, and we are going to have the Secretary of Health and Human Services, Alex Azar, before us this week testifying. What would you like us to ask him about what Health and Human Services should be doing to address the high costs of insulin? I will start with you, Dr. Cefalu.

Dr. CEFALU. Well, we have heard Secretary Azar's statement, and it acknowledged that he wants to drive down the price of drugs. Hopefully, he is serious about that. He is certainly in the position to do so, and he certainly has a past history to understand the complexity of the system.

So, once again, for our purposes, wanting to make sure that he understands—and I am sure he does—the complexity and the position of every stakeholder in this convoluted system. We have heard a lot today pointing at one stakeholder, and I just want to reiterate to him that it is the system that needs to be fixed.

So, again, fix the rebate. Where does this rebate go? Who is benefiting? Who is profiting? That is where transparency is going to come in. Once it gets down to a level, the patient is certainly not getting the rebate at the point of sale. Recently, we have heard that some of the health plans are passing along a portion of the rebate to the patient. That is fantastic. We encourage that. But then it gets back to why there are rebates at all.

The other thing—and I wanted to just make one statement about the advances in insulin—the newer formulations, these are an advance to the point where they give a long-acting profile, they are more physiologic. One can argue that over time in many patients the glycemic control may be the same, but they often increase advantages to hypoglycemia, which is going to prevent a person from getting tight glycemic control and improving quality of life.

So these incremental changes have made a difference. The question is the cost of these insulins and why the increase in cost throughout the supply chain.

So I think he would have a unique perspective on the situation and probably have a unique perspective on the supply chain and where things can be fixed.

Senator SHAHEEN. Thank you. Yes, as you point out, Secretary Azar was an executive at Eli Lilly, so he certainly understands the pharmaceutical industry.

Mr. Grant, what would you suggest that we ask the Secretary about this?

Mr. GRANT. I guess, you know, I live my life kind of, you know, what is fair. You know, we look at folks like you to kind of guide us and give us some direction in what is fair. So I would ask him, you know, what is fair? You know, what is expected, what someone should have to pay for these medications? And, you know, the other question I would ask—you know, for a type 1 diabetic, this is not anything that they brought upon themselves. It is, you know, that one of their major organs stopped working properly. You know, whether it is a baby—I mean, there are babies born with type 1 diabetes. You know, I am thankful that my son got it at 9 and so

he could help with the treatment. But kind of, you know, what is fair?

Again, it was not like I was looking to go outside of our country to purchase medicine for my son, but, you know, what I found last week was, you know, it is almost five times what I could get it for. I mean, you kind of have to do what you have to do. But, you know, what is fair? What can we expect people to really be able to afford and to be able to pay?

Senator SHAHEEN. Thank you.

Ms. Ondik?

Ms. ONDIK. I am not really familiar on how the drug companies operate. Right now I do not take anything for the diabetes because it is not necessary. But I would definitely appreciate if the cost would come down. I am currently on a Medicare Advantage plan, and the medications that I do take are within my reach. And if I do happen to get a prescription that is out of my reach, I will immediately call my doctor and say to her, "I cannot afford this." And then we work together to find something, a drug that will do the same identical thing at a cheaper price for me.

So I would really like to see the medications stay down where those that really cannot afford them have access to them.

Senator SHAHEEN. Well, and your experience certainly speaks to the importance of taking every step you can. As we look at the cost, the increasing cost of diabetes, making sure that we can manage without having people go into diabetic episodes that require hospitalization and other more severe treatments is in the economic interest of the country, never mind the benefits that individuals receive from having that kind of management of their illness.

If I can, Madam Chair, can I just ask Dr. Greene to answer that?

Dr. GREENE. Thank you, Senator. My principal question would be: Why is there no competitive market for insulin in this day and age? We have three manufacturers, and we know from pharmacoeconomic analysis that you do not really see true competition driving down drug prices in a significant way until you have four or more manufacturers in the market. So when I answered Senator Warren earlier in terms of was there a generic insulin, now there are two new follow-on biological versions. There is Basaglar, which is Eli Lilly's follow-on copy of Sanofi-Aventis' long-acting insulin. And then there is Admelog, which is Sanofi-Aventis' follow-on copy of Eli Lilly's short-acting insulin. Both of them are priced slightly under the brand-name competitor, but a savings of maybe \$50 max out of a drug that costs \$300, it does not bring it down to a reasonable rate. And one of the reasons is neither of these moves actually brings the competition of insulin products outside of a three-player market.

So that is the real question I would have: Is there something fundamentally about the nature of insulin as a drug in which there will never be more than three manufacturers? Because if so, thinking about generic competition is never going to work, and we are going to need to think of an entirely different method of thinking about this essential commodity which is a key part of our biomedical infrastructure. If it truly cannot become competitive, we need to think about different ways of acting. If it can become com-

petitive, we have to become much more serious about how to make that happen.

Senator SHAHEEN. Thank you all very much, and it certainly speaks to the importance of transparency to make it more competitive.

The CHAIRMAN. Thank you.

Senator Blumenthal?

Senator BLUMENTHAL. Thank you.

Dr. Greene, you have just summarized very well a dilemma that I see not only as a member of this Committee, but as a member of the Antitrust Subcommittee of Judiciary and the Commerce, Science, and Technology Committee where antitrust also is of interest. I have studied this issue of insulin for years. I want to thank our Chair and Ranking Member for having this hearing because it is a real enigma to me. We love to talk about free enterprise and free markets, and yet the price of insulin and many other generics has risen astronomically without adequate explanation, without any credible explanation. And I have talked to the doctors and the hospital administrators throughout Connecticut who have complained to me almost since the day that I was elected a United States Senator about shortages and rising prices of insulin and other generics, critical medicines, workhorse treatments. They are not some esoteric drug that is used to treat a small number of people. They are workhorse medicines, anesthetics and other treatments that are vital to American medicine.

In Connecticut, there are 355,000 adults with diabetes, costing the state \$3.7 billion a year. And this problem will get worse before it gets better with over a third of adults in Connecticut suffering from pre-diabetes without intervention on the road to their own diagnosis of diabetes. And yet despite this spreading epidemic of diabetes, the prices of insulin continue to rise, and patients who need this drug struggle to afford it.

I am going to ask permission that my full statement be entered in the record.

The CHAIRMAN. Without objection.

Senator BLUMENTHAL. I think this issue is so widespread, it does not admit of rhetorical solutions. There have to be real interventions in the marketplace somehow, perhaps by the government, where essential medicines become out of reach for people. And maybe it is like a utility that has to be better controlled, because your stories are so powerful in human terms, and they are no different than the ones I have seen in my own travels around the State of Connecticut.

So I just would like to know from you, Dr. Cefalu, what specific information in terms of increasing transparency—because you have talked about that issue. What would you like to see from those companies that make insulin?

Dr. CEFALU. So, Senator, let me also again state it has to be throughout the chain. We talk about lack of competition from insulin manufacturers, but we also talk about increased consolidation with the pharmacy benefit managers, which is a concern.

So when we talk about solutions, we want to talk about solutions across the entire chain and not pick out one stakeholder. Isolating

one stakeholder is not going to get the job done unless there is a down throughout the supply chain effect.

So, again, it is important to realize throughout the chain there are issues that I would like this Committee—you need to address.

So what are the things that need to happen? Well, some of the things discussed here, factors that influence the list price of insulin, understanding the negotiations with the manufacturer and the PBM, understanding the negotiation between the PBM and the health plan. What exactly—what is that rebate? It is a different negotiation with the health plan and the pharmacy, and in those situations, what you pay in the pharmacy and what the health plans pay, it is the same product, but yet no one is fully aware. That is the transparency we are looking for.

What we also know is—you mentioned earlier about knowing the price when you build a house and know the price. Well, a patient may go to a pharmacy, and they may be on a high-deductible health plan, and they may pay \$400 for insulin when, in fact, that insulin may have received a 50-percent rebate to intermediaries in the supply chain. So is that fair that someone in a deductible has to pay for a rebate that stays in the supply chain?

So this just reiterates the complexity of the situation and that you have to look at it globally rather than isolating a single partner. And that is the complex issue.

But, once again, transparency in the negotiations, what the PBMs—rebates they are paying, how much the health plan is paying on insulin, how much are you applying for the rebate on the premiums? Again, the rebate should go back to the patient, and it does not help a person who is underinsured or high-deductible health plan to have an acceptable premium when they are paying \$7,500 a year for a deductible for life-saving medications. And that is what needs to be balanced.

Senator BLUMENTHAL. Thank you. My time has expired, but I may have some more questions for the record. Again, I want to thank the Chair and Ranking Member.

The CHAIRMAN. Thank you, Senator.

I want to thank all of our witnesses for testifying today and really helping us as we grapple with this issue. I first founded the Senate Diabetes Caucus some 21 years ago after meeting in Maine with a family whose 10-year-old son had type 1 diabetes, and I will never forget his looking up at me and saying that he wished he could just take 1 day off from having diabetes. But as Mr. Grant well knows from his experience, those children cannot ever take a day off. And they are insulin dependent, as are about a third of adults with type 2 diabetes.

So at that time I vowed to form the Caucus, and working with great co-Chairs like Jeanne Shaheen, we have made real progress in more than tripling the Federal funding for research into diabetes. And it has led to cutting-edge technology like the development of better pumps and continuous glucose monitors and, indeed, most recently an artificial pancreas, which I am very excited about and we would only have dreamed of 20 years ago.

However, I will tell you that when I founded the Caucus, I never dreamed that we would have a problem with the cost of insulin given how long insulin has been around, almost a hundred years.

And it is becoming a barrier to treatment for so many Americans with diabetes who are unable to control their diabetes without insulin.

It is puzzling, to say the least, to me that even older versions of insulin are increasing in price at rates that are untenable for too many Americans with diabetes. Last year and again this year, I received a petition that was signed by thousands of Americans asking what can Congress do to bring down the cost of insulin, and this hearing represents only the first step. I want to deconstruct that complicated web of transactions to figure out who is making how much money and why aren't discounts that are negotiated with manufacturers reaching the patient, particularly the uninsured patient, but also the insured patient who has a high deductible, which is so common, particularly for those who do not have employer-provided insurance and are purchasing on the Affordable Care Act marketplaces.

It is astonishing that for a drug approaching 100 years old and that is serving millions of Americans that we do not see a proliferation of manufacturers but, rather, just three major manufacturers. I do not understand that as well.

So I am committed to continuing to dig into this issue, but I will tell you, it is the most complex web that I have ever seen, and we are going to need the help of many of the experts that are represented in this room and at our witness table as we seek to unravel the web and figure out exactly what is going on.

But I want to thank you for laying the baseline. Mr. Grant, in particular I want to thank you for putting a human face on this problem and telling us what this has meant as you have worked so hard to keep your son healthy, to make sure that that original initial incident when he was just 9 years old and was misdiagnosed as just having the flu when he had a life-threatening disease with his blood sugar over 800 does not happen again. I just cannot imagine how frightening that must have been. We want to keep him healthy, but we also do not want you to go broke in doing so.

So I am committed to trying to get to the bottom of this, and I want to thank you for coming down from Maine. I want to thank all of our witnesses for being here today with us.

Did you want to add something?

Mr. GRANT. I was just going to say thank you for the opportunity to come down here and just share. I really can tell, you know, everybody here is on the same page in wanting to make this better for everybody. So to be a part of it is just an honor, and thank you very much.

The CHAIRMAN. Thank you.

Again, thank you to all of our witnesses. You were an excellent panel today. I want to thank the Committee members and Senator Shaheen for coming today as well.

I would note that Senator Fischer and Senator Gillibrand were also here but had to leave for other obligations.

I will turn to Senator Casey for any closing remarks that he might have.

Senator CASEY. Madam Chair, thank you very much. I want to thank our witnesses for giving us the kind of information we are going to need to take action on this issue or range of issues. Ms.

Ondik, thank you for coming from Pennsylvania. Mr. Grant, thank you for bringing your personal story here. And, of course, Dr. Cefalu and Dr. Greene, for your own expertise and background.

I will submit a statement for the record, but thank you, Madam Chair.

The CHAIRMAN. Thank you very much, Senator Casey.

Committee members will have until Friday, May 18th, to submit questions for the record, so you may be receiving some additional questions. Again, my thanks to our witnesses, to our Ranking Member, to our staff, and to all the Committee members and Senator Shaheen who participated in today's hearing.

This concludes our hearing.

[Whereupon, at 11:46 a.m., the Committee was adjourned.]

APPENDIX

Prepared Witness Statements

**Prepared Statement of William T. Cefalu, M.D.,
Chief Scientific, Medical and Mission Officer
American Diabetes Association**

Thank you, Chairman Collins, Ranking Member Casey, and distinguished members of the Senate Special Committee on Aging for the opportunity to discuss the issue of insulin affordability. As you know, more than 30 million Americans, including 12 million Americans over the age of 65, have diabetes. Approximately 7.4 million of them rely on insulin. For millions of people with diabetes—including all individuals with type 1 diabetes—access to insulin is literally a matter of life and death. There is no medication that can be substituted for insulin. As the leading organization whose mission is to prevent and cure diabetes and to improve the lives of all people affected by diabetes, the American Diabetes Association believes that no individual in need of insulin should ever go without it due to prohibitive costs.

In 1921, Canadian scientists Frederick Banting and Charles Best discovered insulin, revolutionizing diabetes care and making it possible for patients to **live** with the disease. Along with their partner, James Collip, who purified the insulin, Banting and Best sold the patent for insulin to the University of Toronto for \$1 each to ensure affordable insulin for all who needed it. Further discoveries have resulted in new formulations of insulin over the years, advancing from animal insulin, to human insulin, and more recently in the 1990s to analog insulins. In recent years, there have been fewer advancements in insulin formulations yet prices continue to rise, even for off-patent insulins.

The “Economic Costs of Diabetes in the U.S in 2017” report, released by ADA in March, shows that the direct and indirect costs of diagnosed diabetes increased 26 percent in five years to a total of \$327 billion in 2017, making diabetes the most expensive chronic illness in America. Approximately \$31 billion was spent on medications directly used to treat diabetes, including nearly \$15 billion in insulin costs.

In recent years, the cost of insulin has become a growing problem for people with diabetes. Between 2002 and 2013, the average price of insulin nearly tripled, causing patients’ out-of-pocket costs to rise and creating a tremendous financial burden for many who need insulin to survive.

In November of 2016, ADA's Board of Directors unanimously passed a resolution calling on all entities in the insulin supply chain, including manufacturers, wholesalers, Pharmacy Benefit Managers (PBMs), insurers, and pharmacies to substantially increase transparency in pricing associated with the delivery of insulin, and to ensure that no person with diabetes is denied affordable access to insulin. The resolution also called upon Congress to hold hearings with all entities in the insulin supply chain to identify the reasons for the dramatic increases in insulin prices and to take action to ensure that all people who use insulin have affordable access to the insulin they need.

In concert with the Board resolution, the ADA at that time initiated a grassroots petition calling for the same actions. As of May 3, 2018, 311,615 people have signed the petition making it the largest collection of signatures for any single ADA petition. In the time since the resolution and petition were launched, ADA has also collected more than 800 stories about people with diabetes, caregivers, and health care providers who are directly burdened by the increasing costs of insulin.

For example, we heard from Michael, who reported paying more than \$700 a month for the insulin he needs to stay alive. That cost is 59 percent of Michael's monthly mortgage payment and 143 percent of his monthly insurance premium, a substantial financial burden for him.

As a physician and clinician scientist, I have witnessed first-hand how the incredible research advances and innovative therapies resulting from investment in biomedical research have dramatically improved the lives of those with diabetes. However, I have also observed that the incredible innovation may not benefit those who are not able to access and afford such treatments. This became even more apparent to me when I joined the ADA as the Chief Scientific, Medical and Mission Officer in February 2017, where I have had the vantage point to appreciate more fully the daily struggles of individuals with diabetes through their stories.

In the spring of 2017, and in discussions with ADA's Board of Directors, an Insulin Access and Affordability Working Group (Working Group) was established to ascertain the full scope of the insulin affordability problem and to advise the ADA on the development of strategies that will result in viable, long-term solutions to bring down the cost of insulin for all who need it. I serve as Chair of the Working Group, which is composed of outside experts, members of the Board,

and ADA staff. Throughout 2017 and into 2018, the Working Group convened a series of meetings with stakeholders throughout the insulin supply chain to learn how each part of the complex system impacts the out-of-pocket costs for individuals with diabetes. The Working Group held discussions with more than 20 stakeholders representing entities throughout the insulin supply chain, including pharmaceutical manufacturers, distributors, PBMs, pharmacies, pharmacists, health plans, employers, and people with diabetes and caregivers. The final product of the Working Group is a white paper outlining what we learned from discussions as part of our stakeholder interview process and existing public information. The white paper, authored by the Working Group and approved by the ADA's National Board of Directors, includes the Working Group's conclusions and recommendations. The white paper will be published in the June issue of the journal *Diabetes Care*, and it will be made available online today.

On behalf of the ADA and the individuals with diabetes whom we represent, I sincerely thank the Committee for inviting me to this public hearing and allowing me to share our findings as we release this white paper, and to provide comment so as to inform efforts to address this growing problem.

Through a rigorous process that examined all levels of the insulin supply chain, the Working Group learned a lot about a very complicated and complex system. Most importantly, we noted there are numerous stakeholders involved in multiple opaque transactions, and there is much more we need to know. The Working Group concluded the following:

- List prices of insulin have risen precipitously in recent years. Between 2002 and 2013, the average price of insulin nearly tripled.
- The current pricing and rebate system encourages high list prices:
 - As list prices increase, the profits of the intermediaries in the insulin supply chain (wholesalers, PBMs, pharmacies) increase since each may receive a rebate, discount, or fee calculated as a percentage of the list price.
- There is a lack of transparency throughout the insulin supply chain. It is unclear precisely how the dollars flow and how much each intermediary profits.
 - Manufacturers are rarely paid the list price for insulin. The so-called net price—which reflects what the manufacturers receive—is much lower, however, in most cases, the data are not publicly available.

- In the vast majority of cases, discounts and rebates negotiated between PBMs and manufacturers, and between PBMs and pharmacies that affect the cost of insulin for the person with diabetes, are confidential.
 - PBM clients (often-large employers in most cases) are not privy to these negotiations, nor do they know the net price obtained by the PBM for insulins.
- Formulary considerations and decisions are not transparent.
- PBMs have substantial market power.
 - PBMs' primary customers are health plans and employers, not patients.
 - PBMs negotiate rebates from manufacturers using formulary placement as leverage.
 - PBMs often exclude from the formulary insulins made by the manufacturer that offers the lowest rebate.
 - As a result of negotiation, rules for coverage differ from plan to plan and year-to-year, or even within the same plan year.
 - When insulins are excluded from the formulary, moved to a different cost-sharing tier or removed during the plan year, it places a burden on people with diabetes and providers and may have a negative health impact.
 - PBMs receive administrative fees from their clients (health insurance plans) for utilization management services (prior authorization, etc.). Often, it is the PBM that determines which and how many drugs on the formulary are subject to utilization management.
- People with diabetes are financially harmed by high list prices and high out-of-pocket costs:
 - Regardless of the negotiated net price, the cost of insulin for people with diabetes is greatly influenced by the list price for insulins.
 - Out-of-pocket costs vary depending on the type of insurance each individual has and the type of insulin prescribed. The costs can be significantly higher for people who are uninsured, who have an insurance plan with a high deductible, and who are in the Medicare Part D donut hole.

- Manufacturer rebates often are not directly passed on to people with diabetes.
- Patients' medical care can be adversely affected by formulary decisions;
 - People with high cost sharing are less adherent to recommended dosing, which results in harm to their health.
 - Formulary exclusions and frequent formulary changes cause uncertainty, increase financial costs for people with diabetes, and could have serious negative consequence on the health of people with diabetes.
- The regulatory framework for development and approval of biosimilar insulins is burdensome for manufacturers.
 - There are not enough biosimilar insulins on the market.
 - Prices for biosimilar insulins are not likely to be reduced unless there are several biosimilars that can be substituted for the brand name analog insulin, rather than only one.
- Prescribing patterns have favored newer, more expensive insulins:
 - Newer insulins, including analogs, are more expensive than older insulins, including human insulins.
 - Human insulin may be an appropriate alternative to more expensive analog insulins for some people with diabetes.

Given the above conclusions, the Working Group also makes the following recommendations, as outlined in the white paper:

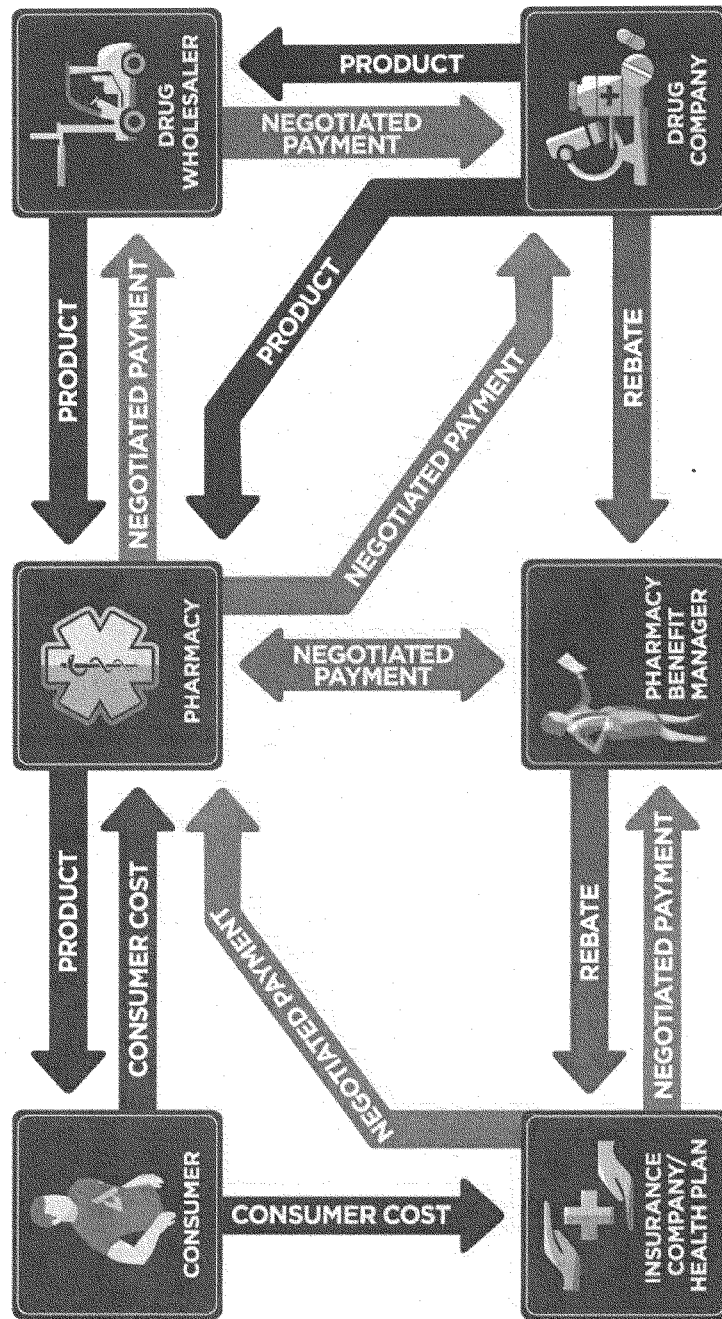
- Providers, pharmacies, and health plans should discuss the cost of insulin preparations with people with diabetes to help them understand the advantages, disadvantages, and financial implications of potential insulin preparations.
- Providers should prescribe the lowest price insulin required to effectively and safely achieve treatment goals.
 - This may include using human insulin in appropriately selected patients.
 - Providers should be aware of the rising cost of insulin preparations and how this negatively impacts adherence to the clinical treatment by people with diabetes.
 - Providers should be trained to appropriately prescribe all forms of insulin preparations based on evidence-based medicine.

- Cost sharing for insured people should be based on the lowest price available.
- Uninsured people with diabetes should have access to high quality, low-cost insulins.
- Researchers should study the comparative effectiveness and cost-effectiveness of the various insulins.
- List price for insulins should more closely reflect net price, and rebates based on list price should be minimized. The current payment system should rely less on rebates, discounts, and fees based on list price.
- Health plans should ensure that people with diabetes can access their insulin without undue administrative burden or excessive cost.
 - Payers, insurers, manufacturers, and PBMs should design pharmacy formularies that include a full range of insulin preparations, including human insulin and insulin analogs, in the lowest cost-sharing tier.
- PBMs and payers should use rebates to lower people with diabetes' costs for insulin at the point of sale.
- There needs to be more transparency throughout the insulin supply chain.
- Payers, insurers, manufacturers, PBMs, and people with diabetes should encourage innovation in the development of more effective insulin preparations.
- The U.S. Food and Drug Administration should continue to streamline the process to bring biosimilar insulins to market.
- Organizations like the American Diabetes Association should:
 - Advocate for access to affordable and evidence-based insulin preparations for people with diabetes.
 - Ensure that health providers receive on-going medical education on how to prescribe all insulin preparations, including human insulins, based on scientific and medical evidence.
 - Develop and regularly update clinical guidelines or standards of care based on scientific evidence for prescribing all forms of insulin, and make these guidelines easily available to health care providers.
 - Make information about the advantages, disadvantages, and financial implications of all insulin preparations easily available to people with diabetes.

The conclusions and recommendations of the Working Group are only a starting point. Beginning with increased transparency within the insulin supply chain, every stakeholder must work together toward a common goal—ensure affordable insulin is within reach for all who need it. The ADA looks forward to working with each entity in the insulin supply chain to address the issues identified and to work collaboratively to reach our goal of affordable insulin. The ADA will soon be releasing a follow-up paper with more specific public policy recommendations on lowering the out-of-pocket costs for individuals with diabetes.

Again, thank you Chairman Collins, Ranking Member Casey, and all members of the Senate Special Committee on Aging for convening a hearing on this critical issue. The ADA looks forward to continuing to work with you to develop strategies to lower the rising costs of insulin.

Insulin Supply Chain: A Complex System



**Prepared Statement of Paul Grant, Father of Son With Type 1 Diabetes,
New Gloucester, Maine**

Good morning. Thank you Senator Collins, Ranking Member Casey, and members of the Senate Aging Committee. It is a privilege and an honor to be here to testify today.

My name is Paul Grant. I am a father of 4 children, Oliver, age 18, Jordan, age 16, Solomon, age 13, and Levi, age 11. We live in the small community of Gray-New Gloucester, Maine. I would describe us as an active family. We play a lot of sports, basketball, baseball, soccer, football, lacrosse, and softball. We are usually on a field or in a gymnasium most days. My children mean the world to me, and I love coaching and watching them play.

At the end of January in 2014, my son, Solomon, became very ill. For at least a week, he laid on the couch with flu like symptoms. He was very lethargic, had stomach pain, grayish pale color, was noticeably thinner, and he had glossy eyes. His mother had taken him to the doctors, but we were told he had the flu and it would just run its course. We treated him with ibuprofen and Tylenol, and made sure he drank lots of fluids. But Sol's condition did not improve. In fact, it only appeared to get worse. I was coaching youth basketball the day that I got a call from my wife. She was sad and upset because Sol was still very ill. She decided to take him to the ER at St. Mary's Hospital in Lewiston. My other three kids and I left basketball and met her at the ER. When I arrived, Sol was in a gurney, hooked up to an IV, surrounded by nurses. The on call doctor eventually came into the room and told us Sol had type 1 diabetes. His blood sugar was over 800. This was more than four years ago now, but I can remember this day as if it were yesterday. You can imagine the feelings his mother and I experienced when we heard the words "Your son has type 1 diabetes." Our son has a disease. We experienced feelings of sadness, confusion, fear, astonishment and bewilderment just to name a few. The three of us spent that weekend in the ICU, and our lives were forever changed.

Today, Sol is 13 years old and a 7th grade student at Gray-New Gloucester Middle School. Several students in the middle and high school also have diabetes. The school system does a good job helping the students manage their disease. Besides going to the nurses' office several times a day to check his blood sugar and carrying around a diabetes bag, things are pretty normal for my 13-year old boy. He has a good group of friends, good teachers, and loves playing basketball. As long as he has insulin and checks his blood sugar regularly, he manages pretty well.

I work for a small general contracting company, Wally J. Staples Builders Inc. We build new homes, additions, and garages. We also complete many interior and exterior renovations and pretty much anything to do with construction. I am a Project Estimator. I absolutely love my job, and have had the opportunity to be part of thousands of construction projects over the years. Unfortunately, like many small businesses, my employer does not provide health insurance. I purchase it for my children and myself through the marketplace, which is very expensive and very complicated. I have to pay a high deductible to keep my monthly premium lower. Consequently, I end up paying a lot out of pocket for necessary supplies for Solomon, approximately \$2,500 plus. Last year, I will have spent close to \$15,000 for health care.

Solomon needs two types of insulin: Humalog and Lantus. In 2017, I would typically pay \$300 for a 90-day supply of Humalog through Express Scripts and around \$150 for a 90-day supply of Lantus. This seemed like a lot until this past January when I called to refill Solomon's Humalog prescription. I was shocked to learn it was now going to cost more than \$900 for a 90-day supply. That is nearly \$1,000 for a treatment that Solomon absolutely needs, and about three times more than I had been paying. I immediately went into panic mode as I was low on Humalog and I had to get it as soon as possible. I tried to get answers from my insurance company but received little help or explanation. I do not think they even understand our health plan—I know I don't. I ended up purchasing a 30-day supply at Wal-Mart to get me by until I could figure things out. The 30-day supply cost me \$322.64 (with a coupon). I had no choice—Sol had to have insulin.

No father wants to see what would happen if you run out of insulin for your child with type 1. I remember Sol's state in the week that he was first diagnosed, when his body first stopped producing its own insulin. I know that I must do whatever I can to make sure that he never has to go without it. I have purchased it on my credit card and I have had to borrow insulin from friends.

When I saw that the price had hiked to nearly \$1,000, I knew it was something I could not afford. I spent several hours and days reaching out to friends in the diabetic community looking for an affordable option. Ultimately, I found a pharmacy in Canada where I could purchase a 90-day supply of Humalog for \$294.97 that in-

cluded a \$50 shipping fee. This is with no contribution from my insurance company. That was January 22 and I just refilled that prescription the beginning of April with the same pharmacy in Canada. Last week, I checked with Express Scripts to see how much a 90-day prescription would be for Solomon's Humalog and it would cost me \$1,489.46 with my insurance.

As I mentioned, I help people build houses for a living. I am good at my job and can tell you very accurately how much it would cost you to build a new house or put an addition on your home—but I can't tell you how much it's going to cost from month to month to buy the insulin I need to help keep my son healthy.

I do not understand why insulin for children with type 1 diabetes is so expensive and why I can purchase it in Canada for so much less. We are just talking about the cost of insulin today, but there are many other things like insulin pumps and glucose monitors out there that would make children's lives and parents' lives so much easier if they were more affordable.

Thank you again for the opportunity to appear before you today to share our story. I would be happy to answer any questions.

Prepared Statement of Lois Ondik, Retiree, Blandon, Pennsylvania

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 Lois Ondik. I am 73 years old and a resident of Blandon, Pennsylvania. I have three children and two grandchildren. I am a retired school bus driver for the Berks County Intermediate Unit.

Five years ago, my doctor diagnosed me with type 2 diabetes. At that time, my doctor wanted me to start on medication to help manage my blood sugar and A1C. A1C measures the amount of hemoglobin in the blood that has glucose attached to it. An A1C level of 5.7 percent is considered normal. An A1C of 5.7 to 6.4 is pre-diabetes and 6.5 and over is type 2 diabetes. Five generations of my family have been diagnosed with diabetes, myself being the fifth generation and now my daughter has just been diagnosed with pre-diabetes, making her the sixth. I understand the toll that it can take on both your body and finances. I was concerned about the side effects of medications and I knew that the cost of medication would likely eat into my budget and my savings. So, I insisted on trying to manage my condition on my own, without medication. For a while, I was able to do so.

During a recent visit with my doctor, I was again told that my blood sugar and A1C levels would soon require me to begin taking medication. And, so again, I thought to myself that there had to be another option.

Then, I saw an advertisement for a diabetes self-management program through Berks Encore, my local Area Agency on Aging, hanging on the bulletin board at my local grocery store. I ended up registering for the diabetes self-management class. I did not know what the class would be about when I signed up, but knew that I needed to manage my diabetes better or face the bills and side effects associated with medication.

The class has been a blessing. We met once a week for two and half hours for six weeks and it was run by two trained leaders. One of my leaders, Martha Sitler, joins me here today.

My classmates were at different levels in their disease, including those with a new diagnosis, people managing with Metformin medication, and people on insulin. I met a woman who used an insulin pump and another who was struggling to manage her blood sugar, even with insulin. Meeting them, learning about the side effects, and knowing how costly the medications can be affirmed my resolve to manage my diabetes on my own for as long as possible.

The class is evidence-based, so I know that I learned about techniques to deal with the symptoms of diabetes that really work. We discussed how to deal with emotions and stress management and talked about foot care, exercise, healthy eating, and many other topics, but especially how to talk to our doctors.

Before these classes, I did not regularly test my blood sugar, but I started to once I joined the diabetes self-management program. I also tracked everything I ate and learned how food and exercise affected my blood sugar. The class helped me understand the amount of food I need per day, including how to balance protein, carbohydrates, and fats to better control my blood sugar.

At the end of every session, each individual created an action plan, something they wanted to accomplish before our next class. For example, I wanted to start exercising. My plan was to start low and slow, to exercise 15 minutes per day, 3 days per week. The following week we were accountable to our classmates and had to report on how we did. Sometimes it is hard to accomplish every goal you set, but

being accountable to my classmates helped me reach my goals. I found the peer-to-peer support to be very important. The class was eye opening to say the least.

After my diabetes self-management program ended, I joined a free walking class entitled "Walk with Ease", sponsored by the Arthritis Foundation of Berks County. The program is presented by Martha Sitler and Kathy Roberts of Berks Encore, my local Area Agency on Aging. Today, my foster dog, Murfee, and I walk every day, and I use two pedometers to track my activity. I went from zero exercise to more than 2.5 miles per day. I think of the walking class as an extension of the diabetes self-management program because of how important exercise is in managing my disease.

I am pleased to say that since starting my class, I lost 13 pounds and lowered my A1C two tenths of a point. In fact, the doctor told me that had my A1C moved two tenths of a point in the opposite direction, she would have insisted I start taking medication. That is where it all fell into perspective, I knew I had the ability to manage my diabetes on my own; I just needed the right tools.

The diabetes self-management program did just that, it gave me the tools I need to manage my diabetes and now I use those tools to live a healthy life. I even told my doctor about the course and recommend that she tell her patients about it. I am now able to manage my disease through lifestyle changes, instead of having to purchase expensive medications and supplies, like insulin.

I believe it is important for people to have access to supports to prevent or better manage their diabetes and that can help them avoid paying for high-cost medications. I am concerned about the rising cost of medications across the board, because it puts treatment out of reach for some people.

Again, thank you for the invitation to testify before the Committee. I look forward to answering your questions.

Thank you.

**Prepared Statement of Jeremy A. Greene, M.D., Ph.D.
Professor of Medicine and the History of Medicine
Johns Hopkins University**

**Submitted to the United States Senate
Special Committee on Aging**

Insulin Access and Affordability: The Rising Cost of Treatment

May 8, 2018

Chairman Collins and Ranking Member Casey, thank you for the opportunity to submit testimony on this vital matter. The affordability of lifesaving medicines has been a subject of central concern in my own career, both as a historian of the pharmaceutical industry^{1 2 3} and an internist in a busy inner-city community health center in East Baltimore. No single issue exposes the tragedy and absurdity of our inability to provide 20th century cures to patients in the 21st century as does the increasing unaffordability of insulin for Americans living with diabetes today.^{4 5}

As you know, diabetes mellitus is a disease that now affects more than 9% of the U.S., population, an estimated 30.3 million Americans as of 2015.⁶ For the 1.25 million of Americans with I diabetes, insulin is an absolute requirement for survival. Their bodies no longer produce this vital hormone, and without access to a pharmaceutical version they die, typically from diabetic ketoacidosis. Of the larger population of Americans living with type II diabetes, whose bodies are no longer responsive to the insulin they do produce, some can manage their illness with lifestyle measures such as dietary change, exercise, and weight loss. Most, however, require treatment with one or more oral medications in order to bring their escalating blood sugar levels under control, and prevent the many serious long-term complications that type II diabetes brings: loss of vision, loss of sensation, stroke, heart disease, kidney failure, loss of limbs, coma,

¹ Jeremy A. Greene, *Generic: The Unbranding of Modern Medicine*. Baltimore: Johns Hopkins University Press, 2014.

² Jeremy A. Greene, "Drug bust: For 30 years, generic medications helped make health care cheaper. Why is their cost surging?" *Slate*. Nov 20, 2014.
http://www.slate.com/articles/business/moneybox/2014/11/generic_drug_prices_why_their_prices_are_suddenly_surging.html

³ Jeremy A. Greene, "When old drugs are made new again," *Forbes*. April 23, 2015.

<http://www.forbes.com/sites/matthewherper/2015/04/23/when-old-drugs-are-made-new-again/>

⁴ Jeremy A. Greene and Kevin Riggs, "Why is there no generic insulin? Historical origins of a modern problem," *New England Journal of Medicine* 2015; 372:1171-5

⁵ Jeremy A. Greene, "Cornering the market on essential drugs" *Slate* September 23, 2015.

http://www.slate.com/articles/health_and_science/medical_examiner/2015/09/generic_drug_price_gouging_how_shkreli_and_other_monopolists_cornered_the.html

⁶ <http://www.diabetes.org/diabetes-basics/statistics/>

and death. For many of these patients, even those who observe dietary change, exercise, and oral medications, the combination simply is not enough control their disease. Between 20 and 30% of patients with type II diabetes require insulin to achieve control of their blood sugars: for these millions of Americans, this drug is a necessary tool to avoid preventable loss of life and limb.^{7 8}

I work as an internist in the East Baltimore Medical Center, a busy urban community health center associated with Johns Hopkins University School of Medicine that functions as a safety net for residents in the broader Baltimore area. Every week in my clinic I see patients with type II diabetes who require insulin to manage their disease and whose blood sugar is not controlled. Controlling diabetes with insulin is not easy, and there are a number of social, biological, economic, psychological, biological, and structural factors through which even the best-behaved patient can face challenges in using their medicines correctly to control this chronic disease. This is especially for many of the patients in my clinic. Factors including language barriers, health literacy, physical side effects, comorbid depression, homelessness, unstable work, and lack of access to regular medical care have all been documented to influence the ability of individual patients to make appropriate use of this lifesaving medicine.⁹ These factors are also known to exacerbate disparities in diabetes outcomes by race, ethnicity, social geography, education level, and income.^{10 11 12} Yet until recently, the cost of insulin itself was not understood to be part of the problem. Insulin was an old drug, an off-patent drug, first patented in 1923—how could the price of this drug meaningfully affect the delivery of care?

And yet in the past decade, when I asked my patients why it was that they were having a difficult time adhering with the insulin regimens that I was prescribing for them, I increasingly heard that the cost of the medicine itself had become prohibitive. I thought that perhaps the problem was that these patients were mistakenly given one of the newer, more expensive versions of insulin, or a patented delivery device such as an injection pen, when what they really needed in order to make insulin a practical part of their lives was older, but more affordable, generic vial of regular and NPH insulin. So I called a series of pharmacies in Baltimore to ask how to make sure that my patients received affordable generic insulin, and was surprised to learn that this thing, “generic insulin”, simply did not exist. Indeed, all insulin for sale in the United States in 2015 came from one of three brand-name manufacturers: Eli Lilly, Sanofi-Aventis, and Novo

⁷ IDF: International Diabetes Federation Diabetes Atlas 8th Edition. Brussels, International Diabetes Federation, 2017.

⁸ Health Action International. *Access to Insulin: Current Challenges and Constraints*. March 23, 2017. <http://haiweb.org/publication/acciss-study-report-access-insulin-current-challenges-constraints/>

⁹ K Capoccia, PS Odegard, N Letassy. Medication adherence with diabetes medication: A systematic review of the literature. *Diabetes Education* 2016; 42(1):34-71.

¹⁰ A Fernandez, J Quan, MM Parker, D Schillinger, AJ Karter. Adherence to newly prescribed diabetes medications among insured Latino and White patients with diabetes. *JAMA Internal Medicine* 2017; 177(3):371-9

¹¹ I Lerman, JP Diaz, ME Ibarguengoitia, FH Perez, AR Villa, ML Velasco, RG Cruz, JA Rodrigo. Nonadherence to insulin therapy in low-income, type 2 diabetic patients. *Endocrinology Practice* 2009; 15(1):41-6.

¹² JR Canedo, ST Miller, D Schlundt, MK Fadden, M Sanderson. Racial/ethnic disparities in diabetes quality of care: the role of healthcare access and socioeconomic status. *Journal of Racial and Ethnic Healthcare Disparities* 2018; 5(1):7-14.

Nordisk. These three brand-name firms dominated the nearly \$27 billion dollar global insulin market, controlling 99% of the market by volume.¹³

We know from a number of studies the off-patent pharmaceutical marketplace that robust price competition does not occur in the pharmaceutical marketplace until four or more manufacturers compete in a given drug market.^{14 15} But in the case of the insulin market, prices have been rising dramatically over the past decade, with no clear indication of why.¹⁶ Eli Lilly's Humalog cost \$21 a vial when it was first introduced in 1996. At the time, that price was substantially more expensive than existing insulin products, but innovative products are expected to cost more when they are first introduced, and then gradually decrease in price once patents expire and competition emerges. By 2017, however, the now off-patent Humalog cost \$275 for a month's supply.¹⁷ All told, the price of insulin products have increased more than 270% in the past decade. These dramatic increases have real consequences in the lives of Americans living with diabetes, who face increasingly untenable choices between insulin and other necessary expenses of daily life.¹⁸

An survey of people living with type I diabetes found that more than one out of four had rationed insulin at least once due to cost in the past year, and more than half of them had rationed insulin monthly, weekly, or daily due to cost.¹⁹ This is not only true for type I diabetes: after a colleague of mine, who runs a busy diabetes clinic including both type I and type II patients began systematically asking her patients whether they ever rationed or withheld insulin due to costs, the same proportion—one in four—of her patients said that they did. Patients who rationed or withheld insulin due to cost were more likely to come from lower income levels, have variable insurance coverage, and were more likely to present with uncontrolled blood sugar levels (and therefore be at higher risk of complications). The most common cause of death worldwide for children with diabetes is lack of access to insulin, and not only in poorer countries.²⁰ Independent studies indicate that more than 25% of life-threatening hospitalizations for diabetes in U.S. inner-city minority patients could be attributed to inability to afford a regular supply of

¹³ Health Action International. *Access to Insulin: Current Challenges and Constraints*. March 23, 2017. <http://haiweb.org/publication/access-study-report-access-insulin-current-challenges-constraints/>

¹⁴ Berndt ER, Mortimer R, Bhattacharjya A, Parece A, Tuttle E. Authorized generic drugs, price competition, and consumers' welfare. *Health Affairs* 2007;26(3):790-799.

¹⁵ Jonathan Alpern, William M. Stauffer, Aaron Kesselheim. High cost generic drugs: implications for patients and policymakers. *New England Journal of Medicine* 2014; 371:1859-62.

¹⁶ Luo J, Avorn J, Kesselheim AS: Trends in Medicaid Reimbursements for Insulin From 1991 Through 2014. *JAMA*

¹⁷ Paul Barret and Robert Langreth. The crazy math behind drug prices. *Bloomberg Businessweek* June 29, 2017. <https://www.bloomberg.com/news/articles/2017-06-29/the-crazy-math-behind-drug-prices>

¹⁸ Lipska KJ, Ross JS, Van Houten HK, Beran D, Yudkin JS, Shah ND: Use and out-of-pocket costs of insulin for type 2 diabetes mellitus from 2000 through 2010. *JAMA* 2014;311:2331-2333

¹⁹ T1 International. *Access to Insulin and Supplies Survey*. 2016. <https://www.t1international.com/insulin-and-supply-survey/>

²⁰ Gale EA: Dying of diabetes. *Lancet* 2006;368:1626-1628

insulin.²¹ Yet uninsured or under-insured Americans face a particular burden, as the price of insulins are higher here in the United States than anywhere else in the world.

Why is there no generic insulin?²²

Until recently, most national debates over the high prices of prescription drugs have centered on the price of newer, on-patent medications, with the assumption that the prices of older, off-patent medications become negligible once they are subject to generic competition. Much of present-day American pharmaceutical policy takes it as a given that the historical relationship between on-patent brand name and off-patent generic drugs serves to balance pharmaceutical innovation and pharmaceutical access. The story goes something like this: in the first (patent-protected) phase of its life, a new drug is given a patent-monopoly to reimburse its developers for the substantial costs of pharmaceutical innovation. In the second (off-patent) phase of its life, competition brings prices down so that a supply of effective but affordable medications are widely available. So far so good. But as the Senate Aging Committee carefully documented in your investigative work leading to the 2016 report on *Sudden Price Spikes in Off-Patent Prescription Drugs*,²³ we are finding that drugs enter a third, uncharted phase, where dwindling competition creates new monopolies and the accelerated series of drug shortages and price hikes now affecting millions of Americans. In spite of recent efforts by the U.S. Food and Drug Administration to create a “fast track” for approvals for generic versions of off-patent pharmaceutical products with little or no competition, and recent actions by several state governments to provide greater transparency into pharmaceutical pricing and eliminate price-gouging of off-patent drugs,²⁴ recent evidence suggests these practices continue.^{25 26 27}

The unaffordability of old drugs is particularly tragic in the case of insulin. Why is a medication discovered almost 100 years ago still not available as a low-priced generic agent? To understanding the problem of access to insulin, it is essential to trace the historical origins of this modern conundrum, and its implications for contemporary policy and practice.

²¹ L. Randall, J. Begovic, M. Hudson, D. Smiley, L. Peng, N. Pitre, D. Umpierrez. Recurrent diabetic ketoacidosis in inner city minority patients: behavioral, socioeconomic, and psychosocial factors. *Diabetes Care* 2011; 34(9):1891-6.

²² Parts of this and subsequent sections of this testimony are excerpted, with updated references, from Jeremy A. Greene and Kevin Riggs, “Why is there no generic insulin? Historical origins of a modern problem,” *New England Journal of Medicine* 2015; 372:1171-5

²³ Special Committee on Aging, United States Senate. *Sudden Price Spikes in Off-Patent Prescription Drugs: The Monopoly Business Model that Harms Patients, Taxpayers, and the U.S. Health Care System*. Washington, D.C.: Government Printing Office, December 2016.

²⁴ Jeremy A. Greene, “Targeting unconscionable prescription-drug prices: Maryland’s anti-price-gouging law,” *New England Journal of Medicine* 2017; 377:101-103. <http://www.nejm.org/doi/full/10.1056/NEJMp1704907>

²⁵ Rachel B. Doyle, “The limits of charity from a drug company” *New Yorker* February 28, 2017. <https://www.newyorker.com/business/currency/the-limits-of-charity-from-a-drug-company>

²⁶ Peter Loftus, “Drug prices soar without generics” *Wall Street Journal* December 26, 2017.

<https://www.wsj.com/articles/cancer-drug-price-rises-1400-with-no-generic-to-challenge-it-1514203201>

²⁷ R Gupta, A Henkel, HP Forman, JS Ross. The impact of off-patent drug acquisitions on prices. *Journal of General Internal Medicine* 2018.

When insulin was discovered in 1921, it was hailed as one of the first “wonder drugs,” capable of transforming a fatal affliction into a manageable chronic condition.²⁸ And yet today—with the exception of two recently-approved “follow on” versions, insulin is only available in more expensive brand-name forms. 99% of the global insulin market by volume is supplied by three firms: Eli Lilly, Novo Nordisk, and Sanofi-Aventis. While many other common medications are available as \$4 generics, there are no similarly low-priced versions of insulin available, particularly for those without insurance (with the exception of ReliOn, a version of Novo Nordisk’s Novolin insulin which Wal-Mart exclusively sells for \$25). For many with insurance—and many more without it—the price of insulin is still too high to pay, with disastrous consequences for individual and systemic management of this most prevalent of chronic diseases.^{29 30}

In a widely celebrated tale of biomedical serendipity, insulin was discovered by an unlikely scientific team at the University of Toronto in 1921, led by a young orthopedic surgeon without laboratory training, Frederick Banting, and a medical student, Charles Best. After improving their technique of extracting the active insulin (initially termed isletin) from whole animal pancreas, they were able to produce enough insulin to treat the first patient, Leonard Thompson, in 1922. A patent was not filed for the discovery until later, in part because academic medicine viewed the patenting of biomedical research in the early 20th century with some distaste. When the Toronto team applied for an American patent on insulin in January of 1923, they were careful to state their goal was not profit, but ensuring the speedy and safe availability of their discovery to the general public. The patent, as they wrote in a letter to the president of the University of Toronto that year, was a form of publication: “when the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly.”³¹

Patenting insulin also allowed those at the University of Toronto to ensure high quality control by controlling *who* could manufacture insulin.³² After attempting to manufacture insulin in a production facility on the campus at the University of Toronto, the original researchers realized that they needed help, as they did not have the pharmaceutical manufacturing expertise needed to produce enough drug for North American markets. In 1923, they teamed up with the Eli Lilly Company, an established pharmaceutical company with experience in glandular extracts. Lilly was allowed to take out American patents to any improvements to manufacturing process, but Toronto would receive the patent rights for rest of world. Throughout that year, the team at Toronto licensed the rights to produce insulin to numerous other companies in different

²⁸ Feudtner JC. *Bittersweet: Diabetes, Insulin, and the Transformation of Illness*. Chapel Hill: University of North Carolina Press, 2003.

²⁹ Piette JD, Heisler M, Wagner TH. Problems paying out-of-pocket medication costs among older adults with diabetes. *Diabetes Care* 2004;27:384-91.

³⁰ Lipska KJ, Ross JS, Van Houten HK, Beran D, Yudkin JS, Shah ND: Use and out-of-pocket costs of insulin for type 2 diabetes mellitus from 2000 through 2010. *JAMA* 2014;311:2331-2333.

³¹ Bliss M. *The Discovery of Insulin*. Chicago: University of Chicago Press; 2013.

³² Cassier M, Sinding C. ‘Patenting in the public interest’: administration of insulin patents by the University of Toronto. *History and Technology* 2008;24:153-71.

countries. One of those companies, Nordisk Insulinlaboratorium (which later merged with Novo Terapeutisk Laboratorium to form Novo Nordisk) in Denmark, would become a major innovator of brand-name insulin products in its own right.

The public health impact of insulin was visible almost immediately after the first demonstration of its efficacy in a Toronto patient named Leonard Thompson in 1922. By October of that year, newspapers in Ontario announced that for the first time in the history of the city of London, Ontario, three months had passed with no deaths due to diabetes. Before the introduction of insulin, the life expectancy for a patient with type I diabetes diagnosed at age 10 was only 1-3 years. By the end of the 1920s, life expectancy had jumped to 32 years; by the onset of WWII it had jumped further to 45 years, while the person diagnosed with type I diabetes in the year 2011 could expect an average life expectancy of 75 years.³³

Modifying insulin: safety, efficacy, and palatability

Insulin was immediately perceived to be a lifesaving drug of vast clinical and public health significance. And yet the initial animal extracts produced by Lilly and others had limitations. First, the short duration of action necessitated frequent injections. In the early 1930s, Hans Christian Hagedorn and colleagues at Nordisk discovered that adding protamine to insulin altered the absorption and prolonged the action.³⁴ These first protamine insulins represented a significant innovation, but their amorphous form did not allow mixing with crystalline fast-acting (regular) insulin. A subsequent innovation, the addition of small amounts of zinc to form the crystalline protamine-isophane insulin, now known as Neutral Protamine Hagedorn, or NPH,³⁵ was patented in 1946. This advance made it possible to combine long-acting and short-acting insulin, allowing many with diabetes to be treated with a single daily injection. Soon afterwards, a method for prolonging the action of insulin without the addition of protamine was discovered, which led to the introduction of the lente insulins in the mid-1950s.³⁶ These discoveries offered more options in titrating insulin regimens, but extended the reach of insulin patents into the 1970s.

Second, these initial beef and pork insulins also were plagued with the problems inherent to extracts of animal tissue. Impurities in the medication could cause local site reactions, and immunological reactions to non-human proteins could decrease efficacy and precipitate allergic responses. A series of innovations in the manufacturing process of insulin in the early 1970s helped to improve purity and reduce these side effects. In short succession, Novo introduced “monocomponent” insulins and Lilly introduced “single-peak” insulins. These improvements in product safety extended insulin patents into the late 1980s.

³³ Gale EA: Dying of diabetes. *Lancet* 2006;368:1626-1628

³⁴ Hagedorn HC, Jensen BN, Krarup NB, Wodstrup I. Protamine insulinate. *JAMA* 1936;106:177-80.

³⁵ Heller S, Kozlovski P, Kurtzhals P. Insulin's 85th anniversary--An enduring medical miracle. *Diabetes Res Clin Pract* 2007;78:149-58.

³⁶ Lawrence RD, Oakley W. A new long-acting insulin; a preliminary trial of lente Novo insulin. *Br Med J* 1953;1:242-4.

By the late 1970s, however, further improvements to the purity of animal extracts were sidelined when it became possible to produce human insulin through recombinant technology. Investors in the field of biotech saw insulin as an ideal product for the new industry after Genentech scientists succeeded in producing the first recombinant DNA human insulin in 1978 by inserting the cloned insulin gene into the bacteria *Escherichia coli*.³⁷ This technology led to Lilly bringing the first recombinant human insulins to the US market in 1982, Humulin R (rapid) and N (NPH). Around the same time, Novo and Nordisk developed methods for chemically converting bovine to human insulin, allowing them to compete in the initial market of human insulin. Novo Nordisk eventually brought their first recombinant insulin to market in 1988. A new web of insulin patents, held by the Lilly, Novo Nordisk, and Genentech, promised to stretch into the 21st century.

Once recombinant technology opened the door to using the genetic code to make insulin, scientists quickly began modifying the very structure of insulin in attempt to improve its physiologic effects. In the late 1980s, it was shown that single amino-acid substitutions could result in significantly more rapid absorption of insulin.³⁸ Theoretically, more rapid absorption allowed injected insulin to more closely mimic the prandial insulin release by the pancreas. Lispro was the first short-acting insulin analog approved in 1996 followed by aspart in 2000 and glulisine in 2004. The same concept that allowed for fast-acting analogues also allowed for engineering long-acting analogues. Since NPH has an unpredictable peak and duration of action less than 24 hours,³⁹ long-acting synthetic insulins could theoretically reduce hypoglycemia and improve glycemic control. Glargine became the first long acting analogue insulin in 2000, followed by detemir insulin in 2005; the first patents on these products expired in June 2014.

Are larger molecules just harder to copy?

Why, then, is a drug originally patented in 1923 not available in generic form in 2014? Some have argued that biological drugs are larger, more complex, and harder to copy than the small molecules on which the generic drug industry was initially built in the second half of the 20th century. Many have hoped that a new era of “biosimilar” insulins would lead to competitive pricing and more affordable insulin products now that the latest crop of insulin patents have expired. Biological drugs developed by biotech firms in recent decades are larger than small-molecule drugs by orders of magnitude, and it is often impossible to know on an atom-by-atom basis whether the molecule is the same. Off-patent biotech drugs are therefore called biosimilar or follow-on rather than generic.⁴⁰

³⁷ Goeddel DV, Kleid DG, Bolivar F, et al. Expression in *Escherichia coli* of chemically synthesized genes for human insulin. *Proc Natl Acad Sci U S A* 1979;76:106-10.

³⁸ Brange J, Ribel U, Hansen JF, et al. Monomeric insulins obtained by protein engineering and their medical implications. *Nature* 1988;333:679-82.

³⁹ Heinemann L, Linkeschova R, Rave K, Hompesch B, Sedlak M, Heise T. Time-action profile of the long-acting insulin analog insulin glargine (HOE901) in comparison with those of NPH insulin and placebo. *Diabetes Care* 2000;23:644-9.

⁴⁰ Perrin C, Ewen M, Beran D: The role of biosimilar manufacturers in improving access to

Yet economists warn that the introduction of biosimilars are unlikely to lead to equivalent price reductions compared to those seen with typical generic medicines. Even an abbreviated approval process for biosimilar approval requires significantly more original data than the typical abbreviated new drug application required for small-molecule generic approval, and can require other forms of data on immunogenicity and other safety studies in humans.⁴¹ It was predicted that price reductions for biosimilar insulins in the US will be in the range of 20–40%, much less than the 80% or greater price reduction for most small molecule generics.⁴² So far, follow-on or biosimilar insulin products have lived up to these diminished expectations. In December 2015, the FDA approved Basaglar, Eli Lilly's follow-on version of Sanofi's long-acting analog insulin glargine (Lantus). Priced at \$234 for a carton instead of \$278,⁴³ Basaglar is technically cheaper than Lantus, but the difference can be a moot point for those for whom paying more than \$200 per month for a single medication is not tenable. More recently, in December 2017 the FDA approved Admelog, Sanofi's follow-on version of Eli Lilly's short-acting analog insulin lispro (Humalog); while Sanofi promises significant savings to consumers it is unlikely that the savings will be substantial. As this trading of follow-on products also documents, the promise of biosimilar competition has not yet expanded the network of insulin producers outside of the original trio of brand-name companies.

The paradox of incremental innovation

Reducing the problem of generic insulin to the contemporary debate over biosimilarity also fails to address the underlying historical problem of why there was no generic insulin in the 2000s, or the 1990s, or the 1980s, or earlier: that incremental innovation itself has repeatedly precluded the formation of a generic insulin industry in North America when earlier patents expired. Simply put, the history of insulin does not follow the standard chronology of pharmaceutical innovation in which patent monopolies naturally give way to generic competition.

Viewed in historical perspective, insulin is not a single entity, but a family of related products that has evolved through a series of incremental improvements. Subsequent iterations of insulin represented actual innovations, each one safer, more effective, or more convenient than the product that came before. And yet at the end of these generations of incremental innovation, insulin is not necessarily any more affordable to the general public than it was when the original patent holders sold their stake for \$1 to insure access to this essential medicine.

Several pharmaceutical industry analysts have described a repatenting tactic called evergreening, in which a nest of subsequent patents—often metabolites or optical isomers—iteratively help to

insulin globally. *The Lancet Diabetes & Endocrinology* 2017

⁴¹ Engelberg AB, Kesselheim AS, Avorn J. Balancing innovation, access, and profits—market exclusivity for biologics. *N Engl J Med* 2009;361:1917-9.

⁴² Heinemann L. Biosimilar insulins: how will this story evolve? *Diabetes Technol Ther* 2012;14:986-8.

⁴³ <https://www.goodrx.com/lantus>; <https://www.goodrx.com/basaglar>

extend the life of a product after initial patent expiry.⁴⁴ Evergreening can shift market share within a related family of products: for example, after Pfizer lost patent exclusivity on the antiepileptic gabapentin (Neurontin) in 2004, the firm managed to retain a healthy share of the market through patents on a metabolic cognate, pregabalin (Lyrica). Critics of evergreening often claim that the incremental innovations from one drug to another “me-too” drug are trivial: pregabalin, for example, is not clearly safer or more efficacious than gabapentin. But the cascading generations of insulin products described in this article can hardly be dismissed as simply “me-too” medicines. Protamine insulin offered a distinct advantage over regular; NPH insulin offered a distinct advantage over protamine, and so on.

On the whole, today’s insulin is demonstrably safer and more convenient to use than products available in 1923. But whether each incremental innovation is worth the price we pay, in a world where insulin remains unaffordable to many diabetics, is a more difficult question to answer. When lente insulin was introduced in the 1950s, some questioned whether the minimal theoretical advantages it offered over NPH warranted the additional complexity introduced by adding another insulin formulation to the market.⁴⁵ The theoretical advantages offered by the monocomponent extract insulins may have been outweighed in some cases by the inconvenience and risk caused by transitioning patients to a form of insulin with different potency.⁴⁶ Although recombinant insulin was heavily advertised as a clinically superior agent in the 1980s, almost no evidence was provided at the time to demonstrate clinical superiority to the best available animal extract insulins.⁴⁷ Although long-acting analogues cause less hypoglycemia than NPH,²⁷ significantly better long-term outcomes have yet to be demonstrated with analogues compared to recombinant human insulin.²⁸ Serial evidence-based reviews conducted by the World Health Organization in 2011 and 2017, and by the Cochrane Collaboration in 2005, 2006, 2007, and 2017 have failed to find substantial evidentiary basis for the widespread utilization of analog insulins over recombinant human insulins. In 2011, the World Health Organization Expert Committee on the Selection and Use of Essential Medicines “concluded that insulin analogues currently offer no significant clinical advantage over recombinant human insulin and there is still concern about possible long-term adverse effects.”⁴⁸ The 2017 WHO report likewise did not recommend widespread use of analog insulins, “noting the small magnitude of benefit and current high price compared to human insulin.”⁴⁹

It is possible that the field of value-based pricing may offer some tools for understanding how to manage future incremental innovations in the field of diabetes care. Value-based pricing systems promise to set the price of a new drug according to its relative value (for example, the degree of

⁴⁴ Hitchings AW, Baker EH, Khong TK. Making medicines evergreen. *BMJ* 2012;345:e7941.

⁴⁵ Slayton RE, Burrows RE, Marble A. Lente insulin in the treatment of diabetes. *N Engl J Med* 1955;253:722-5.

⁴⁶ Logie AW, Stowers JM. Hazards of monocomponent insulins. *Br Med J* 1976;1:879-80.

⁴⁷ Richter B, Neises G, Bergerhoff K. Human versus animal insulin in people with diabetes mellitus. A systematic review. *Endocrinol Metab Clin North Am* 2002;31:723-49.

⁴⁸ Report of the World Health Organization Expert Committee on the Selection and Use of Essential Medicines. Geneva: WHO: 2011.

⁴⁹ Report of the World Health Organization Expert Committee on the Selection and Use of Essential Medicines. Geneva: WHO: 2017

improved efficacy or safety over existing medications).^{50,51} One could imagine that application of such an approach during the introduction of recombinant and analog insulin products could have resulted in a clearer differentiation of how much benefit, and for whom, these newer insulin products afforded. But it is harder to understand how a value-based pricing model can help contain the rising costs of drugs, such as Humalog, whose prices have risen exponentially in the decades following introduction—not when they were new drugs, but when they were approaching the end of their patent life.

No doubt for many patients these incremental innovations were worth the added price. What is surprising in the case of insulin, however, is that the trailing edge of old insulin products did not become a market for generic competition, instead becoming a set of obsolete products that were promptly removed from the American market. Pork and beef insulins are not merely underutilized, they are unavailable for human use in the United States. Even when practitioners prescribe NPH and R insulin in place of glargine and aspart insulin, these “cheaper” prescriptions are filled with newer recombinant products sold as brand name drugs. And yet on the whole, it is hard to say that the patient in 2018 who cannot afford their insulin (let alone the array of patent-protected glucometers and test strips required to titrate it) is better served by only having the option of the marginally more effective agent than the quite effective versions that could have been generically available as of 1968, or 1988, or 2008, had generic manufacturers companies introduced cheaper versions when patents expired. Generic drug companies have evidently not considered it worthwhile to invest in the additional good manufacturing practices needed to produce a version of insulin that may have already become obsolete, when other off-patent small-molecule drugs represented lower-hanging fruit. Only recently, with insulin analogue patents expiring and no other next-generation products on the horizon, have prominent follow-on manufacturers showed serious interest in the competitive insulin market. Indeed, at this point there are no remaining patents on human insulin products—but there are an increasing amount of patents on insulin delivery devices.^{52, 53}

It is hard to overstate the economic and public health impact that generic drugs have played in improving access to safe, effective, and inexpensive medications for the American public. In the early 1960s, less than one out of every ten medicines dispensed in a pharmacy were generic, and the majority of prescription drugs were effectively monopolies. Today, more than 80% of prescriptions are filled generically, which saves the health care system billions of dollars each year.⁵⁴ On a macro level, these cost savings are critical for governments and other payors who are squeezed by rising health care costs; on a micro level they are critical for patients, as lower

⁵⁰ Bach PB, Pearson SD. Payer and policy maker steps to support value-based pricing for drugs. *JAMA*. 2015;314(23):2503-2504.

⁵¹ Anna Kaltenboeck, Peter B. Bach. Value-based pricing for drugs: themes and variations. *JAMA* April 30, 2018. E-publication ahead of print, <https://jamanetwork.com/journals/jama/fullarticle/2680422>

⁵² Jing Luo, Aaron S. Kesselheim. Evolution of insulin patents and market exclusivities in the USA. *The Lancet Diabetes & Endocrinology* 2015;3:835-837.

⁵³ Kaplan W, Beall R: Insulin Patent Profile. Amsterdam, Health Action International, 2016

⁵⁴ Haas JS, Phillips KA, Gerstenberger EP, Seger AC. Potential savings from substituting generic drugs for brand-name drugs: medical expenditure panel survey, 1997-2000. *Ann Intern Med* 2005;142:891-7

medication costs are associated with better compliance⁵⁵ and better outcomes.⁵⁶ But the case of insulin demonstrates that the generic market is a market space like other market spaces—it is not an automatic phase in the life-cycle of a drug. As the increasing waves of generic drug shortages in the past decade also remind us, there is a heterogeneity of *which* drugs become the subject of extensive generic competition after patent expiry, and which attract few if any manufacturers. The history of insulin highlights some of the limits of the generic competition as a public health framework. Nearly a century after its discovery, there is still no inexpensive supply of insulin for people living with diabetes in North America, and Americans continue to pay a steep price for the continued rejuvenation of this oldest of modern medicines.

What can Congress do?

By directing national attention towards the problem of insulin access and affordability, the Senate Special Committee on Aging has already taken an important first step towards resolving this problem. But there are a further set of steps that Congress can take that will be essential to insuring that future patients do not suffer from the increasing inaccessibility of these essential medicines.

Preserving access to insulin is not a Democratic or a Republican issue. This essential medicine, first patented 95 years ago, represents a vital infrastructure of our biomedical and public health system made increasingly precarious through price increases. These soaring prices occurs in a unique market space containing only three manufacturers, which is no longer exhibiting the pricing behavior one would expect of a truly competitive system. Solutions to this problem can be readily proposed from both sides of the aisle. But I repeat that all of these answers are premature if we do not understand how insulin prices are actually determined, if real prices are never visible, and if their impact on supply and demand cannot be understood. My colleagues who work in the field of pharmacoeconomics themselves have no means of studying true drug prices because the listed prices for pharmaceutical products in the United States of America—the AWP, or “average wholesale price”—bears almost no relation to the actual price negotiated between buyers and sellers through undisclosed bundling and discounting agreements.

The promise of generic competition in reducing costs is based in part on the assumption that the therapeutic marketplace allows direct interaction between the supply from competing producers and the demands of health care consumers. But in the decades since the passage of Hatch–Waxman Act of 1984, a host of mediating bodies have proliferated between drug manufacturers and those who directly consume their products. Beyond prescribing doctors and dispensing pharmacists there are now pharmacy and therapeutics (P&T) committees of hospitals or insurance plans, which determine which drugs are covered and which are not. There are also pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs), two relatively

⁵⁵ Dusetzina SB, Winn AN, Abel GA, Huskamp HA, Keating NL. Cost sharing and adherence to tyrosine kinase inhibitors for patients with chronic myeloid leukemia. *J Clin Oncol* 2014;32:306-11.

⁵⁶ Tamblyn R, Laprise R, Hanley JA, et al. Adverse events associated with prescription drug cost-sharing among poor and elderly persons. *JAMA* 2001;285:421-9.

obscure and thinly regulated parts of the health care sector that determine which manufacturers obtain contracts to supply most hospital and pharmacy chains in the United States. What we first imagine as a free market for price competition turns out, on closer examination, to be a space crowded by different forms of middlemen, whose roles in influencing supply and demand in the generic drug sector are poorly understood. In recent years, the General Accounting Office has investigated the pricing structures of GPOs and the U.S. Senate has held hearings on the competitiveness of the PBM industry. But independently these efforts have been insufficient to piece together all the steps between producer and consumer in which the true price of insulin is set.

While existing state pharmaceutical pricing transparency laws are an important start to addressing the rising cost of off-patent prescription drugs,⁵⁷ none of these measures has yet been able to fully capture the real costs of drugs moving through interstate commerce, which are still protected as trade secrets. More action is clearly needed, at the federal level, in order to achieve a meaningful knowledge of insulin price increases and forge rational policies to respond appropriately and effectively. I urge you to consider the recommendations of the recent National Academies of Science, Engineering, and Medicine Consensus Study Report, *Making Medicines Affordable*, which call on Congress to require quarterly disclosure of information on a drug-by-drug basis from insurance plans (regarding the net prices paid for drugs, including patient cost sharing) and biopharmaceutical companies (about the average net volume of and prices for drugs, including discounts provided to pharmacy benefit managers and insurance plans), as well as annual public reports stating list prices, rebates, and the average net price of each drug sold in the United States, with a requirement for the U.S. Department of Health and Human Services to inform relevant Congressional committees of all net drug price increases that exceed the growth in the consumer price index for the previous year.⁵⁸

Congress alone holds the power to illuminate how the hidden pieces in the puzzle of drug pricing actually fit together. Only Congress has the power to follow the molecule through all the steps from production to consumption and understand where, exactly, the market is being distorted and help provide evidence that will allow us to reach a true and lasting solution. As this Special Committee did just a few years ago when confronted with the problem of rising prices of off-patent drugs, I urge you to find continued space for bipartisan investigation into this issue affecting millions of Americans.

⁵⁷ Nevada Senate Passes Insulin-Price Bill Tough on Drugmakers, *U.S. News and World Reports*, May 19, 2017, <https://www.usnews.com/news/best-states/nevada/articles/2017-05-19/nevada-senate-passes-insulin-price-bill-tough-on-drugmakers>

⁵⁸ Norman R. Augustine, Guru Madhavan, and Sharyl J. Nass, *Making Medicines Affordable: A National Imperative*. Washington, DC: National Academies of Science, Engineering, and Medicine, 2018.

Additional Statements for the Record

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

Thank you, Madam Chairman, for holding this hearing today. I would also like to thank our witnesses for their testimony, particularly Lois for her compelling personal story. As we have learned today, living with diabetes is a far too common experience. To quote Lois, “the rising cost of medication across the board can put treatment out of reach for some people.” I couldn’t have said it better myself. No senior should have to ration their insulin or choose between medication and food, simply because of the price of their medications. And, as Lois shows us, it is essential for Americans to have access to programs that provide the tools to better manage diabetes. I applaud our local Area Agencies on Aging for their leadership and dedication to helping seniors live full and healthy lives, all while saving on their health care costs. It is imperative that we work together and I look forward to continuing this important dialog.

Closing Statement, Senator Richard Blumenthal

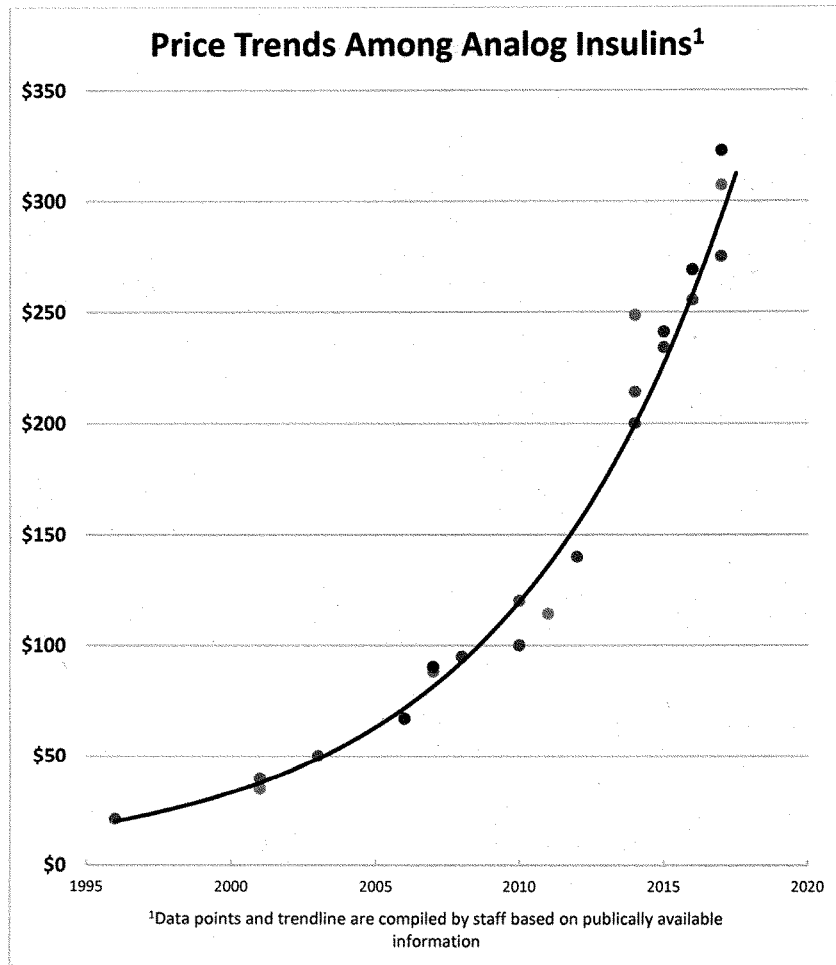
I want to start by thanking Senators Collins and Casey for holding a hearing on the increasingly high cost of insulin, and the higher cost of individuals struggling to gain access to it. There are 355,000 adults in Connecticut with diabetes, costing the state \$3.7 billion per year. This problem will get worse before it gets better, with over a third of adults in Connecticut suffering from prediabetes and, without intervention, on the road to their own diabetes diagnosis.

Yet, unfortunately, despite the diabetes epidemic that has enveloped our country, insulin prices continue to rise and patients who need this drug struggle to afford it. One doctor from Yale-New Haven Hospital described a 78-year old patient who refused to increase her dose of insulin, despite it being absolutely necessary, because she couldn’t afford to do so.

Another doctor at Hartford Hospital said that patients forgoing necessary treatments ultimately end in the emergency room there. This problem is widespread in Connecticut, particularly amongst low-income individuals, and begs the question that I believe brings us all here today: how can a one hundred year old drug suddenly cost so much that our most vulnerable citizens cannot afford to access it?

I believe this is the question we are all seeking to find answers to, not only for insulin, but countless other drugs that have seen astronomical and unjustified price spikes over the years. I will continue to push for policies that increase transparency, lower drug prices, and eventually, improve care, but that cannot be done without a strong commitment to everyone here in Congress.

I want to thank each of you for contributing your stories and information to this important discussion and look forward to finding a way to implementing the suggestions you’ve given us today at this hearing.



Statement of Sabrina Burbeck, Family With Type 1 Diabetes

Chairman Collins, Ranking Member Casey, and members of the committee: My name is Sabrina Burbeck, and I am from Old Town, Maine. I am writing to tell you about my family's experience with diabetes and insulin. When my brother was thirteen, he was diagnosed with type 1 diabetes. Since then it has been a struggle for my family to afford his insulin as the prices have risen so much over the years. In 2012, I gave birth to my second son, Dakota, who was diagnosed at 18 months with type 1 diabetes. He is now five and has relied on insulin to survive since his diagnosis. Right now we are lucky because he has state provided healthcare that helps to cover some of his drug costs. My brother is not so lucky. He must pay for his insulin out of pocket, even with a discount card he spends \$150 per vial. He should be using two vials a month, but instead he stretches out his doses for as long as he can in order to afford it. I am a single mom on a fixed income, and I live in fear of not being able to afford the insulin my son needs to survive. If my son loses his healthcare, he will be fighting that much harder for his life. No one should live in fear of having to make the choice to eat that month or pay for meds. I thank the committee for taking the time to address this issue, and I hope, for the sake of my brother and my son, that you can change our system to ensure insulin is affordable for all Americans.

Statement of Gail DeVore, Type 1 Diabetic

Chairman Collins, Ranking Member Casey, and members of the committee: My name is Gail DeVore, and I am from Denver, Colorado. I have had type 1 diabetes since Valentine's Day, 1972. For the last 46 years, I have seen the invention of home glucose meters, insulin pumps, new forms of insulin, continuous glucose monitors (CGM), and many other advancing treatment options for type 1 diabetics. I have also had the privilege of using all these options, which allow me to be complication-free and in good health. These are not "special devices" or extraordinary treatment options. These devices allow a type 1 diabetic to live without as much fear of complications and an early death due to diabetes. The ability to constantly monitor the status of our blood sugars is critical in saving our lives. However, it all comes with a very high price. At my pharmacy, one bottle of the insulin I use is \$330. My prescription is for four bottles. At other pharmacies, this same single bottle of insulin can cost as much as \$600. Supplies can also cost about \$1,000 per month on top of that, despite insurance coverage and prescription benefits. These costs are exorbitant. Considering the risks type 1 diabetics like myself face, the costs are unacceptable. I thank the committee for taking the time to address this issue, and I implore you to work on implementing policies that ensure type 1 and other types of diabetics have access to affordable insulin.

Statement of Clayton McCook, Daughter With Type 1 Diabetes

Chairman Collins, Ranking Member Casey, and members of the committee: My name is Clayton McCook, and I am from Oklahoma City, Oklahoma. I write to you today on behalf of my nine-year-old daughter, Lily, who lives with type 1 diabetes. The day she was diagnosed six years ago, our lives changed forever. We went from being a young family full of blissful innocence to one living with chronic illness. Each month Lily goes through about one and a half vials of insulin, but as she grows, she will need two. Each vial costs \$325. That comes out to nearly \$500 a month now and eventually will be over \$600. This only accounts for her insulin and not for her diabetes supplies, which are also very expensive. I am lucky; I work as a veterinarian and make good money, but even with that, my wife works multiple jobs to supplement our income and ensure we can afford Lily's insulin. My daughter is one of the strongest people I know, and I never worry about her ability to care for herself as time goes on. However, I worry every day about the direction that insulin prices are headed. The cost of insulin is always increasing, even though the drug was brought to market nearly 100 years ago. We pay hundreds of dollars for a decades-old medication that costs a fraction of the list price to produce. What will happen if Lily cannot afford her medication? She needs her insulin to survive and will continue to need it for the rest of her life. I want my daughter to grow up to live the life she wants, but with the burden of the cost of insulin, I worry that could be impossible. We need insulin to be affordable in this country. Thank you for taking the time to look into the problem for my family and others throughout the United States. I look forward to the action you take to ensure all diabetes patients, including Lily, are able to access the insulin they need to survive.

PATIENTS FOR AFFORDABLE DRUGSTM

Chairman Collins, Ranking Member Casey, and members of the committee.

My name is David Mitchell, and I am from Bethesda, Maryland. Today I write you as a cancer patient and founder of Patients For Affordable Drugs (P4AD.) We are the only national patient group focused exclusively on policies to lower drug prices. We don't accept funding from any organizations that profit from the development or distribution of prescription drugs. We hear every day from people with diabetes who struggle to afford their life-saving insulin and to manage their disease.

Sue Knipmeyer from Grand Junction, Colorado tells us: "I have been taking insulin to treat my Type I diabetes for 54 years. Without it, I will die. My insulin costs me about \$649 a month and affording this life-saving medication has led me and my husband, Bill, to file for bankruptcy and move to lower our living expenses. I don't know how anyone can afford this, but I know that I cannot."

Carolyn Wilson from Vancouver, Washington tells us: "I have diabetes, and today my insulin has become too expensive. I currently pay \$410.10 per month for insulin. I simply can't afford it, and I'm forced to make tough decisions when thinking about affording my medications or paying for groceries. I haven't taken insulin in over a month to avoid paying for the drug. As a former radiology instructor, I know the dangers in skipping my doses. I am not even the worst off-- my daughter's insulin is \$800 per month. I feel bad even complaining about mine."

These are just two stories from the nearly 900 people who have reached out to us about the price of insulin. Insulin was invented in 1923, and the patent for it was sold for \$3 because the scientists wanted to prevent exactly what has happened- insulin is now too expensive for many people. Advances in care are important for patients with diabetes, but we know that drug corporations are not using their profits to invest in innovation. They are spending it on advertising and marketing, stock buybacks and executive compensation.

The simple and outrageous fact is that insulin hasn't changed much since 1923, yet the prices continue to climb. Insulin production and distribution are controlled by just three companies that move prices in lockstep resulting in a 300 percent increase over the last decade.

Patients are suffering and making impossible choices between insulin and food; they are cutting their doses or going without and for diabetics that can be deadly. We appreciate the time this Committee is taking to look into the accessibility and affordability of insulin. We hope that the Committee takes tangible steps to work to bring down the cost of insulin to patients. Insulin doesn't work if people can't afford it.

Thank you for your consideration of this vital issue.

The Endocrine Society
Testimony Submitted for the Record

On behalf of our more than 18,000 physician and scientist members, the Endocrine Society appreciates the opportunity to provide testimony on the issue of insulin affordability and its impact on the millions of Americans who rely on this therapy to survive. Our members treat people with diabetes and work to advance research in the field. As such, we see the impact of rising insulin costs on our patients: Our members have shared that they regularly spend a lot of time during discussing what medications patients can afford instead of focusing on their patients' health. Many doctors are uncomfortable discussing costs with patients; many patients are embarrassed to admit they cannot afford medication, and some do not acknowledge they are not taking their full dosages in order to extend the length of their prescriptions. Our Society believes something must be done to help our patients and we thank the Senate Special Committee on Aging for its thoughtfulness in identifying opportunities to address this growing problem.

Of the more than 30 million Americans with diabetes, approximately 7 million use insulin to manage their disease. Diabetes is most expensive chronic disease in America, costing more than \$327 billion annually, including \$15 billion for insulin. Medical costs for patients with diabetes are twice as high as for patients without the disease. In fact, one in three Medicare dollars is spent treating diabetes and the—often unnecessary—complications and hospitalizations that can result from not taking insulin and other medications as prescribed.

Over the past 15 years, the cost of insulin has nearly tripled further exacerbating already high costs for patients, and the healthcare system more broadly. Given the influx of high deductible insurance plans that offer lower premiums but force patients to pay full cost for medications until meeting their deductible, rising insulin cost has had a direct impact on out-of-pocket expenses for many Americans. Those who are uninsured or in the Medicare Part D donut hole face similar challenges. The lack of affordable insulin has resulted in patients skipping doses, rationing their medication, taking on more debt, or having to make other difficult tradeoffs to afford their insulin.

These challenges are particularly problematic for the one in four seniors who have diabetes. These individuals are more likely to be taking insulin than other demographics and may also be struggling to afford their medications due to fixed incomes and other costs incurred from comorbidities. Unfortunately, these decisions are not a choice; access to affordable insulin can be a matter of life and death.

Identifying ways to reduce out-of-pocket costs for patients on insulin is critical given the significant scope of the problem and its impact on millions of Americans. We are encouraged that entities in the drug supply chain are beginning to take steps to address this issue. For example, Novo Nordisk is pledging to limit annual percentage price increases to single digits and is partnering with CVS Caremark to offer Novolin R, Novolin N, and Novolin 70/30 for \$25 per 10ml vial. Eli Lilly is offering insulin at a steep discount for patients in high deductible plans and exploring benefit design changes to mitigate out-of-pocket costs. Many companies offer drug savings cards and patient assistance programs (PAPs). And United Healthcare is starting to pass rebates onto patients at the point of sale.

However, we believe there are additional opportunities to build on this progress including broadening the eligibility criteria for PAPs, allowing insulin offered at discounted rates to count toward deductibles, and understanding whether drug savings cards may be having the unintended consequence of driving patients toward higher cost medications. We believe that increasing transparency, improving access to patient assistance programs, integrating cost information into electronic health records, and reducing cost-sharing would help mitigate out-of-pocket costs. While we recognize that tackling this problem is challenging due to its complexity, we believe there are several steps the Committee can take to begin improving insulin access and affordability.

Increasing Transparency

We believe the first step toward understanding what is driving the cost of insulin is increasing transparency across the drug supply chain. Unfortunately, understanding the complexity of the supply chain, who is profiting, and to what extent, is an extraordinarily difficult but necessary measure for meaningful changes to take place. The insulin supply chain

is comprised of is comprised of manufacturers, pharmacy benefit managers (PBMs), health plans, drug wholesalers, and pharmacies that are mutually dependent on negotiations with each other to maximize profitability. While the list price of insulin (the price manufacturers set and that uninsured patients may have to pay at the pharmacy) has risen precipitously, the net price (the price manufacturers receive for insulin from PBMs and other large customers) has grown at a steady, albeit much slower rate based on data we have received from the manufacturers.

As a result, a widening gap has begun to emerge between the net price and list price with little understanding of who is benefiting from the disparity as this does not lead to lower costs for patients. This is, at least in part, driven by increasing discounts and rebates that are used as an incentive to have a certain brand of insulin included in the lowest cost tier of a particular formulary. Typically, only one brand of insulin is included in this tier, leading to competitive environment in which manufacturers try to outbid the other companies without lowballing the price too much.

While price competition is desirable, these negotiations are entirely confidential, making it difficult for anyone to know how much each entity in the supply chain is profiting and what portion of the discounts or rebates are actually being passed along to patients. We believe that increasing transparency across the entire supply chain could help determine potential solutions, as each entity plays a different role in determining the cost of insulin. We urge the Committee to engage with all stakeholder groups across the supply chain to discuss the cause of rising insulin costs and what can be done to remedy the problem.

Improving Access to Patient Assistance Programs

Another option for reducing out-of-pocket costs for patients most in need is to make Patient Assistance Programs (PAPs) more accessible. PAPs are offered by all drug manufacturers to help patients afford their medication. While each of the insulin manufacturers has a PAP, the eligibility requirements are largely restrictive and the application forms are often difficult to complete. Patients who have some level of insurance coverage typically do not qualify, nor do

patients who are on Medicare or Medicaid. Our endocrinologist members have described that the application process requires significant staff time, considerable documentation (sometimes including personal financial information), and must be completed annually. They have also shared how difficult it is for their patients to obtain information about PAPs and their application.

The Society believes that expanding the eligibility requirements (loosening income restrictions, expanding PAPs to include Medicare and Medicaid, etc.) for accessing these programs would be helpful as well as making the application process less onerous. We have discussed with the manufacturers the feasibility of a common application, similar to the common college application process, that could be used for each program and saved for future use. While expanding access to PAPs does not address the underlying issue of rising insulin costs, it may be a short-term solution for certain patients while other options are explored.

Reducing Patient Cost-Sharing

We also encourage Congress to explore policies that would reduce patient cost-sharing for insulin and ensure that patients receive rebates at point of sale. This includes evaluating the feasibility of exempting insulin from coinsurance in high-deductible plans and whether insulin could be added to preventive drug lists without increasing premiums. Uninsured patients are disproportionately exposed directly to the high cost of insulin. Those who are insured are also affected while in the deductible phase or when their brand of insulin has a nonpreferred formulary status that leads to higher cost-sharing. One policy option to address this is to cover insulin in the same manner as other preventive drugs regardless of the patient's benefit design. We hope Congress will consider this and other policies if they can reduce cost sharing without increasing premiums, which will only drive more people into high deductible plans and further exacerbate this problem.

Improving Treatment Decisions

Improving treatment decisions at point of care could also be helpful in reducing the financial and administrative burden on patients and physicians. While such improvements do not directly address the high cost of insulin, they would allow for more informed discussions about treatment options and may reduce some degree of financial burden on patients. Patients who may not be able to afford their insulin may be able to use a cheaper form of the

drug (e.g. human insulin) or another treatment approach. However, it is not always possible for physicians to know what particular insulin is covered on a patient's formulary and what the out-of-pocket costs will actually be when the patient picks up the prescription. Integrating cost and formulary information into electronic health records would enable physicians and patients to have a conversation about affordable treatment alternatives. Providing such information would allow the patient and physician to pick the most appropriate and affordable therapy, increase compliance with the therapy, and reduce unnecessary stress on patients and healthcare providers.

In addition, over the last 20 years, physicians have received training on many of the newer, more expensive insulins, but lack the knowledge of how to use human insulin, which is much less expensive. While human insulin may lack some of the advantages of the newer insulins (and would not be appropriate for every patient), it could be lifesaving for patients who are rationing or going into debt to cover the cost of their medications. Congress should explore options for integrating cost and formulary information into EHRs, as well as opportunities to provide physician education on lower cost solutions for patients who cannot afford their insulin.

The Endocrine Society thanks the Committee for its interest in addressing insulin affordability. It is our hope that with policy changes, patients will have greater access to this lifesaving therapy without its current financial burden.



Advocating for people with type 1 diabetes around the world

T1International and Patient Testimony for Insulin Access and Affordability: The Rising Cost of Treatment

T1International's 2018 global survey explored out-of-pocket costs for people with type 1 diabetes. More than 25% of American respondents said that they have had to ration insulin at least once per year due to cost. Fourteen percent of those respondents have had to ration their insulin monthly, weekly, or daily due to insulin cost.

To the type 1 diabetes community, this data does not come as a shock, but it adds hard data to the countless anecdotal stories that people living with type 1 diabetes across the USA have shared.

Every day we hear from patients struggling to afford the costs of their insulin, whether they are insured with high deductibles, on insurance plans with poor coverage, or uninsured.

Parents like Nicole Smith-Holt of Minnesota are now grieving because their children were forced to ration insulin:

My son, Alec Smith, passed away at home alone on June 27th 2017. He was 26 years old.

How is it that in this day in age, people are dying from something that can be managed with proper education and access to the medication and supplies. The rising cost of insulin and supplies makes it very difficult for people with diabetes to follow doctor's orders for treatment.

When my son had insurance, he was spending about \$200 a month for his supplies and insulin. When he turned 26, he lost my insurance because of his age and his expenses for his diabetes were about \$1300 a month. Honestly, who could afford that? My son died because he was trying to ration his insulin. From my research, I can tell you that dying from DKA is a very painful death.

My son was in the prime of his life, he had so much to look forward to. There is so much I will never get to see him do and achieve. Over the 2 short years that Alec had diabetes, I saw how the insulin cost steadily rose each year and how stressful that was for him. I saw how all the stress and fear took a toll on his health and his outlook on life. Why is it that, in America, the pharmaceutical companies set the price without justification as to why? Profits should never come before the lives of people, but they took my son's life. — Nicole Smith-Holt, Minnesota

The system is truly broken and pharmaceutical companies, insurers, and pharmacy benefit managers must be held accountable through transparency and regulatory measures.

T1International believes that the three insulin manufacturers who dominate more than 90% of the global insulin market – Eli Lilly, Novo Nordisk, and Sanofi – must be addressed first because they are at the top of the chain. They ultimately set the price, which hits the uninsured, the most vulnerable in society, the hardest.





Advocating for people with type 1 diabetes around the world

The companies often tout their assistance programs as a solution to unaffordable insulin. It is incredibly difficult to qualify for these programs and some require technology that the poorest cannot access. At most only 10% of people in need will actually benefit from Lilly's newest program, for example. That estimate is coming from the company itself.

Many patients with type 1 diabetes, like Angela, AnaElena, and Karyn, have confirmed that they were not able to get help from pharmaceutical assistance programs:

When I went through my first lay-off as an airline employee with type 1 diabetes, I realized quickly that I was going to be forced to pay expensive insurance payments to continue the good coverage I had at the time of the lay-off so that I could afford my insulin and supplies. I applied for every assistance program recommended to me through my physician and the local Health Department. I was denied access to all of those programs because they used my income until that point as a reason to cite that I could not benefit from the programs.

One of the phrases that I heard in 2001, and continue to hear from those with diabetes who can't afford their insulin, is "Go to the ER when you run out of insulin and your blood sugar is high because only then can you not be refused treatment". Having to wait until we are near death to receive treatment is simply not American to me. – Angela Lautner, Kentucky

After two years without insurance, I bought a plane ticket and a week's hotel stay for the cost of a month of insulin in the USA. When I went to the pharmacy there to buy Humalog I was shocked to find that a month's supply only cost \$20. I bought as much as they would allow, and it lasted a year. Some of it expired, but I used it anyway. Desperate people do desperate things.

People will claim that it is not that difficult or serious, and that there is "always help". I can tell you with 100% certainty that this is not true. Do people want to help? Sure, but so much depends on where you live and what is available. Can you find a band-aid solution? Maybe. For me, finding help for one of the most expensive chronic illnesses in America was like finding a needle in a haystack. I can assure you that I have checked every program, I have spoken to advocates, called my politicians, written them...and in six years have not gotten anywhere. – AnaElena Djafari, Texas

There are days that I ration my insulin, because I just cannot afford the high price tag. I have used expired insulin. My blood sugars seem to be perpetually in the upper 200s to 300s, if not worse. My insurance premiums and deductibles are staggering.

Middle class people fall into a hole of not qualifying for any assistance programs, but still don't have enough money to buy life-saving medications. Most doctors won't take my insurance, leaving me without proper guidance and care.

I'm a hard working individual with a reasonably decent job, which at one time was called the "American Dream". The American Dream no longer exists, especially for those with chronic illnesses

T1International is a registered charity (CIO) in England and Wales (1168249).





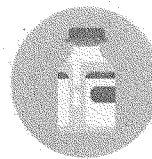
Advocating for people with type 1 diabetes around the world

like diabetes. Our dream is to make it above middle age, to keep our vision, and to not feel like we've been hit by a train every day due to excessively high blood sugar levels.

My dream no longer consists of owning a home, having children or growing old. Having access to diabetic supplies and insulin, to feel okay when I wake up in the morning – that is my dream.

– Karyn Wofford, Georgia

On average, Americans spend more on insulin than any other country. Even with insurance, many are spending around half their after tax income on insulin and other supplies they need to stay alive. "Insurance helps but it is 9k a year for a 30k year salary," one patient told us.



1 vial of Novolog costs:

- \$0 in Italy
- \$4 in Australia
- \$22 in India
- \$48 in Singapore
- \$14 - \$300 in the USA

Out of pocket for someone with type 1 diabetes

The pharmaceutical companies and PBMs are getting away with all of this because they can. The opacity of the USA healthcare system needs to be uncovered and brought to light.



1 vial of Humalog costs:

- \$0 in Portugal
- \$69 in Chile
- \$435 in the USA

Out of pocket for someone with type 1 diabetes



If the insulin manufacturers say that the PBMs and insurers are to blame, they should have no problem sharing basic information about their products. T1International will continue to demand answers to two simple questions, which will provide essential transparency:

1. How much does it cost Lilly to manufacture a vial of Humalog?
2. What are Lilly's profits on each vial?

These questions represent the foundation of the injustice so we will pose them again and again, until they are answered.

Our Recommendations

We request state and federal legislation to require insulin manufacturers to disclose manufacturing costs, profits, expenditures for marketing, and funding provided to patient advocacy organizations. Bi-partisan legislation like that passed in Nevada and California is the first step to addressing this extortionate pricing on the state-level.

We recommend that all legislators support national efforts to allow Medicare and Medicaid to negotiate pharmaceutical prices. Medicaid is financed by our tax dollars and states have an obligation to spend that money responsibly. The purchasing power of both Medicare and Medicaid will pressure insulin manufacturers to decrease prices.





AMERICA'S HEALTH INSURANCE PLANS

Statement For The Record

Submitted to the Senate Special Committee on Aging

"Insulin Access and Affordability: The Rising Cost of Treatment"

America's Health Insurance Plans (AHIP) appreciates this opportunity to offer our comments on issues affecting the cost and availability of insulin products for diabetes patients. We thank the committee for calling attention to these important issues.

AHIP is the national association whose members provide coverage for health care and related services to millions of Americans every day. Through these offerings, we improve and protect the health and financial security of consumers, families, businesses, communities, and the nation. We are committed to market-based solutions and public-private partnerships that improve affordability, value, access, and well-being for consumers.

Our statement focuses on: (1) the role health insurance providers play in meeting the needs of diabetes patients; and (2) the affordability crisis surrounding insulin products, which is caused by pharmaceutical companies taking advantage of a broken market for their own financial gain at the expense of patients.

Coverage of Insulin Products by Health Insurance Providers

Our members are strongly committed to ensuring that patients with diabetes have access to affordable insulin options to facilitate good control of blood glucose levels. Health insurance providers have a strong track record in advancing innovative approaches to help their enrollees successfully manage and control diabetes, prevent complications, and improve their quality of life.

Health plans recognize the real health consequences to their members from poor control of blood glucose levels—and ensuring access to insulin is a critically important part of these efforts. Because of its clinical properties, insulin is an essential and life-saving medicine for patients with Type 1 diabetes and for many patients with Type 2 diabetes as their condition progresses.

To evaluate coverage of insulin products, AHIP recently reviewed publicly available content for 10 randomly selected commercial health plans to capture different plan sizes (e.g., national, regional, local) and geographies.

We found:

- Each of the plans we reviewed covered a variety of insulin products.
- Plans covered from five insulin products to 14 insulin products on their formularies, with an average of nine per plan.
- Only one drug (Ryzodeg) did not appear on any of the reviewed formularies—all of the other 15 available insulin drugs were covered on at least one of the 10 plan formularies.
- All plan formularies included one or more preferred brands.
- No plans imposed or required prior authorization or step therapy protocols for any of the insulin products listed as a “preferred brand.”

Regarding “preferred brand” status for insulin products:

- For each of the 10 commercial plan formularies reviewed, at least two insulin products are covered as a “preferred brand.”
- At least four insulin products were covered as a “preferred brand” on seven of the 10 plans reviewed.
- One plan included and covered nine insulin products in its “preferred brand” tier.
- The most commonly covered drug on the “preferred brand” tier was Lantus, which appeared on eight of 10 formularies reviewed. The other most common “preferred brand” drugs included Levemir (seven plans), Novolog (seven plans), followed by Humulin, Novolin, and Toujeo, which all were found as low-tier medications on six of 10 formularies.
- Of the 16 insulin medications available on the market, 12 appeared on at least one plan formulary as a “preferred” option.

When making decisions about formulary placement and utilization management programs for insulin and other medications, health insurance providers use expert Pharmacy and Therapeutics (P&T) Committees to review the available scientific evidence and peer-reviewed literature regarding the safety, effectiveness, and value of insulin products and other specific drugs. P&T Committees typically are composed of physicians (including physicians who specialize in the treatment of diabetes, such as endocrinologists, and specialists in other complex medical conditions), pharmacists, and other health care professionals.

P&T Committees review and update formulary lists regularly to make sure the formulary includes safe and effective drugs approved by the Food and Drug Administration (FDA). This review includes an evaluation of current formulary medications as well as any new drugs approved by the FDA. Utilization management criteria are also reviewed regularly and updated if necessary to be consistent with current evidence-based standards of practice. These practices are consistent with private accreditation standards as well.

In addition, health insurance providers negotiate with manufacturers to reduce the net price of medications, so they can pass savings onto consumers and other payers (e.g., employers). For example, if a health plan's P&T Committee determines that two or more drugs are therapeutically equivalent and eligible for formulary inclusion, health plans (or their pharmacy benefit managers) will typically seek to negotiate with manufacturers for rebates and other discounts when placing one or more of these therapeutically equivalent drugs on a preferred formulary tier and/or waiving utilization management tools, such as step therapy protocols.

Through all of these activities, health insurance providers are strongly committed to providing coverage of insulin products and meeting the health care needs of diabetes patients.

The Rising Cost of Insulin, Driven by the Pharmaceutical Industry

The price of insulin—just like the price of countless other pharmaceutical products—has increased sharply over the past decade, at the same time the prevalence of diabetes has risen across the U.S. population. These price increases are a direct result of actions by the pharmaceutical industry to take advantage of a broken market.

Since 2006, while the number and supply of insulin products has grown, the list price of insulin products has increased exponentially—in direct violation of the economic laws of supply and demand. One study shows that the price of insulin has increased more than 240 percent over the past decade; for example, the price of Lantus increased from \$88.20 per vial in 2007 to \$307.20 per vial in late 2017, while the price of Levemir increased from \$90.30 per vial to \$322.80 per vial during the same time period.¹ These sharp price increases harm patients who rely on insulin and reduce the affordability of coverage for all consumers and payers who must bear the cost through higher insurance premiums.

Moreover, despite the fact that insulin products have been on the market for almost a century, there are still no “generic” equivalent versions of insulin products available in the United States. The absence of a generic option in the insulin market provides an excellent case study showing why it is so important for Congress to reduce barriers to the entry of lower cost generic drugs into the marketplace. The CREATES Act (S. 974), which AHIP strongly supports, would take important steps to discourage pharmaceutical companies from abusing Risk Evaluation and Mitigation Strategies (REMS) to block the availability of generic drugs. As evidence for these abuses, the FDA just published a list of name brand drugs and pharmaceutical companies that potentially have abused and gamed REMS to obstruct the development of generic alternatives.²

¹ Several Probes Target Insulin Drug Pricing, Kaiser Health News, October 28, 2017
<https://www.nbcnews.com/health/health-news/several-probes-target-insulin-drug-pricing-n815141>

² Reference Listed Drug (RLD) Access Inquiries, Food and Drug Administration, May 17, 2018
<https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/AbbreviatedNewDrugApplicationANDAGenerics/ucm607738.htm>

As the committee continues to explore these issues, we urge you to recognize that the entire pricing process is driven entirely by the original list price of a branded drug—which is determined solely by the drug company, not by the market or any other participant in the pharmaceutical supply chain. Congress needs to address this reality—**the problem is the price**—as part of any strategy for reducing pharmaceutical costs for the American people.

Out-of-control prescription drug prices are a direct consequence of pharmaceutical companies taking advantage of a broken market for their own financial gain at the expense of patients. The lack of competition, transparency, and accountability in the prescription drug market has created extended, price-dictating monopolies with economic power that exist nowhere else in the U.S. economy. The end result is that everyone pays more—from patients, businesses and taxpayers to hospitals, doctors, and pharmacists.

Bold steps are needed, at both the legislative and regulatory levels, to ensure that people have access to affordable medications. With solutions that deliver real competition, create more consumer choice, and ensure open and honest drug prices, we can deliver affordable pharmaceutical products—while at the same time protecting and supporting innovations to deliver new treatments and cures for patients. Accessible, affordable medicines are the cornerstone to keeping patients with chronic disease healthier and out of emergency rooms. Reducing the price of medicines is a necessary step toward achieving this goal.

Thank you for holding this important hearing. We share your commitment to improving health care for patients with diabetes. We look forward to working with you to advance market-based solutions for confronting the affordability crisis surrounding insulin.

