AUTHENTICATED
U.S. GOVERNMENT
INFORMATION
GPO

PRICED OUT OF A LIFESAVING DRUG: GETTING ANSWERS ON THE RISING COST OF INSULIN

HEARING

BEFORE THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON ENERGY AND COMMERCE

HOUSE OF REPRESENTATIVES

ONE HUNDRED SIXTEENTH CONGRESS

FIRST SESSION

APRIL 10, 2019

Serial No. 116–25

Printed for the use of the Committee on Energy and Commerce

govinfo.gov/committee/house-energy
energycommerce.house.gov

U.S. GOVERNMENT PUBLISHING OFFICE

39–747 PDF WASHINGTON : 2020

COMMITTEE ON ENERGY AND COMMERCE

FRANK PALLONE, JR., New Jersey
Chairman

BOBBY L. RUSH, Illinois
ANNA G. ESHOO, California
ELIOT L. ENGEL, New York
DIANA DEGETTE, Colorado
MIKE DOYLE, Pennsylvania
JAN SCHAKOWSKY, Illinois
G. K. BUTTERFIELD, North Carolina
DORIS O. MATSUI, California
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
JERRY MCNERNEY, California
PETER WELCH, Vermont
BEN RAY LUJÁN, New Mexico
PAUL TONKO, New York
YVETTE D. CLARKE, New York, *Vice Chair*
DAVID LOEBSACK, Iowa
KURT SCHRADER, Oregon
JOSEPH P. KENNEDY III, Massachusetts
TONY CÁRDENAS, California
RAUL RUIZ, California
SCOTT H. PETERS, California
DEBBIE DINGELL, Michigan
MARC A. VEASEY, Texas
ANN M. KUSTER, New Hampshire
ROBIN L. KELLY, Illinois
NANETTE DIAZ BARRAGÁN, California
A. DONALD MCEACHIN, Virginia
LISA BLUNT ROCHESTER, Delaware
DARREN SOTO, Florida
TOM O'HALLERAN, Arizona

GREG WALDEN, Oregon
Ranking Member
FRED UPTON, Michigan
JOHN SHIMKUS, Illinois
MICHAEL C. BURGESS, Texas
STEVE SCALISE, Louisiana
ROBERT E. LATTA, Ohio
CATHY MCMORRIS RODGERS, Washington
BRETT GUTHRIE, Kentucky
PETE OLSON, Texas
DAVID B. MCKINLEY, West Virginia
ADAM KINZINGER, Illinois
H. MORGAN GRIFFITH, Virginia
GUS M. BILIRAKIS, Florida
BILL JOHNSON, Ohio
BILLY LONG, Missouri
LARRY BUCSHON, Indiana
BILL FLORES, Texas
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
RICHARD HUDSON, North Carolina
TIM WALBERG, Michigan
EARL L. "BUDDY" CARTER, Georgia
JEFF DUNCAN, South Carolina
GREG GIANFORTE, Montana

PROFESSIONAL STAFF

JEFFREY C. CARROLL, *Staff Director*
TIFFANY GUARASCIO, *Deputy Staff Director*
MIKE BLOOMQUIST, *Minority Staff Director*

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

DIANA DEGETTE, Colorado
Chair

JAN SCHAKOWSKY, Illinois
JOSEPH P. KENNEDY III, Massachusetts, *Vice Chair*
RAUL RUIZ, California
ANN M. KUSTER, New Hampshire
KATHY CASTOR, Florida
JOHN P. SARBANES, Maryland
PAUL TONKO, New York
YVETTE D. CLARKE, New York
SCOTT H. PETERS, California
FRANK PALLONE, JR., New Jersey *(ex officio)*

BRETT GUTHRIE, Kentucky
Ranking Member
MICHAEL C. BURGESS, Texas
DAVID B. MCKINLEY, West Virginia
H. MORGAN GRIFFITH, Virginia
SUSAN W. BROOKS, Indiana
MARKWAYNE MULLIN, Oklahoma
JEFF DUNCAN, South Carolina
GREG WALDEN, Oregon *(ex officio)*

C O N T E N T S

	Page
Hon. Diana DeGette, a Representative in Congress from the State of Colorado, opening statement	2
Prepared statement	3
Hon. Brett Guthrie, a Representative in Congress from the Commonwealth of Kentucky, opening statement	4
Prepared statement	6
Hon. Greg Walden, a Representative in Congress from the State of Oregon, opening statement	7
Prepared statement	8
Hon. Frank Pallone, Jr., a Representative in Congress from the State of New Jersey, opening statement	9
Prepared statement	11

WITNESSES

Michael B. Mason, Senior Vice President, Lilly Connected Care and Insulins Global Business Unit, Eli Lilly and Company	12
Prepared statement	15
Answers to submitted questions	129
Douglas J. Langa, Executive Vice President, North America Operations, and President of Novo Nordisk Inc.	31
Prepared statement	33
Answers to submitted questions	147
Kathleen W. Tregoning, Executive Vice President for External Affairs, Sanofi	43
Prepared statement	45
Answers to submitted questions	158
Thomas M. Moriarty, Executive Vice President, Chief Policy and External Affairs Officer and General Counsel, CVS Health	58
Prepared statement	60
Answers to submitted questions	181
Amy Bicker, R.Ph., Senior Vice President, Supply Chain, Express Scripts	62
Prepared statement	64
Answers to submitted questions	191
Sumit Dutta, M.D., Senior Vice President and Chief Medical Officer, Optumrx	78
Prepared statement	80
Answers to submitted questions	202

SUBMITTED MATERIAL

Article of November 16, 2018, "Protesters at Sanofi in Cambridge decry high price of insulin," The Boston Globe, by Allison Hagan, submitted by Mr. Kennedy	126

PRICED OUT OF A LIFESAVING DRUG: GETTING ANSWERS ON THE RISING COST OF INSULIN

WEDNESDAY, APRIL 10, 2019

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS,
COMMITTEE ON ENERGY AND COMMERCE,
Washington, DC.

The subcommittee met, pursuant to call, at 11:49 a.m., in room 2322 Rayburn House Office Building, Hon. Diana DeGette (chair of the subcommittee) presiding.

Members present: Representatives DeGette, Schakowsky, Kennedy, Ruiz, Kuster, Castor, Sarbanes, Tonko, Clarke, Peters, Pallone (ex officio), Guthrie (subcommittee ranking member), Burgess, McKinley, Griffith, Brooks, Mullin, and Walden (ex officio).

Also present: Representatives Barragán, Soto, Carter, and Bucshon.

Staff present: Kevin Barstow, Chief Oversight Counsel; Jesseca Boyer, Professional Staff Member; Jeffrey C. Carroll, Staff Director; Waverly Gordon, Deputy Chief Counsel; Tiffany Guarascio, Deputy Staff Director; Judy Harvey, Counsel; Chris Knauer, Oversight Staff Director; Jourdan Lewis, Policy Analyst; Kevin McAloon, Professional Staff Member; C. J. Young, Press Secretary; Jennifer Barblan, Minority Chief Counsel, Oversight and Investigations; Mike Bloomquist, Minority Staff Director; Margaret Tucker Fogarty, Minority Staff Assistant; Theresa Gambo, Minority Human Resources/Office Administrator; Brittany Havens, Minority Professional Staff, Oversight and Investigations; Ryan Long, Minority Deputy Staff Director; and Natalie Sohn, Minority Counsel, Oversight and Investigations.

Ms. DEGETTE. The Subcommittee on Oversight and Investigations hearing will now come to order. Today, the Subcommittee on Oversight and Investigations is holding a hearing entitled, "Priced out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin." This is the second part of a hearing examining insulin affordability and ensuing financial and health challenges, and effects on patient lives. The Chair now recognizes herself for the purposes of an opening statement.

OPENING STATEMENT OF HON. DIANA DEGETTE, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF COLORADO

With seven and a half million Americans relying on insulin, this problem that we are addressing today has affected countless lives. That is why this committee is determined to find answers and to find solutions. As the committee is well aware, despite the fact that insulin has been around now for almost 100 years, it has become outrageously expensive. For instance, the price of insulin has doubled since 2012, after nearly tripling in the past 10 years.

We have all heard stories of what happens when patients can't afford their insulin. People have to forego paying their bills, or ration their doses, or skip doses altogether. I had a listening session in my district a couple of weeks ago and there was a woman who came named Sierra. Sierra has been struggling for over a year and a half to pay for her insulin. Even after rationing her insulin, she is still paying over $700 a month. It is simply unacceptable that anyone in this country cannot access the very drug that their lives depend on all because of the price of insulin has gotten out of control.

As the cochair of the Congressional Diabetes Caucus, this issue is personal with me. Along with cochair, Congressman Tom Reed, we examined these issues last year and we issued a report exposing some of the underlying problems in the insulin market. We put that report into the record at last week's hearing. What we found during our investigation was a system with perverse payment incentives and a complete lack of transparency in pricing.

Then last week as I said, the subcommittee held its first hearing on this issue in the new Congress. We heard testimony from expert witnesses and patients in the diabetes space, and their message was clear. Insulin is unequivocally a lifesaving drug, but because of a convoluted system it has become more and more expensive to the point where far too many can no longer afford it, even though their very lives depend on it.

We heard from Gail DeVore, who is a native of my hometown of Denver, Colorado, who lives with type 1 diabetes. Ms. DeVore described to the committee how the price of her insulin has shot up, and she has to ration her doses against the advice of her doctor. We also heard from Dr. Alvin Powers on behalf of the Endocrine Society who testified, "It is difficult to understand how a drug that has remained unchanged for almost two decades continues to skyrocket in price."

The subcommittee also received testimony last week from Dr. William Cefalu on behalf of the American Diabetes Association. Dr. Cefalu spoke about the national survey the ADA conducted which found that over a quarter of the people they contacted had to make changes to their purchase of insulin due to cost; and those people had higher rates of adverse health effects. The witnesses last week had many different stories about the effects of rising insulin prices, but one consistent theme that emerged was the system is convoluted, opaque, and no longer serves the patients' best interest.

The witnesses were some of the leading experts on diabetes care, and yet they couldn't point to a reasonable explanation for why these prices have gotten so high and that is what leads us here

today. We have representatives from the three drug companies that manufacture insulin, as well as three of the largest pharmacy benefit managers or PBMs. Together, these companies are the ones that produce this drug, negotiate its price, and make decisions that have consequences for the availability and affordability of insulin for millions of Americans.

I want to thank all of the representatives for coming today. I know for some of you, you had to change schedules, you had to make some adjustments and I appreciate it, because all of your companies play a large role in the supply chain of critical drugs, and all the companies have as you know received a lot of criticism.

But we are not interested in just finger pointing or passing the buck. We are interested in finding a solution to this problem, and that is why we put everybody here together on one panel so you can help us identify what the problem is and how we can fix it, and again, it is not my intention, and I think Mr. Guthrie agrees, it is not our intention to unjustly assign blame to any one player. Instead, what I think is that many entities share the blame for a system that has grown up and we need a frank discussion about what is causing the increases and what we can do to bring them under control.

As Ms. DeVore testified last week, "The relief we need is right now, not next week, not next year. We need answers today because the price of insulin has risen too far, and too many people are suffering and even risking death."

[The prepared statement of Ms. DeGette follows:]

PREPARED STATEMENT OF HON. DIANA DEGETTE

Today, the Subcommittee holds its second hearing on the rising price of insulin. With seven and a half million Americans relying on insulin, this problem has affected countless lives. That is why this Committee is determined to find answers and find solutions.

As this Committee is well aware, despite the fact that insulin has been around for decades, it recently has become outrageously expensive. For instance, the price of insulin has doubled since 2012, after nearly tripling in the previous 10 years.

We have all heard the stories of what happens when patients cannot afford their insulin. People have to forego paying their bills, or ration their doses, or skip doses altogether.

I heard from a woman in my district, Sierra, who has been struggling over the past year and a half to pay for her insulin. Even after rationing her insulin, she's still paying over $700 a month.

It is simply unacceptable that anyone in this country cannot access the drug their very lives depend on. All because the price of this drug—a drug that is nearly 100 years old—has gotten out of control.

As the Cochair of the Diabetes Caucus, this issue is personal for me. Along with my Cochair Congressman Tom Reed, we looked into these issues last year, and issued a report exposing some of the underlying problems in the insulin market. What we found was a system with perverse payment incentives, and a lack of transparency in pricing.

Then last week, the Subcommittee held its first hearing on this issue in the new Congress. We heard testimony from expert witnesses and patient advocates in the diabetes space, and their message was clear: insulin is unequivocally a lifesaving drug, but because of a convoluted system, it has become more and more expensive—to the point where far too many can no longer afford it.

We heard from Gail DeVore, a native of Denver, Colorado, who is living with diabetes. Ms. DeVore described to the Committee how the price of her insulin has shot up, and she has to ration her doses, against the advice of her doctor.

We also heard from Dr. Alvin Powers, on behalf of the Endocrine Society, who testified quote, "It is difficult to understand how a drug that has remained unchanged for almost two decades continues to skyrocket in price."

The Subcommittee also received testimony last week from Dr. William Cefalu on behalf of the American Diabetes Association. Dr. Cefalu spoke about the national survey the ADA conducted, which found that over a quarter of those who responded had to make changes to their purchase of insulin due to cost—and those people had higher rates of adverse health effects.

The witnesses last week had many different stories about the effects of rising insulin prices. But one consistent theme that emerged from them was that the system is convoluted, opaque, and no longer serves the patient's best interests. These witnesses were some of the nation's leading experts on diabetes care, and yet they could not point to a reasonable explanation for why these prices have gotten so high.

And that is what leads us here today. We have representatives from the three drug companies that manufacture insulin, as well as three of the largest Pharmacy Benefit Managers ("PBMs"). Together, these companies are the ones that produce this drug, negotiate its price, and make decisions that have consequences for the availability and affordability of insulin for millions of Americans.

These companies play a large role in the supply chain of these critical drugs, and as such, they have received a lot of criticism in recent years for these price hikes. We will have questions for the witnesses today about these increases, and what could possibly justify such dramatic spikes. Today is an opportunity for them to shed light on the true causes of these price increases.

Now, this Committee is not interested in mere finger-pointing and passing the buck. Each of these companies before us today has a role in this problem, and that means they must also have a role in identifying solutions.

Likewise, our intention here today is not to unjustly assign blame to any one player—because it is clear that many entities share in the responsibility.

We need a frank discussion today about what is causing these increases, and what these companies can do to bring them under control. As Ms. DeVore testified last week, quote, "The relief we need is right now. Not next week. Or next year." We need answers today—because the price of insulin has risen far enough, and too many people are suffering.

I thank the witnesses for appearing before us today, and I urge them all to be candid and forthcoming in their discussion of this very important topic.

MS. DEGETTE. Thank you all again for being here today. I urge you to be candid and forthcoming, and I am now very pleased to recognize the Ranking Member Mr. Guthrie, for 5 minutes for purposes of an opening statement.

OPENING STATEMENT OF HON. BRETT GUTHRIE, A REPRESENTATIVE IN CONGRESS FROM THE COMMONWEATH OF KENTUCKY

Mr. GUTHRIE. Thank you, Chair DeGette, for bringing this hearing together, and thank you all for being here. I do echo the remarks that you just made.

Last week, we held a hearing on the rising cost of insulin and heard from patients, doctors, and patient groups of how the rising cost of insulin has affected Americans with diabetes. More than 30 million individuals—and I have two nieces—9.4 percent of the population in the United States have diabetes. In 2016, about 6.7 million Americans age 18 and older used insulin.

The insulin prescribed today is different than the insulin discovered over 100 years ago and the life expectancy of diabetics has improved dramatically. These innovations should not be underestimated and a lot of exciting research is on the horizon. Someday soon, I hope we will have a cure for diabetes. As we discussed last week, however, the average list price of insulin nearly tripled between 2002 and 2013, making this vital drug unaffordable for too many Americans.

Many argue that while list prices have been increasing, net prices have stayed relatively the same or have even gone down. This sounds great, because in theory no one is supposed to pay the

list price for insulin. However, if a patient is uninsured or underinsured, they may end up paying the list price or close to it. We have also heard that more Americans are paying the list price at the pharmacy counter for part of the year because the enrollment in high-deductible health plans has increased. We have struggled to fully understand—and I will emphasize this—fully understand while list prices for medicine such as insulin have continued to rise, the prescription drug supply chain is complex and lacks transparency.

We have had a lot of conversations with participants in the drug supply chain over the last two years to better understand how the pricing and rebating system works. We have been told that manufacturers set the list price and therefore lowering the cost of prescription drugs is as simple as manufacturers lowering their list prices. On the other hand, we have heard that manufacturers can't simply lower their list price because the pharmacy benefit managers or PBMs demand larger rebates, and if the manufacturers do not provide them with these rebates the PBMs won't put their drugs on their formularies for health insurance plans.

Although they are not on the panel today, we have also heard concerns about other entities in supply chains such as health insurance companies. As Chair DeGette said and I will emphasize, we are not here to point fingers at that, that is what we have heard. We want to try to get to a solution. While some may think that one party in the supply chain is solely responsible for the rising price of drugs, there are incentives to increase list prices throughout the drug supply chain. Beyond the potential for manufacturers to make more money by raising prices, a higher list price allows manufacturers to provide larger rebates to PBMs, most of whom have contracts that allow them to keep a percentage of the list price, or receive fees based on the list price. Additionally, the health insurance companies decide whether to pass the rebate along to the patient at the point of sale or keep the rebate to lower premiums across the board for all beneficiaries.

The current system contains many incentives for list prices to increase rather than decrease. Unfortunately, while we keep hearing assurances that net prices are staying flat or decreasing and that almost all rebates are passed on to the health plans; we know that many patients are being disadvantaged by this system and are paying more for their insulin at the pharmacy counter. Your companies have taken steps to try to reduce out-of-pocket expenses for insulin to the patients who need them and that is a good thing. I worry, however, that these are only short-term solutions. It is important that we collectively find a permanent solution that improves access to and affordability of medicine such as insulin.

I thank our witnesses for being here today and I will yield the remainder of my time to my friend from Indiana, Mrs. Brooks.

Mrs. BROOKS. Thank you, Ranking Member Guthrie and thank you to the subcommittee chairwoman for hosting this hearing, for holding this hearing. It is continuing the important work that was started last Congress in examining the impact that rising costs of insulin has on patients struggling to afford this lifesaving drug. Nearly 700,000 Hoosiers have diabetes or pre-diabetes, which is why I serve as the vice chair of the Congressional Diabetes Caucus

founded by Diana DeGette and Tom Reed. We have always worked in a bipartisan manner in that caucus and I hope that we continue in that same spirit today to find solutions.

One of the companies here today, Eli Lilly, has been headquartered in Indianapolis for more than 100 years. They employ thousands of hardworking Hoosiers, many of whom are my constituents. While I know that Lilly has put in place programs to subsidize the cost of insulin for some—and I have read all of your written testimony and everyone has ideas, and everyone has recommendations and that is what we need to get to today.

I look forward to hearing from our witnesses on their recommendations for change, so that no American has to do without insulin or take less insulin than what they must have to stay alive and remain healthy. I thank you all for being here and I yield back.

Mr. GUTHRIE. I yield back.

[The prepared statement of Mr. Guthrie follows:]

PREPARED STATEMENT OF HON. BRETT GUTHRIE

Thank you, Chair DeGette, for holding this important hearing.

Last week we held a hearing on the rising cost of insulin and heard from patients, doctors, and patient groups about how the rising cost of insulin has affected Americans with diabetes. More than 30 million individuals—or 9.4 percent of the population—in the United States have diabetes and, in 2016, about 6.7 million Americans aged 18 and older used insulin.

The insulin prescribed today is different than the insulin discovered over 100 years ago and the life expectancy of diabetics has improved dramatically. These innovations should not be underestimated, and a lot of exciting research is on the horizon. Someday soon, I hope we have a cure for diabetes.

As we discussed last week, however, the average list price of insulin nearly tripled between 2002 and 2013, making this vital drug unaffordable for too many Americans. Many argue that while list prices have been increasing, net prices have stayed relatively the same or have even gone down. This sounds great because in theory no one is supposed to pay the list price for insulin. However, if a patient is uninsured or underinsured they may end up paying the list price, or close to it. We've also heard that more Americans are paying the list price at the pharmacy counter for part of the year because enrollment in high deductible health plans has increased.

We have struggled to fully understand why list prices for medicines such as insulin have continued to rise. The prescription drug supply chain is complex and lacks transparency. We have had a lot of conversations with participants in the drug supply chain over the last two years to better understand how the pricing and rebating system works. We've been told that manufacturers set the list price and therefore lowering the cost of prescription drugs is as simple as the manufacturers lowering their list prices. On the other hand, we've heard that manufacturers can't simply lower their list price because the pharmacy benefit managers or PBMs demand large rebates and if the manufacturers do not provide them with these rebates, the PBMs won't put their drugs on formularies for health insurance plans. Although they're not on the panel today, we've also heard concerns about other entities in the supply chain such as health insurance companies.

While some may think that one party in the supply chain is solely responsible for the rising price of drugs, there are incentives to increase list prices throughout the drug supply chain beyond the potential for manufacturers to make more money by raising prices. A higher list price allows manufacturers to provide a larger rebate to PBMs, most of whom have contracts that allow them to keep a percentage of the list price or receive fees based on the list price. Additionally, the health insurance companies decide whether to pass the rebate along to the patient at the point-of-sale or keep the rebate to help lower premiums across the board for all beneficiaries. The current system contains many incentives for list prices to increase, rather than decrease.

Unfortunately, while we keep hearing assurances that net prices are staying flat or decreasing and that almost all rebates are passed on to the health plans, we

know that many patients are being disadvantaged by this system and are paying more for their insulin at the pharmacy counter.

Your companies have each taken steps to try to reduce out-of-pocket expenses for insulin to the patients who need them, and that is a good thing. I worry, however, that these are only short-term solutions. It is important that we collectively find a permanent solution that improves access to and affordability of medicines, such as insulin.

I thank our witnesses for being here today. I yield back.

Ms. DEGETTE. We are just waiting for the Chair of the full committee and the ranking member for their opening statements. We will just wait one moment.

As soon as he is ready, the Chair will recognize the ranking member of the full committee for purposes of an opening statement, 5 minutes.

OPENING STATEMENT OF HON. GREG WALDEN, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF OREGON

Mr. WALDEN. Thank you, Madam Chair. I appreciate your indulgence. I know we are all coming back from votes and a few things, so I am glad you are having this important hearing today. It is really important.

Last week, we heard a lot of different opinions on why the list price of insulin has increased significantly over the last decade. One of the doctors on that panel commented she believed that high list prices primarily benefit pharmaceutical companies. Now another doctor argued the current rebating system encourages high list prices, and as the list prices increase intermediaries in the supply chain benefit. He argued the solution is not as easy as manufacturers simply lowering their list price, it requires a broader reform across the entire supply chain.

Now all of the witnesses last week agreed that the current pricing system for insulin is actually harming many patients as they make healthcare decisions. We heard stories of individuals rationing their insulin and foregoing other necessities to make ends meet and how this can lead to serious short- and long-term health problems and hospitalization, which I am sure you all understand. It is critical we work toward ensuring that all diabetics have access to insulin. To do so, we need to identify and break through barriers that make it challenging to bringing down the cost of insulin for patients.

For more than two years, we have been examining the various drivers of increased healthcare costs, so I am glad that effort is continuing today. Earlier this year, as part of this work, myself, and Republican leaders Guthrie and Burgess, sent a letter to each of you that asked specific questions about the cost of insulin and the barriers to competition in the insulin market. We wanted to learn more about what is really going on, so I want to thank each of you for your thorough responses to our questions. They are most helpful as we work on this issue.

While the discussion today is centered around the cost and the barriers that exist to reducing costs, it is important we do not forget the critical role that both of you, the drug manufacturers and the pharmacy benefit managers, PBMs, have in making sure patients have access to lifesaving medicines such as insulin. Now the insulin that is available today for diabetics would not exist without significant investments that Eli Lilly, Novo Nordisk, and Sanofi

have made to develop and improve these medicines. These investments have saved the lives of many diabetics. Insulin manufacturers have also created Patient Assistance Programs to help patients get access to affordable insulin.

While there will be questions today about whether the changes in insulin over the past few decades justify how much the list price for insulin has increased over the same period, we know that manufacturers rarely receive the list price for their medicine. Likewise, PBMs provide many important services to patients and use different tools to help control costs while promotinghealthcare. For example, in addition to numerous other programs, CVS Health created a Transform Diabetes Care Program that uses several cost containment and clinical strategies to help produce savings. OptumRx created a tool to improve provider visibility to lower costs, clinically equivalent alternative medicines at the point of prescribing. Just last week, Express Scripts announced a new patient assurance program that will ensure eligible people with diabetes participating in Express Scripts plans pay no more than $25 for a 30-day supply of insulin.

Now while these programs for manufacturers and PBMs are important and useful in the short-term, they are only a band-aid, so we have to work on the long-term and comprehensive solutions. Many of the concerns we heard at last week's hearing on insulin are very similar to the issues that were discussed at our hearing examining the prescription drug supply chain over a year ago, so I appreciate hearing directly from the manufacturers and the PBMs today about your perspectives on why insulin costs are rising.

But just like we heard at the hearing on drug pricing in 2017, to fully understand why the cost of insulin is increasing for many patients, we will need to hear from the other participants in the supply chain including: the distributors, health insurance plans, and pharmacists. But at the end of the day, we have to put the patient, the consumer, first in everything that we do.

I want to thank our witnesses for responding to our questions and I want to thank you for being here today. You will contribute to our work and that is most valuable, and unless somebody else wants the remainder of my time, Madam Chair, I would yield back.

[The prepared statement of Mr. Walden follows:]

PREPARED STATEMENT OF HON. GREG WALDEN

I am glad we are having this important hearing today. Thank you, Chair DeGette, for holding it.

Last week, we heard a lot of different opinions on why the list price of insulin has increased significantly over the past decade. One of the doctors on the panel commented that she believed that high list prices primarily benefit the pharmaceutical companies. Another doctor argued that the current rebating system encourages high list prices and, as the list prices increase, intermediaries in the supply chain benefit. He argued that the solution is not as easy as manufacturers simply lowering their list price and requires a broader reform across the entire supply chain.

All of the witnesses last week agreed that the current pricing system for insulin is harming many patients as they makehealthcare decisions. We heard stories of individuals rationing their insulin and forgoing other necessities to make ends meet—and how this can lead to serious short- and long-term health problems and hospitalizations.

It is critical that we work towards ensuring all diabetics have access to insulin. To do so, we need to identify and break through barriers that make it challenging to bring down the cost of insulin for patients.

For more than two years, we have been examining the various drivers of increasing healthcare costs. Earlier this year, as part of this work, myself and Republican Leaders Guthrie and Burgess sent a letter to each of you asking specific questions about the cost of insulin and the barriers to competition in the insulin market. I want to thank each of you for your thorough responses to our questions.

While the discussion today is centered around cost and the barriers that exist to reducing cost, it is important we don't forget the critical role that both of you—the drug manufacturers and pharmacy benefit managers (PBMs)—have in making sure patients have access to life-saving medicines such as insulin.

The insulin available today for diabetics would not exist without the significant investments that Eli Lilly, Novo Nordisk, and Sanofi have made to develop and improve the medicine. These investments have saved the lives of many diabetics. Insulin manufacturers have also have created patient assistance programs to help patients get access to affordable insulin. While there will be questions today about whether the changes in insulin over the past few decades justify how much the list price for insulin has increased over the same period, we know that manufacturers rarely receive the list price of their medicine.

Likewise, PBMs provide many important services to patients and use different tools to help control costs while promoting better health. For example, in addition to numerous other programs, CVS Health created a Transform Diabetes Care Program that uses several cost containment and clinical strategies to help produce savings. OptumRx created a tool to improve provider visibility to lower-cost, clinically-equivalent alternative medicines at the point of prescribing. Just last week, Express Scripts announced a new patient assurance program that will ensure eligible people with diabetes participating in Express Scripts plans pay no more than $25 for a 30-day supply of insulin.

While these programs from manufacturers and PBMs are important and useful in the short-term, they are only a band-aid. We must work on a long-term, comprehensive solution.

Many of the concerns we heard at last week's hearing on insulin are very similar to the issues that were discussed at our hearing examining the prescription drug supply chain over a year ago. I appreciate hearing directly from the manufacturers and PBMs today about their perspectives on rising insulin costs. But just like we heard at the hearing on drug pricing in 2017, to fully understand why the cost of insulin is increasing for many patients, we will need to hear from the other participants in the supply chain, including the distributors, health insurance plans, and pharmacists. But at the end of the day, we must put the patient first.

I thank the witnesses for being here and I look forward to today's important discussion.

Ms. DEGETTE. I thank the gentleman. The Chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes for purposes of an opening statement.

OPENING STATEMENT OF HON. FRANK PALLONE, JR., A REPRESENTATIVE IN CONGRESS FROM THE STATE OF NEW JERSEY

Mr. PALLONE. Thank you, Madam Chair.

Today, the committee is holding the second of a two-part hearing on the increasing price for insulin. Millions of Americans rely on this lifesaving drug and they are directly affected by the ever-increasing prices. People are having to make sacrifices to be able to pay for their insulin and some are even forced to go without it, sometimes with tragic consequences.

Last week, the subcommittee heard from expert witnesses in diabetes care. They provided testimony about the rising price of various insulin medications and the effects it is having on patients living with diabetes. We heard from an endocrinologist who described a complicated system that makes it difficult if not impossible for him to determine how much his patients will have to pay for their

insulin. We heard from patient advocates who described the hardship patients endure when they can no longer afford their medication or are forced to switch.

These witnesses described a broken system where there is not enough transparency surrounding prices and not enough incentives to keep prices down. Today we have before us the companies that make these drugs, negotiate their prices, and make them available through health plans. Their actions and decisions have a profound impact on the lives of everyday Americans, and we need to hear these companies' response to the criticism we heard last week, and their actions, and what their actions are doing to contribute to rising prices or hopefully reduced prices.

We know that companies need to make money in order to succeed and in a normal market price would reflect what the market can bear. The problem is, the market for insulin is made up of people who can't survive without the product. I am concerned that the market is simply broken down, as I said. It appears there is a limited competition and little incentive to keep prices at a level the patients can afford and perhaps there are incentives in place to keep raising prices.

As a result, we are left with a drug that has been available for nearly 100 years and yet the price tripled and then doubled in just the last couple decades. Clearly, something is not right here. Three companies currently manufacture insulin and they are all represented at the hearing today. They not only make the drug, but they also set the list price. While most people do not end up paying this list price, uninsured patients often do, and even insured patients can be affected when the list price rises, and that is exactly what has been happening as the list price has skyrocketed in recent years and it ripples through the entire system.

We also have the pharmacy benefit managers or PBMs here whose role it is to negotiate lower drug prices on behalf of the insurance plans. But there is not much transparency in these negotiations and there are questions as to whether discounts are being passed down to the patient. When the manufacturers have been criticized for raising their prices, they have often pointed their finger at the PBMs. When the PBMs have been questioned about their practices, they often point their finger back at the manufacturer and so we are left with no accountability.

For the millions of people who are suffering in the system, these back-and-forth arguments are frustrating and frankly unacceptable. Everyone seems to be coming out ahead here except the patient, and no one really should suffer because the high price of insulin puts it out of reach. I hope that we can all learn today about why the costs of insulin are skyrocketing, and the role of manufacturers, and PBMs have played, and then figure out how to deal with it so we can make insulin more affordable.

So unless somebody else wants my time, Madam Chair, I will yield back.

[The prepared statement of Mr. Pallone follows:]

PREPARED STATEMENT OF HON. FRANK PALLONE, JR.

Today the Committee is holding the second of a two-part hearing on the increasing price for insulin. Millions of Americans rely on this lifesaving drug, and they are directly affected by the ever-increasing prices.

People are having to make sacrifices to be able to pay for their insulin, and some are even forced to go without it—sometimes with tragic consequences.

Last week, this Subcommittee heard from expert witnesses in diabetes care. They provided testimony about the rising price of various insulin medications, and the effects it is having on patients living with diabetes.

We heard from an endocrinologist who described a complicated system that makes it difficult—if not impossible—for him to determine how much his patients will have to pay for their insulin.

We heard from patient advocates who described the hardship patients endure when they can no longer afford their medication or are forced to switch.

These witnesses described a broken system, where there is not enough transparency surrounding prices, and not enough incentives to keep prices down.

Today, we have before us the companies that make these drugs, negotiate their prices, and make them available through health plans. Their actions and decisions have a profound impact on the lives of everyday Americans, and we need to hear these companies' response to the criticism we heard last week, that their actions are contributing to these rising prices.

We know that companies need to make money in order to succeed, and in a normal market, prices would reflect what the market can bear. The problem is, the market for insulin is made up of people who cannot survive without this product.

I'm concerned that the market has simply broken down. It appears that there is limited competition and little incentive to keep prices at a level that patients can afford, and perhaps there are incentives in place to keep raising prices.

As a result, we are left with a drug that has been available for nearly 100 years, and yet the price tripled and then doubled in just the last couple decades. Clearly, something is not right here.

Three companies currently manufacture insulin, and they are all represented at this hearing today.They not only make the drug, but they also set the "list price." While most people do not end up paying this list price, uninsured patients often do—and even insured patients can be affected when the list price rises.

That is exactly what has been happening, as the list price for insulin has skyrocketed in recent years it ripples through the entire system.

We also have the Pharmacy Benefit Managers or "PBMs," here, whose role it is to negotiate lower drug prices on behalf of the insurance plans. But there is not much transparency in these negotiations, and there are questions as to whether discounts are being passed down to the patient.

When the manufacturers have been criticized for raising their prices, they have often pointed their finger at the PBMs, and when the PBMs have been questioned about their practices, they often point their finger back at the manufacturer.

And so, we are left with no accountability. For the millions of people who are suffering in the system, these back-and-forth arguments are frustrating and unacceptable. Everyone seems to be coming out ahead here—except the patient.

No one should suffer because the high price of insulin puts it out of reach.

I hope that we will learn today about why the costs of insulin are skyrocketing, and the role manufacturers and PBMs have played.

Thank you, I yield back.

Ms. DEGETTE. I thank the gentleman.The Chair asks unanimous consent that the Members' written opening statements be made part of the record. Without objection, so ordered.

I would now like to introduce our first panel of witnesses for today's hearing. Mr. Mike Mason, who is the Senior Vice President, Lilly Connected Care and Insulins Global Business Unit, welcome; Mr. Doug Langa, Executive Vice President, North America Operations, and President of Novo Nordisk, Inc., welcome; Ms. Kathleen Tregoning, who is Executive Vice President for External Affairs, Sanofi; Mr. Thomas Moriarty, Executive Vice President, Chief Policy and External Affairs Officer and General Counsel, CVS Health; Ms. Amy Bricker, Senior Vice President, Supply Chain of Express

Scripts; and Dr. Sumit Dutta, Senior Vice President and Chief Medical Officer, OptumRx. Welcome to all of you.

I know you are all aware that the subcommittee is holding an investigative hearing and when doing so has the practice of taking testimony under oath. Do any of you have objections to testifying under oath today?

Let the record reflect that the witnesses have responded no.

The Chair then advises you that under the rules of the House and the rules of the committee, you are entitled to be accompanied by counsel. Do any of you desire to be accompanied by counsel during your testimony today?

Let the record reflect that the witnesses have responded no.

If you would, please rise and raise your right hand so you may be sworn in.

[Witnesses sworn.]

Ms. DEGETTE. You may be seated. Let the record reflect that the witnesses have responded affirmatively. You are now under oath and subject to the penalties set forth in Title 18 Section 1001 of the United States Code.

And now the Chair will recognize our witnesses for a 5-minute summary of their written statements. In front of each of you is a microphone and a series of lights. The light will turn yellow when you have a minute left, and red to indicate your time has come to an end. I would appreciate it if you would try to keep your opening statements within the time frame because we want to make sure that all of the members have the opportunity to ask their questions today.

We will start with you, Mr. Mason. You are recognized for 5 minutes for purposes of an opening statement. Thank you.

STATEMENTS OF MICHAEL B. MASON, SENIOR VICE PRESIDENT, LILLY CONNECTED CARE AND INSULINS GLOBAL BUSINESS UNIT, ELI LILLY AND COMPANY; DOUGLAS J. LANGA, EXECUTIVE VICE PRESIDENT, NORTH AMERICA OPERATIONS, AND PRESIDENT OF NOVO NORDISK INC., NOVO NORDISK; KATHLEEN W. TREGONING, EXECUTIVE VICE PRESIDENT FOR EXTERNAL AFFAIRS, SANOFI; THOMAS M. MORIARTY, EXECUTIVE VICE PRESIDENT, CHIEF POLICY AND EXTERNAL AFFAIRS OFFICER AND GENERAL COUNSEL, CVS HEALTH; AMY BRICKER, SENIOR VICE PRESIDENT, SUPPLY CHAIN, EXPRESS SCRIPTS; AND, SUMIT DUTTA, M.D., SENIOR VICE PRESIDENT AND CHIEF MEDICAL OFFICER, OPTUMRx

STATEMENT OF MICHAEL B. MASON

Mr. MASON. Thank you. Chairwoman DeGette, Ranking Member Guthrie, Chairman Pallone, Ranking Member Walden, and other distinguished members, my name is Mike Mason. I am the Senior Vice President for Connected Care and Insulins at Eli Lilly and Company. Thank you for the opportunity to participate in today's hearing. Thanks as well to your staff who met with us. I'm pleased to be here today to continue that conversation.

Eli Lilly was founded in 1876, and today employs over 16,000 people in the United States. We are headquartered in Indianapolis.

Lilly is proud to have introduced the first commercially available insulin product in 1923. For nearly a century, we have committed to helping people with diabetes live better and longer lives. We've invested billions in the discovery of new treatments including biotech insulins Humulin, Humalog, and Basaglar. In 2018, we announced our commitment to a research and development partnership that could eliminate the need for insulin. Lilly is also actively developing connected insulin devices that we hope will help people improve outcomes and adherence.

Now, like many people who work at Lilly, I have a personal connection to the issues we discuss today. Four of my immediate family members live with diabetes. I've seen them cope with the daily burdens of the disease including injections before each meal. I've seen the devastating complications of diabetes in their lives and I know firsthand that they benefit from new, innovative treatments.

Often our phone calls and visits turn to their diabetes. Over the years, we focused on these conversations on how they were managing their diabetes, but within the last two or three years, the conversations have changed. We now spend more and more time talking about how much they pay out-of-pocket for insulin. As a leader at Lilly, it's difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don't have affordable access to chronic medications.

My colleagues and I have reflected on how we got here and what we can do to solve this problem in the short-term and long-term. For starters, we have not increased the list price for insulin since 2017, but we recognize that the issue is more complex than list price and it's important to focus on what people actually pay out-of-pocket for insulin. Most people who need insulins have either private or government insurance that requires them to pay a low, affordable copay. But some people don't benefit from these low copays because their out-of-pocket costs are based on so-called retail or list prices, not negotiated prices or fixed copays.

The people most exposed in our current system are those in the deductible phase of high-deductible health plans, those in the Medicare Part D coverage gap phase, and individuals without insurance. We know long-term solutions are necessary, but we are not waiting to address the gaps in the short-term. The Lilly Diabetes Solution Center connects individuals to a suite of affordability solutions including immediate access to savings offers for the uninsured and privately insured, with no paperwork or applications.

We provide automatic discounts at the pharmacy counter that cap the cost of prescription for Lilly insulin at $95 for those in the deductible phase of high-deductible plans. We recently announced the upcoming launch of a half-price version of Humalog called insulin lispro. With these and other meaningful solutions, we've tried to build a safety net preventing anyone from having to pay retail price for Lilly insulins.

Our solutions are working to reduce out-of-pocket costs. Today, 95 percent of monthly Humalog prescriptions are less than $95 at the pharmacy, 90 percent are less than $50 a month, and 43 percent are zero. As insulin lispro launches and is added to formularies, even more people will pay less. Now while these actions ease the burdens for most people in these coverage gap areas,

they are still stop-gap measures. Long-term, systematic solutions are still needed.

A good place to start is to consider the policy ideas suggested by CVS in their written testimony to foster the widespread adoption of zero-dollar copays on preventive medications like insulin. We agree that this solution would save lives and money while cutting straight to the heart of the affordability issue. Also, we thank this committee for its bipartisan action last week on legislation including the CREATES Act and a bill eliminating pay-for-delay tactics. Systematic change in our healthcare system will require action by all relevant stakeholders. We are ready to play our role and we are confident that a solution is possible.

[The prepared statement of Mr. Mason follows:]

Testimony of Michael B. Mason
Senior Vice President, Connected Care and Insulins at Eli Lilly and Company

Before the

United States House of Representatives
Committee on Energy and Commerce
Subcommittee on Oversight & Investigations

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee; Chairman Pallone, Ranking Member Walden, and other Distinguished Members: My name is Mike Mason, and I am the Senior Vice President for Connected Care and Insulins at Eli Lilly and Company ("Lilly"). Thank you for the opportunity to participate in today's hearing. I would also like to thank the members of your staff who took the time to meet with us to discuss the important issue of affordable access to diabetes medications. I am pleased to be here today to continue our conversation.

Like many people who work at Lilly, I have a personal connection to the issues we will discuss today. Four of my immediate family members live with diabetes. I have seen them cope with the daily burdens of the disease, including finger pricks and insulin injections before each meal. I have seen the devastating complications of diabetes in their lives, and I know first-hand how they benefit from new, innovative treatments. Often our phone calls and visits turn to their diabetes. Over the years, these conversations centered on how they were managing their diabetes. But within the last 2-3 years, these conversations have changed. We now spend more time talking about how much they pay for insulin.

As a leader at Lilly, it's difficult for me to hear anyone in the diabetes community worry about the cost of insulin. Too many people today don't have affordable access for chronic medications.

Achieving affordable access to medications for everyone will require multiple groups to work together, including manufacturers, pharmacy benefit managers, health insurers, distributors, pharmacies, employers, and policymakers. But while long-term solutions are being discussed, Lilly knew we had to act to provide solutions today. Lilly has long provided support for individuals having trouble affording their insulin, including through savings cards and our support of the Lilly Cares Foundation. Over the past several years, however, we have recognized that there is an increased need to address affordability challenges and have been implementing a wide range of initiatives to make our insulins as affordable as possible for as many people as possible.

In 2017, Lilly began participating in savings programs that provide a 40% discount to those with private insurance. We also began the process of commercializing a lower-priced version of our most commonly prescribed insulin, Humalog U100, that will have a wholesale acquisition cost (WAC) or "list price" that is 50% lower than branded Humalog. Our goal is to make a lower-priced insulin alternative available within the limits of the current health care system. Earlier this year we received a response from federal regulators that allowed us to move forward, and we are now bringing this product, called Insulin Lispro, to the market.

We have also implemented other solutions. For example, we provide automatic discounts at the pharmacy counter that cap the cost of a prescription for Lilly insulins at $95 for those in the deductible phase of high-deductible plans. This is a significant benefit for those in the deductible phase of high-deductible plans, who might otherwise be paying thousands of dollars for their insulin before their deductible is met. In addition to these automatic discounts at the pharmacy, we launched the Lilly Diabetes Solution Center, which connects individuals to a suite of affordability solutions. With these programs and others, we've built a safety net to try to

prevent anyone from falling through the cracks and having to pay retail price for their Lilly insulins.

Our solutions are working to reduce out-of-pocket costs. Today 95% of prescriptions for Humalog in the U.S. cost consumers less than $95 at the pharmacy, 90% cost less than $50, and 43% cost $0.[1] As Insulin Lispro launches and is added to formularies and we continue to educate the diabetes and medical community about our Lilly Diabetes Solution Center, even more people will pay less for Humalog.

Although Lilly has taken steps to make insulin more affordable, we recognize that broader systemic change in our current healthcare system is needed. This will require action by all relevant stakeholders, but we are ready to play our role and we are confident that a solution is possible. We look forward to continuing our dialogue with the Subcommittee and other stakeholders about these important issues.

I. Lilly's Investments in Treatments for People Living with Diabetes

Eli Lilly was founded in Indiana in 1876 and remains a U.S. company. We employ over 16,000 people in the U.S. Our headquarters are in Indianapolis—as they have been for over a hundred years—and we also have a significant manufacturing and research and development presence in New Jersey, California, New York, and Massachusetts.

Lilly has been committed to helping people with diabetes for nearly a century. In 1923, Lilly introduced the world's first commercially-available insulin product, at a time when a diagnosis of diabetes was virtually a death sentence. While this was an incredible breakthrough that saved lives, the insulin was sourced from animals using what would by today's standards

[1] Based on IQVIA data, FIA data (August 2018 – December 2018).

seem a crude process and one that raised supply and quality concerns. Over many years, advances were made to enhance the purity, concentration, and dosing regimen of that first insulin. As technology continued to evolve, in 1982, Lilly introduced human insulin, the world's first human health care product created using recombinant DNA technology.[2]

Since then, Lilly has spent billions of dollars in research and development to improve the lives of people with diabetes. In 1996, Lilly launched a new biotech insulin, Humalog, which mimics the body's own rapid insulin response. Humalog has made it easier for people with diabetes to manage their blood glucose and facilitated advancements in modern insulin pumps. In 2015, Lilly obtained approval for the first follow-on insulin biologic, Basaglar, which introduced significant competition in the long-acting insulin market as the lowest-priced basal analog available. This product currently has a list price that is 23% lower than the list price of the most commonly prescribed basal insulin, Lantus®. In 2018, Lilly announced its investment in a drug discovery partnership that we hope could move people with diabetes away from insulin altogether by developing cell therapies that would allow insulin-producing pancreatic beta cells to be delivered through implanted devices.[3] Lilly is also active in the space of digital health solutions and is developing a connected diabetes system consisting of devices that we hope will improve adherence, outcomes, and convenience. Before the discovery of insulin, a child diagnosed with Type 1 diabetes at age 10 typically died within 2.3 years of diagnosis. Insulin was literally life-saving: It expanded the life expectancy of the average person with Type 1

---

[2] https://www.lilly.com/milestones-of-lilly-caring-and-discovery.

[3] *Lilly and Sigilon Therapeutics Announce Strategic Collaboration to Develop Encapsulated Cell Therapies for the Treatment of Type 1 Diabetes* (Apr. 4, 2018), https://www.prnewswire.com/news-releases/lilly-and-sigilon-therapeutics-announce-strategic-collaboration-to-develop-encapsulated-cell-therapies-for-the-treatment-of-type-1-diabetes-300624199.html; Alex Keown, *Eli Lilly Plunks Down $63M Upfront in Deal With Startup Sigilon* (Apr. 4, 2018), https://www.biospace.com/article/eli-lilly-plunks-down-63m-upfront-in-deal-with-startup-sigilon/.

diabetes into the early 40s, and eventually to where it is today in the late 60s. But our work is not done. Our hope is that one day the life expectancy for a person diagnosed with diabetes will be no different than any other American.

Lilly is proud of our history of innovation in the treatment of diabetes, but improved medications and technologies will result in better outcomes only if people with diabetes have affordable access to them. Affordability is of critical importance to Lilly, and it's an area where we have invested time and resources to develop solutions.

II. The Current U.S. Healthcare System: Prices, Rebates, and Insurance Design

The recognition that people increasingly face high out-of-pocket costs for their insulin caused all of us at Lilly to reflect on how we got here and what actions we could take to try to solve this problem in the short-term and in the long-term. The U.S. healthcare system has evolved over the last six to seven years. Historically, people with diabetes paid only a flat co-pay at the pharmacy, and insurance plans covered most medications. More recently, however, the market began moving to restrictive formularies,[4] which limit the number of medications covered on someone's health plan. In some classes like meal-time insulin, insurers started covering only a *single* brand of medication. To ensure that people's insurance plans would continue to cover their treatments, pharmaceutical companies, including Lilly, have had to pay larger discounts in the form of rebates. At the same time, mandatory discounts for federal programs were also increasing. With the cost to secure access increasing, pharmaceutical companies raised list prices[5] to remain viable, maintain access for patients using their

[4] Drug formularies are ranked lists of drugs that insurers and PBMs use to determine whether certain medicines will be covered by insurance.

[5] Any discussion of drug pricing within the current system requires a clarification of terms because the "price" or "cost" of a medication may represent different concepts to different participants in the healthcare system. Manufacturers like Lilly typically set a medication's "list price," which is the amount that the manufacturer charges

medications, and ensure that they are able to continue to fund lifesaving research and development.

Because of the increasing rebates and fees that Lilly provides to purchasers and insurers (or their PBMs), and other fees and costs Lilly incurs, increases in list prices for Lilly insulins have not necessarily resulted in net price increases. For example, between 2014 and 2018, for our most broadly used Lilly insulin product, Humalog U100, the list price increased by 51.9%.[6] During that same time period, the amount of rebates Lilly paid increased at a greater rate, causing the average net amount that Lilly received—often referred to as the "net price"—to decline by 8.1%.[7] That translates into insurance plans on balance paying a lower net effective price for Humalog.

The chart below shows the average list price and net price for Humalog U100 from 2014 through 2018.[8]

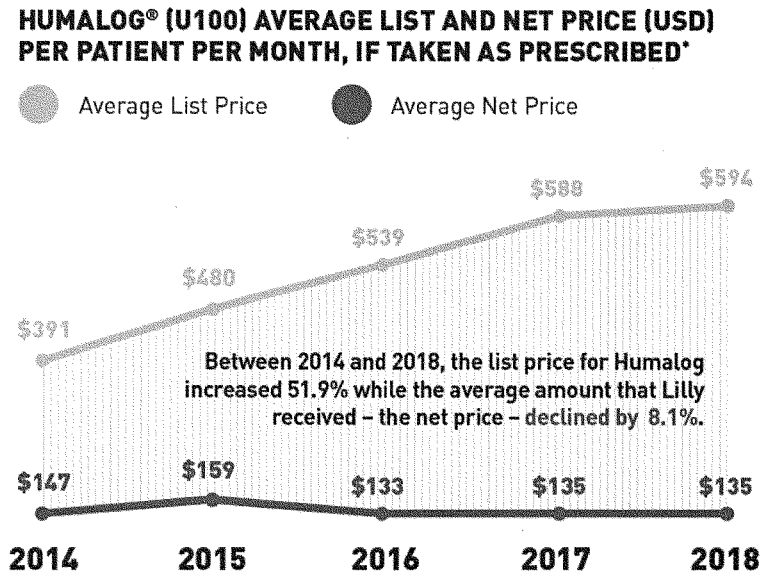
---

to its wholesale distributor customers. The wholesalers then re-sell the medication to pharmacies at a price that those parties separately negotiate. The pharmacies, in turn, dispense the medication to patients and in most cases are paid a price that is individually negotiated by the patient's insurer or by a PBM retained by the insurer. Importantly, manufacturers typically provide rebates and/or fees to insurers or their PBMs, and to federal and state health programs, that reduce the cost of the medication to those entities. Manufacturers also pay other discounts and fees and incur costs related to co-pay assistance to patients and affordability programs. All of these payments reduce the amount that is ultimately realized by the manufacturer (which is sometimes referred to as a "net price").

[6] Eli Lilly and Company 2018 Integrated Summary Report at 16, https://investor.lilly.com/static-files/ae580ba4-5d84-4862-a5d2-99a1d784d7a8. Humalog U100 is the most broadly used Lilly insulin product. The last list price increase for Humalog U100 was May 2017. The net price in the chart represents the average revenue Lilly realized per patient per month for Humalog U100 if taken as prescribed. Because of rebates and fees Lilly provides insurers and/or PBMs, increases in list prices do not always reflect increases in net prices.

[7] *Id.*

[8] *Id.*



*Average List and Net price per patient per month is calculated based on average prescribed utilization of Humalog U100, the most broadly used presentation of Humalog (Source: IQVIA LAAD Data 2014-2018). In 2018, per IQVIA reported data, if taken as prescribed, the average Diabetes patient using Humalog U100 would have consumed approximately 19 MLs of insulin per month; this equates to approximately 2 vials or 6.4 Kwikpens. The actual utilization per patient per month may differ significantly depending on multiple factors, including prescription amounts and adherence behaviors.

Overall, the system continues to work well for the majority of people who are prescribed a Lilly insulin. As noted above, the out-of-pocket cost for Humalog, Lilly's most commonly prescribed insulin, is less than $50 a month for 90% of retail prescriptions, and less than $100 for 95% of retail prescriptions.[9] Moreover, as discussed further below, individuals without

[9] Based on IQVIA data, FIA data (August 2018 – December 2018).

insurance or on Medicare Part D whose income is less than 400% of the federal poverty line can obtain Lilly insulins for free.

Additionally, under Medicaid, Lilly insulins are available at little or no cost to individuals or to the government.[10] Indeed, Humalog is essentially free to Medicaid programs, as Lilly pays a rebate of approximately 100%.[11] Public programs designed to assist the medically needy and financially vulnerable, including Medicaid, have expanded greatly in recent years. With enactment of the Affordable Care Act ("ACA"), the Medicaid population increased from 54.5 million in 2010 to 73.4 million in 2017.[12] Providing insulin to this population at little or no cost is a significant step towards ensuring affordable access for those in need.

But despite the fact that the current system works well for the majority of people prescribed Lilly insulin, we recognize that it does not work for everyone. Individuals' specific out-of-pocket costs vary significantly depending on numerous factors, most notably the type and terms of their insurance coverage, which Lilly does not control. Depending on the terms of someone's insurance, list price changes often have no effect on their out-of-pocket costs for insulin. But some people, including those enrolled in high-deductible health plans and Medicare Part D, may incur higher out-of-pocket costs for certain prescriptions because of their insurance design. Although Lilly pays a rebate for access on insurance plans, patients don't always benefit from the rebates at the pharmacy.

---

[10] Letter from Joe Kelley to Hon. Greg Walden *et al.* at 21 (Feb. 27, 2019).

[11] Letter from Joseph Kelley to Hon. Frank Pallone, Jr. and Hon. Diana DeGette at 3 (Feb. 13, 2019).

[12] Statista, Total Medicaid Enrollment from 1966 to 2017 (in millions), https://www.statista.com/statistics/245347/total-medicaid-enrollment-since-1966.

III. Gaps in Affordable Access

Lilly has long provided support for people living with chronic conditions who face high out-of-pocket costs for their medications, but in recent years we have recognized an increasing need to address affordability challenges, as more people bear a greater share of their medications' costs. To that end, Lilly has focused on identifying the primary coverage gaps for people taking our insulins and has identified three groups of people most likely to be paying higher out-of-pocket amounts: (1) individuals in the deductible phase of private high deductible health plans; (2) individuals in the coverage gap phase (or "donut hole") of Medicare Part D; and (3) individuals without insurance. Each of these gaps is detailed below.

High Deductible Private Insurance

In recent years, employers focused on providing employees health insurance plans with low premiums and increasingly selected high deductible health plans to achieve that. These plans require members to pay thousands of dollars before insurance coverage starts. In about half of these plans, employers give special treatment to medication for chronic diseases, such as exempting those medicines from deductible requirements through the use of preventive drug lists. In the other half, employers choose a plan design that utilizes rebates paid by pharmaceutical companies on drugs like insulin to buy down premiums for the general population. The result is that people who take insulin or other medications for chronic conditions pay full retail prices at the pharmacy during the deductible phase of coverage and do not directly benefit from rebates paid in connection with those medicines. This places a great burden on people with diabetes and others who rely on medications to treat chronic conditions.

Medicare Part D Coverage Gap

Once a person covered by Medicare Part D has spent a certain amount on covered prescription drugs, a coverage gap known as the "donut hole" begins. While in that phase, the person will pay up to 25% of the plan's cost for brand-name drugs. Our review of data indicates that since enacting our current safety net of solutions, almost 90% of the people exposed to a prescription cost above $100 for Humalog at a retail pharmacy were enrolled in Medicare Part D. In most cases, federal regulations prohibit Lilly from subsidizing the cost of insulin for people on Medicare during the coverage gap.

No Insurance

The third primary group of people that Lilly has identified as lacking access to affordable insulin are those without any insurance coverage, who pay retail price at the pharmacy throughout the year. Lilly estimates that each month there are approximately 1,600 prescriptions for Humalog filled at a retail pharmacy by likely uninsured individuals or individuals in a period of transition between insurance coverage who pay near list price for their prescription.

IV. Lilly's Solutions

Recognizing that individuals exposed to high prescription drug costs have a real and pressing need for immediate solutions, particularly those who rely on medications to treat life-threatening, chronic conditions like diabetes, Lilly has instituted multiple programs designed to reach each of the segments of people who need assistance affording their insulin.

These solutions are currently helping more than 20,000 additional people each month more easily afford their insulin. We want people to use our solutions, and our intent is to make these solutions as easy to access as possible. For example, if you are uninsured or have private

insurance you can gain immediate access to savings offers with no paperwork or applications to complete. If you or a loved one is having trouble paying for our insulin, please call our Lilly Diabetes Solution Center at 833-808-1234. Lilly's solutions are discussed further below.

Automatic Discounts

Lilly currently offers savings directly to people in the high-deductible phase of their insurance plans by capping their prescription cost at $95 at the pharmacy. When a person in a high-deductible insurance plan fills a prescription for a Lilly insulin, the individual generally will pay no more than $95 out of pocket at the pharmacy, and Lilly will pay the remainder of the cost.[13] The discount is automatically applied at the point of sale, and therefore has an immediate impact on the cost paid by the insured person. This takes place behind the scenes when the insurance claim is processed and does not require the individual to enroll in any programs or request that the savings offer be applied. In fact, individuals may not even be aware of these "buy-downs" or may be surprised by them.

These buy-downs are in addition to the rebates that Lilly is already paying. Indeed, when Lilly pays the cost of a person's prescription during the deductible phase and also continues to pay the full contractual rebate, it loses money on each prescription. This is not a sustainable long-term solution, but it is one that Lilly felt was necessary to ensure that individuals had access to affordable insulin while we work towards broader systemic changes.

These automatic discounts are not available to all people, however. Federal regulations prohibit us from subsidizing prescriptions for people insured through government programs such

[13] Significantly, the portion that Lilly pays is counted towards the patient's deductible.

as Medicare Part D. This program also cannot be used by individuals without insurance because there is no insurance claim to process, triggering the savings offer.

Lilly's Insulin Lispro

As discussed above, we recently announced the introduction of a lower-priced version of Humalog. We sought to bring a lower-priced version of our product to the market because we recognized that other solutions, though important, still left some people vulnerable to high out-of-pocket amounts for insulin. We expect the introduction of Lilly's Insulin Lispro to particularly benefit individuals enrolled in Medicare Part D who are on the coverage gap. Because of legal restrictions outside of our control, these individuals do not have access to as many of our other solutions as people covered by private insurance plans. By introducing this second version, Lilly can provide a lower-priced insulin quickly without disrupting access to branded Humalog, on which hundreds of thousands of people currently depend.

It is important to note that our introduction of Insulin Lispro will not prevent any other companies from manufacturing a generic version of Humalog. None of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product.

Other Discount Programs

Since 2017, Lilly has participated in Blink Health (www.blinkhealth.com) and Inside Rx (www.InsideRx.com), savings programs that offer savings of up to 40% off the list price of Lilly's most commonly prescribed insulins. These programs are available to people through smart phone applications and offer savings at the point of sale. Our participation in these

programs was an initial step to provide discounts to people on Lilly insulins who had private insurance or were uninsured.

Donations of Free Insulin

For many years, Lilly has provided free insulin products to a variety of organizations and programs. We broadened the scope of that support from emergency relief organizations to include donations to relief networks that supply insulin to nearly 150 free clinics. These clinics provide not only free insulin, but also access to medical care and other free medications and supplies.

Since January 1, 2014, Lilly has provided over 5 million free pens/vials of Humalog, Humulin, and Basaglar to these organizations and programs in the U.S. Program qualification requirements vary depending on the nature of the program and as determined by the organization, but in all instances, the insulin provided is free to qualifying individuals.

Lilly Cares

Lilly also supports and donates insulin to Lilly Cares, a separate charitable organization.[14] Lilly Cares provides free insulin to patients who do not have insurance or have Medicare Part D and have a household annual adjusted gross income of up to 400% of the federal poverty level.

Lilly Diabetes Solution Center

Recognizing that some solutions described above will not help people unless they know about them, Lilly launched the Lilly Diabetes Solution Center ("LDSC") in August 2018. The Solution Center is a patient-focused helpline staffed by medical professionals, which connects

[14] https://www.lillycares.com/resources.aspx.

people living with diabetes to any of Lilly's various resources and solutions based on their individual needs. These solutions include savings cards (requiring no paperwork and no application), an immediate supply of insulin, or information about one of the clinics that can offer free insulin that Lilly has donated. The LDSC also can connect patients to Lilly Cares. Lilly has publicized the LDSC through press releases, social media channels, and advertising campaigns—including direct-to-consumer print ads—that directly target people with diabetes, the general public, and specific communities of color with a higher risk of diabetes.

These solutions help ensure that insulin is affordable for people who fall within the coverage gaps described above. But some people might ask—why doesn't Lilly just drop the list price of its insulin products? This is an important and fair question. The answer is that lowering list prices is too disruptive under the current health care model. Distributors, PBMs, insurance companies, long-term care facilities, and pharmacies have all entered into contracts that are based on a rebate model tied to current WAC or list prices. No pharmaceutical manufacturer has lowered list price for a significant medication because it is too disruptive to the system and thus to people who rely on that medication. Introducing a new, lower list price second version of a medication is the only practical approach under the current health care model. In the face of these complex dynamics, systemic change is needed. In the meantime, we have taken action within the constraints of the current system to lower insulin prices, for example by introducing a half-price version of Humalog.

IV. Towards a New Approach

While Lilly has worked hard to introduce the many solutions it has in place to make insulin affordable for people with diabetes today, we recognize that we need more than a series of patchwork fixes, and that long-term change will require the participation of all industry

stakeholders. We appreciate the Subcommittee's attention to these important issues, and we look forward to continued dialogue about potential solutions.

One proposal that Lilly believes is worthy of consideration is adding insulin to preventive medications lists, which would lower out-of-pocket costs such as by exempting insulin from deductibles (sometimes called "first dollar coverage"). Because of how the private health care system works today and the complexity of high deductible health plans, some people have full coverage for treatments to manage their chronic conditions while others must meet out of pocket and deductible requirements for the same treatments. Making people with chronic diseases like diabetes pay high prices for their medications does not make sense as a matter of public policy. While billions of dollars are spent in the United States each year on medical expenses directly related to diabetes, only 6% of that is spent on insulin.[15] The vast majority is spent to treat the serious and costly complications of diabetes. When people with diabetes take their medications, they live healthier lives, reducing overall health care costs. As a result, insurance design that makes insulin and other medications for chronic conditions available at low out-of-pocket costs is a matter of sound public policy.

A nationwide systemic preventive drug list that assesses the holistic nature of treatment and takes into account the overall savings afforded by access to preventive treatment would address this disparity in affordability, while also reducing overall costs to the system. We also look forward to the re-introduction of the Chronic Disease Management Act in this Congress which will provide legal certainty to health plans that want to exempt chronic medications from deductible requirements.

---

[15] American Diabetes Association, *Economic Costs of Diabetes in the U.S. in 2017* at 8 (Mar. 22, 2018), http://care.diabetesjournals.org/content/diacare/early/2018/03/20/dci18-0007.full.pdf.

Lilly also supports the policy objective of reducing the out-of-pocket burden as advanced by HHS' recently proposed rule.[16] We believe the proposal has the potential to lower peoples' out-of-pocket costs at the pharmacy counter by enabling manufacturers' discounts to flow directly to individuals. But in order to effectively address this issue, the proposal must be extended to private insurance, not just Medicare Part D.

* * *

As I explained above, for me, ensuring affordable access to diabetes medication is personal. Like all of us at Lilly, I recognize the impact of higher out-of-pocket costs on individuals struggling to afford their insulin. We are committed to doing our part to address this issue in a meaningful way.

Thank you for the opportunity to be here. I look forward to your questions.

---

[16] *See* HHS, Proposed Rule, *Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees*, 84 Fed. Reg. 2340 (Feb. 6, 2019).

Ms. DEGETTE. Thank you.

Mr. Langa, you are recognized for 5 minutes.

STATEMENT OF DOUGLAS J. LANGA

Mr. LANGA. Thank you, Chair DeGette, Ranking Member Guthrie, and members of the subcommittee. My name is Doug Langa. I am the Executive Vice President, North America, and I am the President of Novo Nordisk Incorporated.

For over 90 years, Novo Nordisk has been dedicated to improving the lives of people with diabetes. We care deeply about the people who need our medicines and we're troubled knowing that for some our products are unaffordable. For a company committed to helping people with diabetes, patients rationing insulin is just simply unacceptable. Even one patient rationing insulin is one too many. We need to do more. We all need to do more. This is why I appreciate the opportunity to take part in a dialogue here today.

On the issue of affordability, we all hear a lot about list price, and I will tell you that at Novo Nordisk we are accountable for the list prices of our medicines. We also know that list price matters to many, particularly those in a high-deductible health plan and those that are uninsured. Why can't we just lower the list price and be done? In the current system, lowering list price won't bring meaningful relief to all patients, and it may jeopardize access to the majority of patients who have insurance and are able to get our medicines through affordable copays. That's because list price is only part of the story. Once we set the list price, the current system demands that we negotiate with PBMs and insurance plans to secure a place on their formularies. Formulary access is critical because it allows many patients to get our medicines through copays at reasonable costs. The demand for rebates has increased each and every year. In 2018, rebates, discounts, and other fees accounted for 68 cents of every dollar of Novo Nordisk gross sales in the U.S. As a result, net prices of our insulin products have declined year over year since 2015. Despite the investment that we make in rebates, some patients including those with insurance end up paying list price or close to it at the pharmacy counter. As a manufacturer, Novo Nordisk has no control over what insured patients pay at the pharmacy counter. This is dictated by benefit design.

In the last few years, we've seen more patients with benefit designs that require them to pay high out-of-pocket costs, so despite these ever-increasing rebates that we pay to get on formularies, patients don't get the full benefit of those rebates at the pharmacy counter. This needs to change. It's time for people with diabetes to benefit directly from the rebates that we pay. I take the mission of this company to help people with diabetes very seriously and personally. I lost my own father-in-law to this disease, so I do know firsthand what it does and how it affects patients and their families.

When the healthcare market began to shift toward high-deductible health plans and we saw that more people were struggling to afford their medications, we took action. Back in 2016, we pledged to limit list price increases to single-digit percentages annually. We were one of the first companies to make that commitment and we

have honored it ever since. Our pricing pledge complemented other programs that we've had in place for years with the goal of reducing patients' out-of-pocket costs.

Through our nearly two decades old partnership with Walmart, Novo Nordisk's high-quality human insulin is available at Walmart pharmacies for less than $25 a vial. In 2017, we partnered with CVS Health and Express Scripts to expand the $25 human insulin offerings to tens of thousands of pharmacies nationwide. Our human insulin is an FDA-approved, safe and effective treatment for both type 1 and type 2 diabetes and it's used by about 775,000 patients today.

Since 2003, we have also provided free insulin to eligible individuals through our Patient Assistance Program. Nearly 50,000 Americans received free insulin through the effort in 2018 alone. Today, a family of four making up to $103,000 a year could qualify for a Patient Assistance Program. We also offer copay assistance on a wide variety of our insulin medicines which last year helped hundreds of thousands of patients lower what they pay at the pharmacy counter.

Although these valuable programs help many people today, we can't stop there. Patients are telling us that we need to do more, and we hear them. The challenge is that the current system is broken. Bringing relief to patients is going to require bigger, more comprehensive solutions built on cooperation between all stakeholders in the insulin supply chain. We want to be a part of those solutions, and we look forward to working with all stakeholders to ensure that this lifesaving medicine remains available to everyone who needs it.

Thank you and I do look forward to answering the questions today.

[The prepared statement of Mr. Langa follows:]

TESTIMONY OF DOUGLAS J. LANGA

NOVO NORDISK INC.

BEFORE THE U.S. HOUSE OF REPRESENTATIVES

COMMITTEE ON ENERGY AND COMMERCE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

APRIL 10, 2019

Introduction

Chairwoman DeGette, Ranking Member Guthrie, and Members of the Committee, on behalf of the over 42,000 employees of Novo Nordisk, including nearly 6,000 in the United States, I appreciate the opportunity to be here for today's hearing. My name is Doug Langa, and I am the Executive Vice President, North America Operations, and President of Novo Nordisk Inc. I joined the company in 2011, after working in the pharmaceutical and device industries in a number of roles for more than 25 years, including in marketing, market access, sales, and accounts management.

At Novo Nordisk, we are dedicated to improving the lives of patients living with diabetes and supporting efforts to prevent its life-threatening complications. As an industry leader in developing innovative treatments for diabetes, we are deeply concerned about the factors that limit access to our medicines—including affordability. It is our ambition that everyone who could benefit from our medicines can access them, at costs that they can afford.

My testimony today will offer our company's perspective on the pressures that exist in the U.S. healthcare system around the pricing of insulin medications, including how changes in benefit designs and the increasing commonality of high-deductible health plans have contributed to rising out-of-pocket costs for prescription medicines. My testimony will also address the innovation that has occurred in insulin and diabetes care and management. This is an important issue, as some have inaccurately suggested that insulin therapy has not changed since it came into use approximately 100 years ago. The truth is that the insulin medicines we sell today, including human insulin, are not the same therapies that were used nearly a century ago. Innovations in insulin and diabetes care over the years have dramatically improved the way patients manage their disease. And we are not slowing down; we have new treatments in the pipeline that will continue to meaningfully improve patients' lives.

Further, I will discuss Novo Nordisk's commitment to addressing affordability. Novo Nordisk provides a number of programs to help patients who cannot afford their medications—some of these programs have been in place for nearly two decades. As I will describe in further detail, Novo Nordisk offers a diabetes Patient Assistance Program ("PAP") and co-pay assistance programs; and partners with Walmart, CVS Health, and ESI to offer high quality Novo Nordisk human insulin for approximately $25 a vial. While these programs are important options when

patients do not have adequate insurance coverage, they are not a substitute for the much needed reform to the drug supply chain.

We can—and must—do our part to bring relief for patients who cannot afford the out-of-pocket costs of their medications. But we cannot solve the affordability problem alone. The U.S. healthcare system is complex, and many entities play a part in determining what patients pay for their prescriptions. A solution that will bring meaningful relief for patients must address the roles of all participants in the drug supply chain.

Pharmaceutical companies set the Wholesale Acquisition Cost (known as "WAC," and also commonly referred to as the "list" price) which is the price we charge to wholesalers and distributors who purchase medicines from our company. How pharmaceutical companies like Novo Nordisk set WAC, or list, prices and the relationship these prices bear on the ultimate price patients pay at the pharmacy counter should be examined. But WAC price is only part of the story, and any effort to understand and solve the problems inherent in the supply chain for prescription medicines must explore the rebates, discounts, and fees paid to pharmacy benefit managers ("PBMs"), insurance plans, distributors, and other entities in the supply chain. After our medicines leave our facilities and enter the supply chain, we have limited visibility into how the actions of downstream entities ultimately impact the price that patients pay for medicines at the pharmacy counter. We look forward to working with this Committee, and other stakeholders in the complex U.S. healthcare system, to develop solutions that will help patients affordably access the medications they rely on.

As described at the close of this testimony, I will address some of the proposed solutions that Novo Nordisk believes could bring meaningful change for patients. Novo Nordisk is committed to doing its part and to helping find solutions to the very real affordability challenges that patients are experiencing.

About Novo Nordisk

For more than 90 years, Novo Nordisk has been uniquely focused on the development of pharmaceutical products and devices to help people with diabetes. The company began when a husband and wife from Copenhagen, August and Marie Krogh, a professor and physician respectively, visited the United States in 1922 and learned that people with diabetes were being treated with insulin. Mrs. Krogh was a physician who herself had type 2 diabetes, but she also treated patients with type 1 diabetes in her practice. After meeting with the two Canadian researchers who discovered insulin, Mr. and Mrs. Krogh brought that innovative therapy back to Denmark.

While our company has grown rapidly since its founding, and we have broadened our work to include medications to treat obesity, hemophilia, and hormone imbalances, our principal mission since day one has been improving the lives of people with diabetes. Today, over 29 million patients use our diabetes products, and our medications are available in more than 170 countries. In the United States, we offer a variety of diabetes medicines, including short- and long-acting insulins and Glucagon-like peptide-1 receptor agonist ("GLP-1") products for diabetes and obesity. We also offer innovative delivery methods, including injection pens that make dosing and administration of medicines more convenient and less painful for patients.

Although we are proud of the innovative therapies we have been able to bring to patients, we recognize that prevention is more effective than even the best treatment. For that reason, Novo Nordisk has created initiatives dedicated to the prevention and early detection of type 2 diabetes.

The innovative medicines and delivery systems we produce are the result of significant and ongoing investment in research and development. But we know that these investments will not help patients if they cannot afford the out-of-pocket costs for our medicines. Like you, I am deeply troubled by reports of patients rationing insulin because they cannot afford it. As a company whose legacy is rooted in the treatment of this serious disease, the people of Novo Nordisk believe that this is unacceptable. Even one patient rationing insulin is one too many.

The U.S. Healthcare System and Insulin Pricing

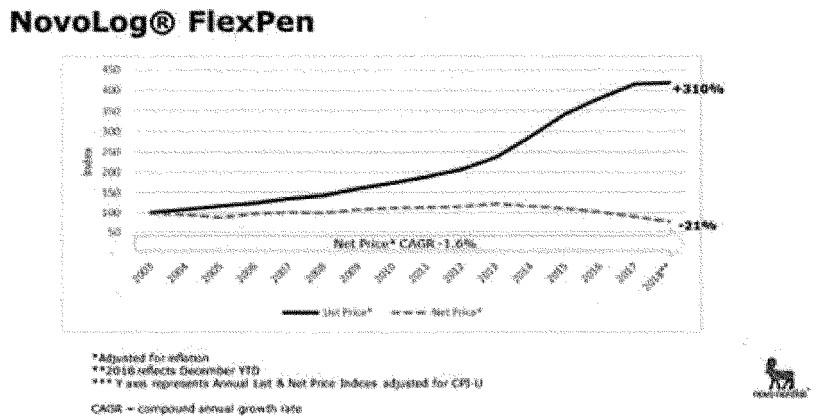
As an innovator and manufacturer of prescription medicines, Novo Nordisk sets the WAC price for the medicines it sells. Although many other participants in the healthcare supply chain impact what patients ultimately pay at the pharmacy counter, there is no doubt that the WAC price is a significant component, particularly for those patients with high-deductible health plans, those who have co-insurance, and those who are uninsured and not covered by any government drug benefit programs.

It is important to recognize, however, that WAC price is not set in a vacuum. Rather, WAC price is set against the backdrop of the competitive environment in which we operate. After Novo Nordisk sets the WAC price, we negotiate discounts, rebates, and other price concessions with supply-side entities, like PBMs, who act on behalf of employers and health insurers and determine whether our medications will be covered on their formularies. Because of consolidations that have occurred over the past several years, the PBMs testifying here today now control access to medications for over 80 percent of the covered U.S. population, or roughly 220 million people. With such a substantial market share, these companies are able to exert considerable leverage in negotiations. If they do not extract the rebate concessions they demand (and we recognize that PBMs are under pressure from employers and health plans to deliver certain dollar amounts in savings), they can and do exclude products from formularies, essentially making them unavailable to patients who rely on them every day. The pressure to provide higher rebates is constant and escalating, and rebate percentages have increased year-over-year for the last several years.

Recently, pharmaceutical companies have come under pressure to explain the increasing out-of-pocket costs for certain medicines, including insulin. While increased competition in a marketplace would usually lead to lower prices, our current healthcare system is built on misaligned incentives that have led to rising costs in medicines. Chief among these misaligned incentives is the fact that the rebates pharmaceutical companies pay to PBMs are calculated as a percentage of WAC price. That means a pharmaceutical company fighting to remain on formulary is constrained from lowering WAC price, or even keeping the price constant, if a competitor takes an increase. This is because PBMs will then earn less in rebates and potentially choose to place a competitor's higher-priced product on their formulary to the exclusion of others.

Exclusion from a major formulary would have significant consequences for patients and for our company. If our medicines were not covered on formulary, patients whose diabetes is well-controlled by a Novo Nordisk product would be forced to either switch to another product, which might not work as well for them, or pay much more to stay on their physician-prescribed Novo Nordisk medicine. This is not a hypothetical risk: just last week, the Committee heard from Gail deVore, who testified that she cannot afford Fiasp® because it is not on her formulary, and she therefore mixes it with NovoLog® against her doctor's orders. For the company, exclusion from a major formulary typically results in a significant financial loss (as well as loss of market share), which would compromise Novo Nordisk's ability to continue to innovate with the goal of defeating diabetes.

For these reasons, we are acutely focused on the rebates our payers, including PBMs, will demand when we set WAC prices. Last year, across all products and channels, we paid an average of 68 cents for every dollar of sales to PBMs and other payers and supply-side entities in the form of rebates and other discounts and fees—nearly $17.8 billion. These rebates, discounts, and other price concessions are the single largest investment Novo Nordisk makes in ensuring its products are broadly available to patients. And the percentage we pay has been increasing each year—it is up from 64 percent in 2017, 59 percent in 2016, 56 percent in 2015, and 48 percent in 2014. Further, because of the portion of our gross sales consumed by rebates and other discounts, net prices for our medicines, including our insulins, have declined year-over-year for every year from 2015 through 2018, and experienced double-digit declines in 2017 and 2018. By way of example, the following graph shows WAC and net prices for NovoLog®Flexpen® dating back to 2003.



As this graph shows, WAC price increases (factoring in the negotiations and concessions described above) have translated year-over-year to a 1.6% overall decline in NovoLog®FlexPen® net price when adjusted for inflation.

In spite of its complexities, this system of WAC prices and rebates works for many patients who have health insurance and who are charged reasonable co-pays for their prescriptions. But it does not work for everyone: many patients do not see the full benefit of the discounts we provide to PBMs to secure formulary access, and some see little to no benefit at all. In particular, uninsured patients and patients covered by high-deductible health plans pay close to the full WAC price for our medicines. Others, such as those with co-insurance or Medicare Part D patients in the coverage gap, may also pay a substantial portion of the WAC price. This is true even where Novo Nordisk has already paid a substantial rebate to the PBM to secure formulary access for the particular medication.

Unfortunately, as a pharmaceutical company, we do not have the ability to control what an individual insured patient pays for his or her prescriptions; that is a function of the individual's health plan benefit design. Similarly, we do not have control over whether the rebates we pay to ensure formulary access actually result in lower out-of-pocket costs for patients; that is the decision of the PBM, which determines how to apply the rebate. But we do know that more patients are facing an affordability challenge. Although there have always been some patients without insurance or who pay an above-average portion of WAC price for other reasons (and Novo Nordisk has attempted to relieve the burden on those patients through various affordability programs, described below), the number of patients struggling to afford their medicines has grown in recent years. This is due, in part, to the increasing prevalence of benefit designs that require patients to shoulder large out-of-pocket costs, such as high-deductible health plans. The number of individuals covered by this type of plan has increased over the last ten years and, according to the Centers for Disease Control and Prevention, high-deductible health plans now represent approximately 43 percent of private insurance plans in the United States. For these patients, the price they pay at the pharmacy counter simply does not reflect the significant rebates Novo Nordisk provides to the PBMs managing their pharmacy benefits.

My intent in highlighting the problems inherent in the complex U.S. healthcare system is to underscore that fixing the rising out-of-pocket costs of prescription drugs will require the commitment of all stakeholders in the supply chain. We at Novo Nordisk are committed to doing our part. We recognize the impact that changes in the healthcare market, especially the growth of high-deductible health plans, have had on patients. As we became aware that more patients were struggling to afford their medicines, we took steps to try to address the problem, including our commitment in 2016 to limit WAC price increases to single digit percentages annually. We have honored that pledge since we made it. We have also expanded our affordability programs, which I describe in greater detail below. But we know that we can do more, and we will do more. Novo Nordisk looks forward to being part of the solution that helps patients obtain access to affordable medicines.

Innovation in Diabetes Treatment and Care

Over the last five years, Novo Nordisk has invested over $10 billion in research and development, much of which is aimed at finding new therapies that improve diabetes patients'

ability to manage and live with this chronic disease. In fact, Novo Nordisk is the largest private funder of diabetes research and development in the world. Novo Nordisk has also formed research collaborations to further innovation in diabetes, including one with the Massachusetts Institute of Technology to develop a capsule device that contains compressed insulin, which is injected into the patient after the capsule reaches the stomach. This capsule would potentially replace insulin injections through pens or syringes, making it easier for patients to receive their medication. We are also conducting research into stem cell therapies to treat diabetes in collaboration with the University of California, San Francisco, as well as other chronic diseases. In 2016, we began a $2 billion investment in a new production facility in Clayton, North Carolina, which, once operational in 2020, will be the only facility outside Denmark where we manufacture active pharmaceutical ingredients for diabetes medications. To our knowledge, this project is the largest active pharmaceutical manufacturing construction project in the United States. These are just some of the innovative and cutting-edge research and development and manufacturing projects underway at Novo Nordisk.

These efforts build on the work we have already done throughout Novo Nordisk's history to continuously improve our insulins and other medicines in a way that offers meaningful change to patients who live with this disease each day. Recently, some have suggested that the insulin now on the market is essentially the same product as the insulin first produced almost 100 years ago. That is simply not the case. Early diabetes treatments used bovine and porcine insulins. Novo Nordisk was the first to convert porcine insulin into human insulin in the 1980s using recombinant DNA technology. Human insulin revolutionized the treatment of diabetes because it could be produced in a purer form and reduced the occurrence of allergic reactions. Human insulin is an FDA-approved, high-quality treatment and remains safe and effective for managing both type 1 and type 2 diabetes. In fact, human insulin was used in the Diabetes Complications and Control Trial in the 1990s that set new standards of care in diabetes. Human insulin is part of the standard of medical care in the United States and throughout the world. Today, approximately 775,000 people in the United States use our human insulins. In 2018, those medicines constituted 21 percent of our insulins sold in this country and 44 percent sold worldwide.

The development of analog insulins in 2000 represented another significant change in diabetes therapies. Our analog insulin, which we sell under the name NovoLog®, is a modified form of human insulin in which the amino acid structure of the insulin molecule has been altered at specific sites to change the onset and duration. For patients, this provides better control of mealtime blood glucose levels by more closely matching the body's natural insulin action. In doing so, the medication allows for a more flexible lifestyle, as injections can be taken immediately before, or even just after, meals. This flexibility offers a meaningful improvement in quality of life for patients because it means that they do not have to take insulin at the same time every day.

Five years later, we launched Levemir®, a long-acting insulin that has shown improved glucose control benefits by providing blood sugar control for up to 24 hours and a reduction of hypoglycemia risk. In addition, Levemir® is considered to be weight neutral, meaning it is not typically associated with the weight gain patients often experience with insulin treatment.

In 2015, we introduced Tresiba®, a long-acting basal insulin, offering once daily dosing at any time of day for both type 1 and type 2 diabetes patients. This medication's unique mechanism of action allows for improved blood sugar control with a lower risk for nighttime hypoglycemia as compared to other basal insulins. In addition to its standard concentration, Tresiba® is available in a more concentrated formula for those patients who require higher doses of insulin, allowing them to take a single dose per day with a pen device. Most recently, in 2017, we introduced Fiasp®, a new short-acting insulin that offers quicker onset. These two recent advances, Tresiba® and Fiasp®, have allowed people who are insulin-dependent to safely and effectively control their diabetes around mealtime, when blood sugar rises quickly after eating, as well as overnight. For patients, better nighttime control may mean the difference between getting a good night's sleep and sleep interruptions caused by diabetes.

We have also created new, more accurate and convenient delivery systems that allow patients to take their insulin through pen injection devices rather than with a traditional vial and syringe.

These developments in diabetes care and treatment demonstrate Novo Nordisk's commitment to improving the lives of its patients through new medications and delivery systems. We will continue to innovate to address the needs of patients and to meet our goal of defeating diabetes.

Novo Nordisk's Commitment to Patients and Affordability

For many years, Novo Nordisk has invested in programs to help patients afford their medicines. Like our investments in research and innovation, we view these investments as part of our overall commitment to improving the lives of patients living with diabetes. Although these programs are not intended to take the place of adequate insurance coverage, they are important options that are aimed at ensuring all patients can successfully and affordably manage their diabetes.

Novo Nordisk has offered a Patient Assistance Program since 2003. The PAP provides free medicines, including all Novo Nordisk insulin medications, to eligible patients who do not have insurance; Medicare patients who incur high costs while in the Part D coverage gap or who do not have Part D coverage and have been denied the Extra-Help/Low-Income subsidy; and patients who are Medicaid eligible but have been denied Medicaid.[1] With a maximum income requirement of 400 percent of the federal poverty limit, 59 percent of American households could qualify for free Novo Nordisk medicines under our PAP.[2] Thus, a family of four with income up to $103,000 may receive free medications through our PAP. For individuals, the income limit for participation is $49,960. Typically, we are able to ship medicines to patients who qualify for our diabetes PAP within seven to ten days of the patient submitting a complete

---

[1] Information about the PAP and its eligibility criteria can be found on the Novo Nordisk website. In addition, at www.novocare.com, patients can get help on how to access our company's assistance programs and receive guidance about applying for these programs.

[2] *See* Kaiser Family Foundation, "Distribution of the Total Population by Federal Poverty Level (above and below 400% FPL)," at https://www.kff.org/other/state-indicator/population-up-to-400-fpl/?currentTimeframe=0&sortModel=%7B%22colId%22:%22Location%22,%22sort%22:%22asc%22%7D.

and accurate application. In 2018, nearly 50,000 Americans received free insulin from Novo Nordisk through this program.

In addition to the PAP, Novo Nordisk offers coupons or co-pay assistance to help patients by decreasing what they pay at the pharmacy counter. We offer this assistance on a variety of our medicines, including NovoLog®, Tresiba®, Levemir®, and Fiasp®. In 2018, Novo Nordisk provided more than $200 million in assistance to patients through coupons and co-pay cards.

Through partnerships with Walmart, CVS Health, and ESI, Novo Nordisk human insulin is available at approximately $25 a vial to any cash-paying patient, regardless of income and insurance coverage status. Through a longstanding partnership with Walmart (which began in 2000), safe and effective Novo Nordisk-manufactured human insulin is available at Walmart stores for $25 per vial. In 2017, we partnered with CVS Health and ESI to expand the $25 human insulin offering to tens of thousands of pharmacies nationwide. Last year, we also started to provide human insulin in a convenient pen injection device through Walmart. Through the CVS Health and ESI programs, commercially eligible patients can purchase this same Novo Nordisk insulin for around $25 at 68,000 pharmacies in the CVS Health retail network and 40,000 ESI participating pharmacies. In total, through these partnerships, Novo Nordisk estimates that it is currently providing high quality, affordable Novo Nordisk-manufactured human insulin to over 500,000 people. While newer analog insulins offer significant improvements in terms of *how* they are absorbed into the body, human and analog insulins work exactly the same way in lowering blood glucose once in the bloodstream. In fact, the standards of care set by the American Diabetes Association guidelines do not recommend one type of insulin over another. It is my sincere hope that patients who are struggling to afford their insulin and who might be rationing will consider this affordable and safe option. Again, one patient rationing insulin is one too many.

Novo Nordisk has adjusted these programs over the years to address our patients' needs for affordable medications and to address the gaps inherent in the healthcare system. We will continue to monitor the effectiveness of these assistance programs, including enhancing outreach to patients and physicians to raise awareness of the programs we offer, so that all who need assistance may find a program that fits their needs. In addition, we will continue to explore additional steps to provide relief to patients who need it. However, as I have described, these are not comprehensive solutions, and more is needed to address a complex system in need of reform.

Policy Proposals

In addition to the many ways Novo Nordisk demonstrates its commitment to people with diabetes, Novo Nordisk supports policy changes and legislation that, when implemented properly, benefit patients and address high out-of-pocket pharmacy costs.

One policy change that could help address affordability, particularly for patients with chronic diseases like diabetes, is the Chronic Disease Management Act ("CDMA"). Although this bill has not been introduced in the House of Representatives in this Congress, Novo Nordisk has consistently supported this bill in previous Congresses. The CDMA would require that the IRS preventive drug list include medicines that prevent chronic disease progression or

complications, like insulin.[3] Under current law, patients in a high-deductible health plan with a health savings account ("HSA") must pay 100 percent of their treatment costs for chronic diseases unless deemed "preventive;" the definition of "preventive," however, is narrow and only includes treatments that would prevent a disease in the first place. The CDMA would modify current law to give these plans the flexibility to cover services and medicines used to treat chronic diseases such as diabetes before meeting the plan deductible. As noted previously in this testimony, high-deductible health plans represent a growing percentage of plans offered today, with 20.2 million Americans enrolled in these plans in 2016.[4] Diabetes patients in high-deductible health plans with an HSA are particularly vulnerable to high out-of-pocket costs because their health plans are not responsible for providing any coverage for insulin until these patients spend through their respective deductibles. This can create significant financial hardships. As we have all seen, insulin rationing due to affordability can cause tragic and senseless deaths, as well as medical emergencies, which drive avoidable and expensive hospitalization costs. Novo Nordisk urges Congress to pass legislation to change the IRS definition of "preventive" to include insulin so that diabetes patients in high-deductible health plans with HSAs can gain first dollar coverage for insulin.

Novo Nordisk also fully supports the policies underlying the OIG's proposed rebate rule.[5] The proposed rule, if appropriately implemented, will address some of the very challenges described earlier in this statement by moving Medicare Part D away from a system that provides rebates to entities such as PBMs and toward providing upfront pharmacy discounts to patients at the point of sale. Importantly, the proposed rule could lower patients' out-of-pocket pharmacy costs for millions of Part D beneficiaries by realigning market incentives so that discounts are directed to those patients who need prescription drugs. While Novo Nordisk supports the proposed rule and its implementation in both Medicare Part D and the commercial market, we urge a cautious approach before making a full transition into the commercial market. Novo Nordisk believes that the wholesale conversion of both markets simultaneously could be challenging in the marketplace and disrupt patient access to medications.

Additionally, Novo Nordisk encourages adoption of policies that support diabetes prevention measures. Novo Nordisk has worked to improve access to diabetes prevention interventions by supporting increased funding for the National Diabetes Prevention Program ("DPP"). The DPP is a public-private partnership that offers evidence-based, cost-effective interventions to help prevent type 2 diabetes in communities across the United States. By working to increase the DPP's appropriations, both directly and through our leadership in the Diabetes Advocacy Alliance, we are helping to ensure individuals in every state have access to this important program. We urge Congress to work with the Centers for Medicare and Medicaid

---

[3] Chronic Disease Management Act of 2018 (H.R.4978/S. 2410).

[4] America's Health Insurance Plans (AHIP). "2016 Survey of Health Savings Account – High Deductible Health Plans." February 2017. https://www.ahip.org/wp-content/uploads/2017/02/2016_HSASurvey_Draft_2.14.17.pdf .

[5] Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees. 84 Fed. Reg. 2340 (Feb. 6, 2019).

Services to explore ways to encourage and increase provider participation in the DPP to ensure Medicare patients have access to these important interventions to help prevent type 2 diabetes.

At the state level, Novo Nordisk is an active advocate for legislation requiring states to develop data-driven diabetes action plans, which include policy recommendations from state Medicaid agencies and public health and state employee health benefits departments on how individuals at risk for diabetes can be better identified and how diagnosed patients can achieve better outcomes. Through Novo Nordisk's advocacy in collaboration with the American Diabetes Association, this legislation has been adopted in 23 states and has included funding recommendations for expanded access to evidence-based DPPs and reimbursement for diabetes self-management education.

Conclusion

It is time for all of us to do our part to ensure affordable access to insulin in the United States—not just to those for whom the system is working, but critically to those for whom the system is not working. Novo Nordisk pledges to be a part of that solution and to work with the Committee and others in our complex healthcare system to address the complicated landscape of laws, regulations, market forces, and supply-chain stakeholders that affect the price people pay for insulin. It is time for real change, and we look forward to being an effective partner with this Committee and others in Congress, the Administration, and the healthcare industry in that critical effort.

Ms. DEGETTE. Thank you.

Ms. Tregoning, now you are recognized for 5 minutes.

STATEMENT OF KATHLEEN W. TREGONING

Ms. TREGONING. Chair DeGette, Ranking Member Guthrie, and members of the subcommittee, thank you for the opportunity to appear before you today to discuss issues related to pricing, affordability, and patient access to insulins in the United States. I am Kathleen Tregoning, Executive Vice President External Affairs at Sanofi. My goal today is to have an open, transparent discussion about how the system works, Sanofi's role in it, and how it can be improved.

Patients are rightfully angry about rising out-of-pocket costs for many medicines and we all have a responsibility to address a system that is clearly failing too many people. As a mom, I was heartbroken at hearing the testimony before this subcommittee of other parents who have not only endured the terrible challenge of facing illness, but have also struggled to afford the medications that they or their children desperately need.

My own family is the beneficiary of a breakthrough in medicine. My husband, John, has FH, a genetic disorder that makes the body unable to remove LDL or bad cholesterol from the blood. He inherited this condition from his father who passed away from a heart attack at 40 years of age when John was just 12 years old. Despite taking statins, watching his diet, and exercising regularly, John, himself, had a double bypass at the age of 36 and still couldn't get his cholesterol under control. Then came a class of drugs called PCSK9 inhibitors, an innovative treatment that helps people like my husband lower their bad cholesterol.

I cannot overstate what this breakthrough means for him, our family, and our future, including for our 7-year-old son, Jack, who has inherited the same condition as his father and grandfather. I fully appreciate how important it is for science to continue to solve the medical challenges that impact so many families, and I recognize that those breakthroughs are meaningless if patients are not able to access or afford them.

Over the last 20 years, Sanofi has been a leader in the advancement of new treatments to help people manage their diabetes. At the same time, we recognize the need to address the very real challenges of affordability. Two years ago, Sanofi announced our progressive and industry-leading pricing principles. We made a pledge to keep list price increases at or below the U.S. National Health Expenditure Projected Growth Rate and we stand by this commitment. In 2018, our average aggregate list price increase in the United States was 4.6 percent, while the average aggregate net price, that is the actual price paid to Sanofi, declined by 8 percent, the 3rd consecutive year in which the amount we receive across all of our medicines went down.

Insulin is a clear example of the growing gap between list and net prices. Take Lantus, for example, our most prescribed insulin. The net price has fallen by over 30 percent since 2012, and today it is lower than it was in 2006. Yet, since 2012, average out-of-pocket costs for Lantus have risen approximately 60 percent for patients with commercial insurance and Medicare.

Every actor in the system has a role to play and Sanofi takes our responsibility very seriously. In addition to our pricing policy, we have developed assistance programs to help patients afford their Sanofi insulin, including copay assistance for commercially insured patients, including those in high-deductible health plans, and free insulin for uninsured low-income patients. Sanofi's commitment to patient affordability means that today approximately 75 percent of all patients taking Sanofi insulin pay less than $50 a month.

But we recognized that more needed to be done. Last year, Sanofi launched a unique program that allowed individuals exposed to high retail prices to access Sanofi insulins for $99 per vial, the lowest available cash price in the United States. Based on feedback from patients, providers, and the advocacy community, today we announced that we are expanding this program. Beginning in June, uninsured patients regardless of income level will be able to access any combination of the Sanofi insulin they need for $99 per month at the pharmacy counter.

This transformative and first-of-its-kind program is the latest in a series of progressive and important steps Sanofi has taken to help patients afford the insulin they need. This action does not eliminate the need for broader system reform. I agree with the witnesses from last week's subcommittee hearing that holistic reforms to the system are not only needed but overdue. Sanofi also supports a number of recommendations outlined in my written testimony including many of the policies included in Chair DeGette's Congressional Diabetes Caucus report.

Thank you for the invitation and I look forward to answering your questions.

[The prepared statement of Ms. Tregoning follows:]

Testimony of Kathleen W. Tregoning
Executive Vice President, External Affairs
Sanofi

Before the House Energy and Commerce Subcommittee on
Oversight and Investigations
April 10, 2019

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee, thank you for the opportunity to appear before the House Energy and Commerce Subcommittee on Oversight and Investigations to discuss issues related to pricing, affordability, and patient access to insulin in the United States.

I am Kathleen Tregoning, Executive Vice President, External Affairs, at Sanofi. I am here today to have an open discussion about the current system for pricing and accessing insulin in the U.S., the actions we have taken to improve patient access and affordability to insulin, and our ideas about what more can be done.

At Sanofi, we work passionately every day to understand and address the health care needs of patients around the world. We are dedicated to solving patients' most serious health challenges in numerous therapeutic areas, including diabetes, cardiovascular disease, immunology, oncology, multiple sclerosis (MS), rare diseases, and rare blood disorders. We are also devoted to preventing diseases through the research, development, and delivery of vaccines. And we contribute to improving the health of people around the world through our broad portfolio of consumer health products.

Sanofi has a rich history in the United States dating back over 100 years. We currently employ more than 13,000 professionals across the United States in a broad range of critical roles, including business operations, research and development, and manufacturing. Our most significant U.S. presence is in Massachusetts, where we are the largest employer in the life sciences industry, and New Jersey, home to our U.S. headquarters. We also have major business, manufacturing and R&D operations in Pennsylvania and Tennessee.

Last year, Sanofi spent almost $7 billion globally on research and development, an increase of approximately 7 percent from 2017, which reflects our commitment to bringing better therapies to patients. Sanofi plans to maintain this level of R&D investment through 2021, and our R&D pipeline now contains 81 projects, including 33 new molecular entities in clinical development, and 35 projects that are in Phase III or have been submitted to regulatory authorities. This investment means that Sanofi potentially will seek approval for nine new

medications in the next three years, primarily in therapeutic areas where Sanofi sees the greatest nexus between our expertise and patient need: diabetes, vaccines, oncology, immunology, rare diseases, and rare blood disorders.

Our work in R&D includes more than a dozen compounds for the treatment of various kinds of cancers, and we are employing cutting-edge approaches in an effort to make significant advances for patients. Our research includes potential treatments to help the body's own immune system fight cancer, and antibody drug conjugates that we believe can deliver cytotoxic drugs to tumors while sparing normal tissue. Just last month we announced successful results with one such candidate in a mid-stage trial in lung cancer, and we intend to initiate a pivotal study later this year.

I. Evolution of Insulins

Sanofi's innovations in diabetes, and, specifically, for insulin, have been significant.

The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and wake up at night for injections in order to control blood glucose levels. Each such injection of insulin caused a sharp spike in the patient's insulin levels, which could cause symptoms of low blood sugar ranging from shakiness and confusion to, in the extreme, coma or death. Injections also had to be timed before every meal, disrupting patient's lives, sleep times, and ability to eat with friends and family. As such, the consistent goals of insulin therapy over the last century have included reducing the frequency of insulin administration and flattening the post-administration peak of insulin in the bloodstream. Prior attempts to achieve these goals included cumbersome mechanical pumps that had to be worn on the body for constant infusion, and NPH insulin, which had an intermediate duration of action but still caused a pronounced peak in insulin levels.

The discovery and development of glargine changed all of that. Sanofi scientists succeeded in fundamentally altering the human insulin molecule at the amino acid level, changing its pharmacological characteristics to give patients a steady release of insulin with just a single daily administration. Unlike anything that came before it, glargine forms tiny solid crystals upon injection that dissipate over time to provide a flatter, stable, long-lasting effect that mimics the flat profile of insulin release from a healthy pancreas and reduces the risks caused by low blood sugar. The once-daily administration of glargine also provided a significant boon to patient lifestyles. The FDA first approved insulin glargine under the tradename Lantus® in 2000. Since its launch, Lantus has been studied in more than 90 million patient lives. Sanofi went above and beyond the regulatory authorities' approval requirements and conducted the first large Cardiovascular Outcome trial (CVOT - (ORIGIN)), to demonstrate the cardiovascular effects of an antidiabetic drug. Sanofi sponsored over 200 clinical trials, with more than 200,000 patients treated, resulting in over 2000 peer reviewed publications.

Since its discovery of insulin glargine, Sanofi has developed a new glargine formulation and a combination product to meet individual patient needs. While Lantus® provides significant

improvement for long acting (basal) insulin, for some patients, Lantus does not provide sufficient 24-hour basal insulin coverage. For other patients using higher doses, Lantus has a peak of action, which could lead to hypoglycemia. In order to more closely mimic endogenous basal insulin secretion, and to help type 2 diabetes patients meet their glycemic goals, Sanofi developed a next generation basal insulin, Toujeo®. Approved by the FDA in 2015, Toujeo provides an improved therapeutic effect at a higher concentration of glargine and exhibits a different and longer-acting profile than Lantus®.

Recognizing that approximately half of patients treated with basal insulin were still not achieving their blood glucose (HbA1c) targets, Sanofi launched Soliqua 100/33® in 2017. Intended for adults whose Type 2 diabetes is inadequately controlled on basal insulin or an oral antidiabetic medicine, Soliqua is a fixed ratio combination of Lantus and a non-insulin glucagon-like peptide receptor agonist (GLP-1 RA) that starts working after eating a meal. GLP-1s have been shown to reduce post-mealtime glucose peaks, which have been linked to cardiovascular disease in patients with diabetes; however, their use has been limited by gastrointestinal (GI) side effects. Soliqua has demonstrated reduction in average and overall glucose levels and reduction in GI side effects, with similar rates of hypoglycemia – thus allowing balance of lowered glucose levels without more hypoglycemia. Moreover, Soliqua has been found to have a beneficial effect on body weight, addressing one of the unwanted side effects of insulin.

These three products are among five insulin products currently manufactured by Sanofi.

In 2000, Lantus launched in a vial, so patients needed to inject the product with a syringe. Since that time, we have developed several more convenient injection devices for administering insulin. Our latest pen delivery system, SoloSTAR®, has been a key improvement in easing the daily burden of insulin administration for patients. Sanofi partnered with premier design firms to develop this pre-filled, disposable injection pen for self-administration that has improved the lifestyle and medication compliance of millions of diabetes patients. The SoloSTAR contains numerous features specifically designed to address the needs of people with diabetes, who often have health complications such as impaired vision and reduced dexterity. The pen's features include a clutch that couples and decouples complex internal mechanisms from each other to allow patients to "dial up" a dose for injection; dose dial stops that prevent patients from setting an excessive dose; a rotating dial that can easily correct an over-dialed dose; and a specially designed injection button that is easy for people with diabetes to depress and receive a highly accurate delivery of the set dose. All of the pen's complex mechanical features and parts were seamlessly incorporated into the SoloSTAR's design, while still providing a robust and reliable feel suitable for daily use by patients with a chronic condition. Sanofi launched the Lantus SoloSTAR in 2007, and it very quickly became the gold standard for pre-filled, disposable injection pens. It has won awards for its novel design.

Sanofi developed Toujeo SoloStar with several innovative design features and attributes, ranging from the length of time it can be held without overheating the contents, to other ergonomic features designed to make the pen delivery system easier to use. Additionally, Sanofi developed SoloStar Max®, which holds more units in the reservoir (900 vs 450) and gives

the patient the ability to dose up to 180 units in one injection vs the 80 units in the SoloSTAR pen, allowing for fewer injections and potentially for fewer refills and related copays.

We continue to study the safety and efficacy of our products for higher risk patient populations who would benefit from the more stable pharmacokinetic and pharmacodynamic profile, such as children and geriatric patients with diabetes. Sanofi understands that randomized clinical trials do not always provide a full picture of patient outcomes, so we have launched one of the most comprehensive real world evidence studies for a diabetes medication in the United States. We are studying Toujeo in diverse settings, ranging from a randomized, pragmatic prospective trial to predictive analytics and machine learning applied to large patient datasets. We believe that studying our medications in real world settings will continue to help drive needed innovation in diabetes treatment.

Looking to the future, our scientists are working on ways to potentially transform diabetes care by treating the underlying disease. To this end, Sanofi has a multi-pronged approach, through which we seek to prevent the progression of diabetes to insulin-dependence or restore insulin-producing cells through stem cell technologies. In addition, we recognize that the greatest contributor to the current diabetes epidemic is obesity. Our researchers are exploring the molecular mechanisms by which obesity leads to diabetes, and working to design molecules that aim to restore healthy metabolism and thereby stop diabetes in its tracks. This type of research, and the development of these new technologies, takes many years, and we continue to invest in these projects with the hope that we can eventually transform the lives of these patients.

II. Rising Costs of Insulin for Patients

While the treatment of diabetes has been transformed by medical innovations, including multiple new discoveries to improve the quality and delivery of insulin, the landscape in which patients access medications has also fundamentally changed, and not for the better. We understand the anger of patients who cannot afford the insulin they need due to rising out-of-pocket drug costs.

In order to develop meaningful solutions for patients, it is critical to take a comprehensive look at what is driving rising costs for patients. Given the number of factors that contribute to determining out-of-pocket costs for patients, every actor of the supply chain, including manufacturers, has a role to play in solving this problem.

We want everyone – including patients, providers, payers, pharmacy benefit managers (PBMs), policy makers, and regulators – to understand why we set prices as we do, and we want to reaffirm our commitment to our core principles of access, affordability and innovation.

While list prices of medicines often receive the most attention, they reflect the initial price we set for our medicines. The list price is <u>not</u> the amount Sanofi receives <u>or</u> the price typically paid by government and commercial insurers, employers, or PBMs. Under the current system,

players within the supply chain – including PBMs, plans, wholesalers, distributors, and group purchasing organizations – receive either rebates and/or fees based on a percentage of the list price. Their economic incentives are therefore directly linked to the list price. As long as the net price grows at a predictable rate or even decreases, the greater the list price, the greater the economic returns for many players in the supply chain.

List price is the starting point for negotiations with payers and sometimes impacts patient out-of-pocket costs. But focusing solely on the list price does not tell the whole story. In the current system, manufacturers pay significant rebates as a percentage of the list price to government and private payers, as well as other intermediaries, in an effort to improve access for patients. As described later in my testimony, due to these rebates, the average aggregate net price of our products, including our insulin products, has declined over the last several years.

In some cases, affordability issues are the result of changes in health plan designs, such as the increase in the number of high deductible health plans (HDHPs). Among those with private health insurance, enrollment in HDHPs has increased since 2010. The design of these plans generally requires patients to pay the full list price of medicines during the deductible phase of the program, rather than the negotiated drug price available in the insurance portion of the plan.

In other cases, affordability issues are caused by changes in insurance design, which increasingly require patients to pay higher cost-sharing amounts for their medicines, even when the prices of those medicines have stayed relatively flat or declined for the health plan. For example, the average net price of Lantus, our most prescribed insulin, has declined by over 30 percent since 2012, while the average out-of-pocket burden for patients with commercial insurance and Medicare has increased by approximately 60 percent over that same period. In this case, not only are discounts apparently not being passed on to patients, but patients are in fact being asked to pay <u>more</u> when PBMs and health plans are paying <u>less</u> for the medicine.

Increasing out-of-pocket costs also can result from changes to prescription drug formularies, which have a significant impact on the amount of out-of-pocket costs a patient will be asked to pay. A recent opinion piece in the New York Times[1] highlights how changes to prescription drug formularies can not only create confusion and frustration for providers and patients but also ultimately increase costs for patients when the medicines they need are not covered on a formulary's preferred tier.

Sanofi provides rebates to PBMs and health plans to improve patient access to, and affordability for, Sanofi insulins. We want these rebates, which have grown in recent years and have resulted in substantially lower net prices, to benefit patients. Unfortunately, under the current system, savings from insulin rebates are not consistently passed through to patients in the form of lower deductibles, co-payments or coinsurance amounts.

---

[1] *See* https://www.nytimes.com/2019/01/18/opinion/cost-insurance-diabetes-insulin.html.

Given the complexity in the system and number of factors that impact out-of-pocket costs, every part of the health care system has an obligation to work to solve this problem. I appreciate that this Subcommittee is taking a holistic approach to collecting information on what is causing the problem for patients. As we consider solutions to address patient access and affordability, it is essential that we not undermine the incentives and rewards for scientific risk-taking and discovery that are the hallmark of the United States ecosystem and economy.

III. Sanofi Actions to Improve Patient Access & Affordability

As a global health care leader, Sanofi has a long-standing commitment to promoting health care systems and policies that make our insulins accessible and affordable to patients in need. We believe we can play an important role in the development of constructive solutions that will benefit both patients and the healthcare system as a whole.

Sanofi is – and will continue to be – an industry leader in helping to address this challenge. While many factors, including decisions affecting patient out-of-pocket spending and insurance coverage, are influenced or controlled by others in the health care system, we recognize that there are actions we can take to help improve access and affordability for patients.

For our part, we recognize that we must price our medicines transparently and according to their value, while at the same time contributing to broader solutions that improve patient outcomes and the financial sustainability of the U.S. health care system. That is why in May 2017 Sanofi announced our progressive and industry-leading pricing principles to help stakeholders understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines.[2]

These principles include a pledge to keep annual list price increases at or below the projected U.S. National Health Expenditure (NHE) growth rate, an estimate of medical spending calculated by the Centers for Medicare and Medicaid Services (CMS) and often used as a measure of healthcare inflation. These principles apply to all of our prescription medicines if a price increase results in more than a $15 annual increase in the price of the medication. In addition, we committed to making both our average aggregate list and net price changes across our portfolio transparent to help illustrate how revenue accrues to Sanofi versus other parts of the pharmaceutical supply chain.

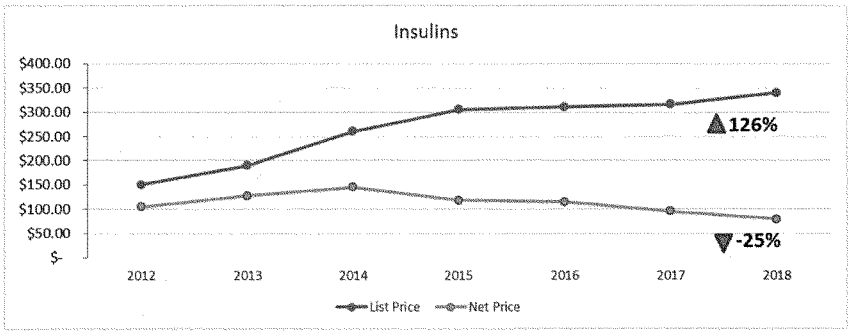
In 2018, all of our price increases were consistent with our principles, as are all pricing actions we have taken in 2019. Across our entire portfolio of medicines, the average aggregate list price increase was 4.6 percent while the average aggregate net price – that is, the actual price paid to Sanofi – declined by 8.0 percent.

[2] *See* https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf

The declining average aggregate net price in 2018 represents the third consecutive year the amount that health plans and PBMs pay Sanofi for our medicines has declined.

Specific to insulin, the average aggregate net price across all Sanofi insulin products has declined for the past four years, and based on existing contracts, will fall again in 2019. **For our entire insulin portfolio, the average net price is 25 percent lower today than it was in 2012.**[3]

Sanofi Insulins List vs. Net Price Changes[4] Between 2012-2018



When considering the patient access and affordability challenges of insulin, it is important to not only look at list price changes over time, but also net price changes. For example, Lantus, our oldest and most prescribed insulin, is frequently cited in stories about increasing insulin prices. While the list price of Lantus has increased significantly since it was approved, the net price – the amount Sanofi receives after discounts and rebates – has been declining for several years. In fact, the net price of Lantus today is lower than it was in 2006.

Unfortunately, competition among various diabetes treatments, and the resulting insulin net price declines, has not resulted in lower out-of-pocket costs for patients. As noted previously in my testimony, while the net price of Lantus has declined by over 30% since 2012, out-of-pocket costs for patients with commercial insurance and Medicare Part D have increased by approximately 60% over that same period of time.

In addition to our pledge to limit price increases in the U.S., Sanofi's pricing principles include a commitment to transparency in how we price new medicines coming to the market for the first time.

---

[3] Based on internal review of pricing actions and payer contracting.

[4] List Prices are calculated by dividing Gross Sales (sales at List Prices before discounts and rebates) by total trade units sold. Net prices calculated by dividing Net Sales (sales after discounts and rebates) by total trade units sold.

When we set the price of a new medicine, we hold ourselves to a rigorous and structured process that includes consultation with external stakeholders and considers four factors:

1) A holistic assessment of value, including: (a) clinical value and outcomes, or the benefit the medicine delivers to patients, and how well it works compared to a standard of care; (b) economic value, or how the medicine reduces the need – and therefore costs – of other health care interventions; and (c) social value, or how the medicine contributes to quality of life and productivity. Our assessments rely on a range of internal and external methodologies, including health technology assessment (HTA) approaches and other analyses that help define or quantify value and include patient perspectives and priorities.

2) Similar treatment options available or anticipated at the time of launch in order to understand the competitive landscape within the disease areas in which the medicine may be used.

3) Affordability, including the steps we must take to promote access for patients and contribute to a more sustainable system for payers and health care delivery systems.

4) Unique factors specific to the medicine at the time of launch. For example, we may need to support ongoing clinical trials (including longer-term outcomes studies), implement important regulatory commitments, or develop sophisticated patient support tools that improve care management and help decrease the total cost of care.

Applying these methodologies, Sanofi has launched a number of innovative products at prices well below the competition. In the insulin space, we launched, and are committed to maintaining, Admelog®, a biosimilar of insulin lispro, at the lowest list price of any mealtime insulin.

With the right incentives in the system, our approach to setting launch prices for these new medicines coupled with our limit on list price increases should have had the effect of ensuring affordable access for patients.

Sanofi Patient Support Programs

Sanofi has adopted a variety of approaches to work within the current system to improve access and affordability of insulin for patients. We have developed some of the most forward leaning programs to help patients afford Sanofi's insulin products.

Commercially insured patients qualify for our co-pay assistance program, regardless of income, which reduces the financial burden for insulin products. Through this program, over 90% of participating patients pay either $10 or $0 per month for their Sanofi insulin. While current regulations prohibit us from offering this type of program to patients insured under Medicare

or similar federal or state programs, Sanofi supports efforts that would expand this access program to all those who might benefit.

Additionally, we created the Insulin Val***you*** Savings Program in 2018. The intent of the Insulin Val***you*** Savings Program is to provide relief for those who currently pay high variable retail prices for their insulin and do not qualify for other assistance programs. Through this program, eligible individuals can access all Sanofi insulins for $99 per 10 mL vial or $149 for a pack of SoloStar pens – roughly a one-month supply – at a discount of up to 60 percent below the list price, resulting in savings of up to $3,000 per year. There are no income requirements, and the program is available at U.S. pharmacies. Since it was launched last April, the program has resulted in approximately $10 million in patient savings.

For eligible uninsured and underinsured low-income patients, including Medicare patients, Sanofi offers many of our medicines, including our insulin products, at no charge through its Sanofi Patient Connection patient assistance program. We are proud that, in 2018, more than 93,000 patients participated in the Sanofi Patient Connection program.

Despite the many challenges and perverse incentives that exist in our health care system, Sanofi's commitment to patient affordability means that today, approximately 75 percent of all patients taking Sanofi insulin pay less than $50 per month. We believe many others may be eligible for one of these programs to reduce their costs, and we continue to promote these programs to raise awareness about the support that is available.

Last week, Sanofi joined other insulin manufacturers to fund a program that limits insulin co-pays to $25 for patients covered under ESI and Cigna plans. While this out-of-pocket maximum is greater than patients may pay if they enroll directly in Sanofi's co-pay assistance program, which may reduce a commercially insured patient's out-of-pocket burden to as low as $0, we believe this new initiative launched by ESI and Cigna will unquestionably lower out-of-pocket costs for some patients.

IV. Solutions

I am proud of Sanofi's leadership to help improve access and affordability to insulin products for patients. However, despite the actions we have taken, on behalf of everyone at Sanofi, I know more needs to be done. My testimony today is intended to provide a more transparent and open picture into the system surrounding access to insulin therapies in order to enable this Subcommittee to consider a common set of facts and design solutions to meet urgent patient needs. I hope we can all agree on market-based policy solutions that will incentivize a high-value, highly competitive, and sustainable health care system that improves the affordability of innovative medicines in the U.S.

It is my belief that targeting list price alone will not be sufficient to address patient access and affordability. Just lowering list prices, without guarantees that those lower-priced medicines would be included on formularies at affordable, low co-pay tiers may not solve the problem for

most patients. Sanofi's Insulin Val***you*** savings program offers significantly less expensive access to all of our insulin products even when compared to recent actions by others to lower list prices. The solution to insulin access and affordability must include protections for patients, tying responsible pricing to both access and affordability.

There are a variety of ways to accomplish this goal, and Sanofi could support any number of options that align to our core principles:

1) The U.S. should continue to maintain a strong ecosystem for innovation. As such, any policy proposals should strictly avoid directly and artificially controlling the price of medicines, either through price controls set by the federal government, or worse, outsourcing that decision to other governments. Policy proposals that we believe would fundamentally undermine the unique innovation ecosystem of the United States include reference pricing, importation, or price controls set by CMS.

   Based on our experience in other countries, these approaches may be effective at controlling budgets for central payers, but come at a steep cost for patients – namely limiting access to innovative treatments. Additionally, given that the U.S. is the world's leader in science and innovation – and the jobs that come with it – these approaches pose additional risks to the U.S. economy and future scientific discovery. Finally, and most importantly, given the differences between systems, these approaches may do little to improve access and affordability for patients.

   As we have experienced, within the current system, declining prices for payers or new treatments priced at responsibly lower list prices are no guarantee that those actions will translate to affordability or access for patients.

2) Changes to the pricing system must be holistic, and the benefits should accrue to patients. As noted previously, simply enacting price controls will not solve the problem of access and affordability for patients. We believe system incentives need to change to encourage smaller list price increases, or list price reductions, by requiring health plans to cover those medicines that meet these standards at affordable co-pay levels and only allow access restrictions consistent with the product label and accepted evidence-based best clinical practice.

If policies solely target the list price of medicines without these common-sense patient protections, our shared goal of lowering insulin costs – for both government and patients – while maintaining the engine of innovation in the United States to bring innovative medicines to patients will not be fully achieved. To appropriately accomplish our shared objective of greater access and affordability for patients, Sanofi is willing to contribute our fair share to offset any financial impact to the health care system as long as patient access and affordability are improved for all patients.

Sanofi supports and recommends several policy solutions to incentivize responsible pricing behavior. To ensure that these changes do not create a windfall for manufacturers or health plans and PBMs, Sanofi recommends applying these policies only to medicines that satisfy certain limits on price increases. This approach will shift the current incentives in the system to reward "good" behavior in a manner that truly helps patients. Several of the solutions outlined below are also priorities for Members of this subcommittee and I look forward to the opportunity to work with you on advancing these and other policy initiatives:

First, reducing out-of-pocket costs for patients is our top priority. Sanofi has identified a number of ways to effectively reduce out-of-pocket costs for consumers and broadly supports tradeoffs between price and access to help patients, including the following:

- Whether through legislation, implementation of the Anti-Kickback Safe Harbor rebate proposed rule, or changes in market dynamics, link lower list prices to improved access and affordability for patients.
- All payments in the supply chain should be de-linked from list price, which would remove the perverse incentive that sometimes feeds the cycle of higher list prices paired with higher rebates.
- Require a substantial portion of the discounts and rebates paid by manufacturers to reduce costs for patients at the pharmacy counter.
- Change government price reporting rules and the Anti-Kickback statute in a manner that would promote value-based contracting.
- Implement an annual out-of-pocket cap for Medicare beneficiaries.
- Allow Medicare beneficiaries to access manufacturer co-pay assistance programs.
- Change or clarify government price reporting rules to make it easier to reduce list prices on medicines that have been on the market for a long time – namely by (1) making clear that the government pricing metrics for the new, lower list price drug do not have to be averaged with the metrics for older, higher list price drug and (2) permitting a company to treat the new lower price drug as a new product for purposes of Medicaid rebate calculations, which will help to link the rebate liability for the new drug to the new drug's lower price as opposed to the higher price for the old drug.

Second, Sanofi supports policies that further cultivate a highly competitive free market system and reward the type of entrepreneurial risk-taking necessary to the discovery and development of life-saving new medicines. A key element of that system is strong and predictable intellectual property protection. However, after a reasonable period of time – which I believe is already reflected in U.S. law – generic and biosimilar medicines should quickly enter the market to offer long-term access at lower costs. To help accomplish these goals, Sanofi supports:

- Increasing competition among medicines. Whether through prohibiting "reverse payment" patent settlements, requiring timely access to samples for generic or biosimilar manufacturers, establishing a clear patent listing of biologics through a "Purple Book", or further encouraging the development of biosimilar insulin products, Sanofi supports robust competition to encourage continued development of life-saving medicines. At Sanofi, we make product supply available to generic and biosimilar manufacturers developing data necessary for FDA applications for their products. We do this in a timely manner and on commercially reasonable terms. We support both the CREATES Act and the Purple Book Continuity Act as passed out of the full Committee last week.

- Increasing system-wide transparency, which would improve competition by making relevant information available to patients and policymakers. Providing more information about what is driving costs in the system and how money is flowing through the system will allow for increased competition and better-informed decision making. Policies that include price reporting requirements to incentivize responsible pricing behavior have the potential to change current practices, but they should be modified to protect confidential information and preempt similar state law policies in order to create a single set of requirements.

- Requiring health plans and PBMs to disclose an annual list of medicines for which the net price has decreased, as well as how the decrease (or value generated by it) was allocated among the health plans, PBMs, government payer, and patients.

Finally, Sanofi supports many of the recommendations made by the Congressional Diabetes Caucus in its whitepaper[5] entitled: "Insulin: A lifesaving drug too often out of reach," including the following:

- Encourage the development and use of value-based contracts between insulin makers and PBMs.

- Promote the use of payment arrangements between insulin makers and wholesalers that involve standardized fees instead of rebates.

- Require insulin makers, PBMs, and health insurers to disclose the value and volume of rebates that they receive and share with other entities in the insulin supply chain.

- Link patient out-of-pocket costs to negotiated prices instead of list prices.

- Allow generic manufacturers to produce older, off-patent insulin formulations.

- Require manufacturers to disclose their insulin's list pricing process.

---

[5] https://diabetescaucus-degette.house.gov/sites/diabetescaucus.house.gov/files/Congressional%20Diabetes%20Caucus%20Insulin%20Inquiry%20Whitepaper%20FINAL%20VERSION.pdf

- Standardize the process for requesting exemptions or filing appeals from formulary changes.
- Standardize drug formulary disclosure of patient cost-sharing information.
- Limit the number of changes an insurer is permitted to make to a formulary each year.
- Cap out-of-pocket expenses for prescription drugs that are needed for chronic conditions.

V. Conclusion

I look forward to having a productive conversation about the complexities of the current prescription drug pricing system and proposals to improve affordable patient access to high quality, innovative life-saving medications such as insulin to drive optimal health outcomes.

Thank you for the invitation to speak with you today and I look forward to working with you.

Ms. DEGETTE. Thank you so much.

The Chair now recognizes Mr. Moriarty for 5 minutes, thank you.

STATEMENT OF THOMAS M. MORIARTY

Mr. MORIARTY. Thank you, Chairwoman DeGette, Ranking Member Guthrie, and members of the subcommittee. My name is Thomas Moriarty and I serve as the Chief Policy, and External Affairs Officer, and General Counsel for CVS Health. Thank you for the opportunity to discuss ways to make healthcare more affordable, particularly for the millions of Americans with diabetes and those who are pre-diabetic.

A real barrier in our country to achieving good health is cost, including the price of insulin products which are too expensive for too many Americans. Over the last several years, list prices for insulin have increased nearly 50 percent. Over the last 10 years, list price of one product, Lantus, rose by 184 percent. The primary challenge we face is that unlike most other drug classes there have been no generic alternatives available even though insulin has been on the market for more than 30 years.

Despite this, CVS Health has taken a number of steps to address the impact of insulin price increases. We negotiate the best possible discounts off the manufacturers' price on behalf of the employers, unions, Government programs, and beneficiaries that we serve. Our latest 2018 data indicates that we have been able to reduce the total cost of diabetes drugs including insulin by 1.7 percent, despite brand inflation in that year of 5.6 percent.

Importantly, patient adherence has also increased. Specifically, we have replaced two very high cost insulins, Lantus and Toujeo, with an effective lower-cost, follow-on biologic called Basaglar. By making Basaglar preferred, member out-of-pocket costs declined by over 9 percent. Among patients who switched to Basaglar, their A1C or blood sugar levels were improved by 0.43. To put this in perspective, every one-point improvement in A1C among patients with uncontrolled diabetes is correlated with approximately $1,400 savings per year in medical cost for each patient. This is a real-life example of how competition works.

Despite these efforts, we know this is not enough. Let me share a story about a company and their experience with diabetes. This company saw the human toll on their colleagues and continued to see escalating costs. In response, the company began offering employees and their families zero-dollar copays for insulin, providing coverage for diabetes medications even before the deductibles were met. That means there are no out-of-pocket costs, so employees are more likely to take their medications, improve their health, and achieve lower costs. That company is CVS Health, and when something works for us, we offer these solutions to our clients.

We also offer a number of tools for patients to help reduce their out-of-pocket costs and provide transparency at the doctor's office, at the pharmacy counter, and directly to the patient. For Caremark members, when they are in the doctor's office getting a prescription, we provide their doctors with real-time information about what is covered under their insurance and if there are effective, lower cost, therapeutic alternatives available. We also provide this information directly to patients online or on their phone. For CVS

Pharmacy customers, regardless of their PBM or health plan, the Rx Savings Finder tool enables our pharmacists to work with patients to find the most affordable medications that they need.

Beyond these tools, a coordinated care approach to diabetes is essential. We've taken the lead with a program we call "Transform Diabetes Car" which furthers our focus on providing patient care that eases the complexity of self-management, improves health, and reduces overall costs. Using connected glucometers, a high-touch engagement model, and local points of care, clinicians are better able to support specific member needs as their care requirements evolve.

Finally, Madam Chairwoman, despite what we've accomplished we know that more needs to be done. Let's bring more effective, lower cost alternatives to market faster by ending pay-for-delay schemes. Let's foster the widespread adoption of zero-dollar copays on preventive medications like insulin, recognizing that if we treat these diseases effectively, we can save lives and save money, and let's pass your proposal to reform Medicare to provide additional support services for patients with diabetes to manage their own care.

We look forward to working with you and the committee to help accomplish our shared goals. Thank you, and I'll answer any questions that you may have.

[The prepared statement of Mr. Moriarty follows:]

Testimony of Thomas M. Moriarty
Executive Vice President, Chief Policy and External Affairs Officer, and General Counsel for CVS Health
United States House of Representatives, Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
April 10, 2019

Chairwoman DeGette, Ranking Member Guthrie and members of the Subcommittee, my name is Thomas Moriarty, and I serve as the Chief Policy and External Affairs Officer and General Counsel for CVS Health. Thank you for the opportunity to join you today to discuss ways to make health care more affordable, particularly for the millions of Americans with diabetes and those who are prediabetic.

A real barrier in our country to achieving good health in our country is cost, including the price of insulin products, which are too expensive for too many Americans.

Over the last three years, list prices for insulin have increased nearly 50 percent. And, over the last ten years, the list price of one product, Lantus, rose by 184 percent. The primary challenge we face is that unlike most other therapeutic classes, until recently, there have been no generic alternatives available, even though insulins have been on the market for more than 30 years.

Despite this, CVS Health has taken a number of steps to address the impact of insulin price increases:

We negotiate the best possible discounts off the manufacturer's price on behalf of employers, unions, government programs, and the beneficiaries that we serve.

And our latest 2018 data indicates we have been able to reduce the total cost of diabetes drugs, including insulin, by 1.7 percent despite brand price inflation of 5.6 percent. And importantly, patient adherence has increased.

One of the ways we have driven the 1.7 percent decline in costs is by leveraging our clinical expertise. We have replaced two very high-cost insulins – Lantus and Toujeo – with an effective lower-cost follow-on biologic alternative called Basaglar. By making Basaglar preferred, member out-of-pocket costs declined 9 percent per 30-day prescription. Among patients who switched to the alternative, their A1c – or blood sugar levels – were improved by 0.43. To put this in perspective, every 1-point improvement in A1c among patients with uncontrolled diabetes is correlated with approximately $1,400 savings per year in medical costs per patient. This is a real-life example of how competition works.

Despite these efforts, we know this is not enough. Let me share a story about a company and their experience with diabetes. The company saw the human toll on their colleagues and continued to see escalating financial costs.

In response, the company began offering employees and their families zero-dollar co-pays for insulin, providing coverage for diabetes medications even before their deductible was met. That means there are no out-of-pocket costs, so employees are more likely to take their medications, improve their health, and achieve lower costs.

That company is CVS Health. We know when something works for us, it can work for our clients. And we apply this experience in our work as a pharmacy and as a pharmacy benefits manager (PBM).

We also offer a number of tools for patients to help reduce their out-of-pocket costs and provide transparency at the doctor's office, at the pharmacy counter, and directly to patients.

- For Caremark members, when they are in the doctor's office getting a prescription, we provide their doctors with real-time information about what is covered under their insurance and if there are effective lower-cost therapeutic alternatives.
- We also provide this information directly to patients online or on their phone.
- For CVS Pharmacy customers, regardless of their PBM or health plan, the Rx Savings Finder tool enables our pharmacists to work with patients to find the most affordable way to get them the medications that they need.

Beyond these tools, a coordinated care approach to diabetes is essential. We've taken the lead with a program we call Transform Diabetes Care, which furthers our focus on providing patient care that eases the complexities of self-management, improves health, and reduces overall costs. Using connected glucometers, a high-touch engagement model, and local points of care, clinicians are better able to support specific member needs as their care requirements evolve.

Finally, Madam Chairwoman, despite what we've accomplished, we know that more needs to be done.

- Let's bring more effective lower-cost alternatives to market faster by ending pay-for-delay schemes.
- Let's foster the widespread adoption of zero-dollar co-pays on preventive medications like insulin – recognizing that if we treat these diseases effectively, we can save lives and money.
- And let's pass your proposal to reform Medicare to provide additional support services to help patients with diabetes manage their own care.

We look forward to working with you and the Committee to help accomplish our shared goals. I look forward to answering questions that you may have.

Ms. DEGETTE. Thank you so much, Mr. Moriarty.

Now, Ms. Bricker, you are recognized for 5 minutes.

STATEMENT OF AMY BRICKER

Ms. BRICKER. Chair DeGette, Ranking Member Guthrie, and members of the subcommittee, thank you for inviting me to testify at this hearing. My name is Amy Bricker, Senior Vice President of Supply Chain for Express Scripts. As a registered pharmacist, I began my career in the community pharmacy setting. As Senior Vice President of Supply Chain, I am now responsible for key relationships and strategic initiatives across the pharmaceutical supply chain working directly with drug manufacturers and retail pharmacies with the objective of keeping medicine within reach for patients including those with diabetes.

Diabetes is of particular interest to me as I have witnessed the impacts of this disease personally. My younger brother, Jeff, was diagnosed with type 1 diabetes as a child. Diabetes is a life-changing diagnosis and can have devastating effects if not managed appropriately. I am passionate about ensuring patients have access to the medications they need. Today I will provide an overview of Express Scripts innovative approach to reduce the cost and raise the quality of care for people with diabetes and the more than 80 million Americans we serve.

At Express Scripts we negotiate lower drug prices with drug companies on behalf of our clients, generating savings that are returned to patients in the form of lower premiums and reduced out-of-pocket costs. Additional savings are provided through our clinical support services which enable individuals to lead healthier, more productive lives. When it comes to prescription drugs, our goal is the best clinical outcome at the lowest possible cost.

We offer innovative programs to help us achieve that goal including several programs that address the cost of insulin for patients. One example, our Diabetes Care Value Program closely manages the disease State through a holistic approach that combines the highest level of clinical care, advanced analytics, and patient engagement supported by technology. The program offers remote monitoring so that our specialist team can intervene when patient blood sugars are dangerously high or low. This program resulted in a 19 percent reduction in drug spending for diabetes.

We launched Inside Rx, a cash discount program for patients that are either uninsured or faced with high co-insurance, partnering with drug manufacturers to provide the negotiated rebate at the point of sale resulting in average discounts of 47 percent per brand drugs including an average of $150 in savings per insulin prescription. Our National Preferred Flex Formulary provides employers and health plans the flexibility to immediately add drugs to their formulary if a drug manufacturer chooses to offer a lower priced version of a drug.

Recently, Eli Lilly announced it is reducing the list price of its Humalog insulin by 50 percent. We are excited about their decision to lower the list price on this medication and encourage other manufacturers to do the same. Most recently, Express Scripts announced the Patient Assurance Program which caps the out-of-

pocket costs at $25 for 30-day supplies of insulin. We did this in collaboration with the manufacturers represented here today.

Express Scripts remains committed to delivering personalized care to patients with diabetes and creating affordable access to their medication. As expressed in several public statements, Express Scripts welcomes lower list prices. However, list prices are exclusively controlled by manufacturers. In the absence of lower list prices, the role of negotiated rebates has become increasingly important as a drug pricing strategy.

In today's system, rebates are used to reduce healthcare costs for consumers. Employers use the value of these discounts to keep benefit premiums affordable, and offer workplace wellness programs among other employee, and member-focused health initiatives. Half of Express Scripts clients receive 100 percent of rebates negotiated on their behalf. In total, 95 percent of rebates, discounts, and price reductions received by Express Scripts are returned to employers, plan sponsors, and consumers.

Our 2018 Drug Trend Report showed a 4.3 percent decrease in spending for diabetes medications for plans enrolled in our clinical solutions. For insulin, the same plans saw a 1.5 percent decline in unit cost. Express Scripts achieved this result by driving competition among manufacturers while also leveraging pharmacy discounts to drive savings. Looking to the future, we continue to support efforts by Congress and the administration to use market-based solutions that put downward pressure on prescription drug prices through competition, consumer choice, and open and responsible drug pricing.

In closing, we are proud of what we have done to date, and we look forward to working with the committee to improve the affordability of insulin products. Thank you for your consideration of this testimony.

[The prepared statement of Ms. Bricker follows:]

"Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin"

by

Amy Bricker, R.Ph.
Senior Vice President, Supply Chain
Express Scripts

Before the

House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

April 10, 2019

Chair DeGette, Ranking Member Guthrie, and members of the Subcommittee, thank you for inviting me to testify at this hearing. I am Amy Bricker, R.Ph., Senior Vice President, Supply Chain for Express Scripts.

I am a registered pharmacist and spent the beginning of my career working in the retail pharmacy setting. Prior to joining Express Scripts, I served as regional vice president of account management for Walgreens Health Services. During my ten years at Express Scripts, I have held leadership roles in pharmacy network management, supply chain economics, and retail contracting and strategy. As Senior Vice President, Supply Chain, I am responsible for key relationships and strategic initiatives across the pharmaceutical supply chain, including working with drug manufacturers and retail pharmacies to create value for Express Scripts' clients and keep medicine within reach for patients. My team also has responsibility for developing value-based contracts to address key disease states, including diabetes. Until recently, I had the honor of serving on the Medicare Payment Advisory Commission (MedPAC).

Express Scripts helps more than 80 million Americans achieve better care at a lower cost, including those in health plans, union-sponsored plans, state employee health plans, and public purchasers, Medicare Part D and Medicaid. We are proud to serve TRICARE, the health program for 9.4 million uniformed service members, retirees, and their families, for more than 10 years. Express Scripts' tools include an innovative specialty pharmacy care model for costly and complex drugs; clinically based drug utilization reviews; clinically based formulary management; medical and drug data analysis; and specialized Therapeutic Resource Centers, with pharmacists specially trained to serve a range of conditions.

Cigna completed its combination with Express Scripts in December 2018. The combination integrates two complementary companies, each with industry-leading cost trend capabilities, which together are positioned to deliver better care, expanded choice, and greater affordability. Our combined company's 74,000 employees come to work every day to enhance the health, well-being and peace of mind of the more than 160 million customer relationships we serve globally.

Cigna is a global health services company; our subsidiaries are major providers of medical, pharmacy, dental, disability and related products and services in more than 30 countries and jurisdictions around the world, including South Korea, China, India, the Middle East, and Europe. Cigna is also the largest provider of expatriate benefits in the world. In the United States, Cigna is one of the largest health services providers. We emphasize whole-person health and clinical quality to deliver choice, affordability and enhanced quality of life for our customers and clients. Key enablers of our success are collaborative relationships with providers, an emphasis on outcomes- and value-based reimbursement, robust patient support services, and transparency tools for customers and clients to make informed decisions that address their specific needs.

We strive to be a constructive participant in public policy discussions and to contribute workable solutions to societal challenges in all of the countries, markets, and jurisdictions in which we operate. The United States drives the most innovation in health services. Innovation can yield

exciting and life-changing new therapies and treatments. But innovation often comes with a high price tag, especially in the pharmaceutical sector. At Cigna and Express Scripts, we believe we can do better by our citizens to achieve better health, with greater choice, affordability, and predictability. We are focused on accelerating solutions that support both innovation and price stability, and we challenge ourselves every day to achieve those goals.

We are already making good progress. Cigna and Express Scripts' solutions for driving lower drug spending and fostering the use of lower net cost treatments are making medications more accessible for Americans. In 2018, Express Scripts' clinical first approach returned $45 billion in savings to our clients – employers, health plans, government programs, unions, and others. [1] Because of our innovative solutions and approach to pharmacy care, our clients achieved the lowest drug trend in 25 years, just 0.4 percent across employer-sponsored plans. Further, we delivered an unprecedented 0.3 percent decline in drug spending across Medicare plans. The average 30-day prescription cost Americans only 6 pennies more than in 2017. All of this was accomplished in an environment where manufacturers raised list prices 7.3 percent. We guide patients to effective, lower-cost therapies, and secure deep discounts from manufacturers and pharmacies.

I appreciate the opportunity to testify on affordability and access to insulin products in the United States. Cigna and Express Scripts support the Committee's efforts to make insulin more affordable, and new innovations more accessible, to all patients and payers in the United States.

With that context as background, our statement today focuses on the following topics:

- Our efforts to improve quality and drive value to lower health care costs;
- Increases in the list prices of insulin;
- The role of rebates in the prescription drug supply chain;
- Rebates for insulin products;
- Opportunities to improve affordability and patient care; and,
- Legislative and regulatory solutions to lower insulin costs for patients.

Our Efforts to Improve Quality and Drive Value to Lower Health Care Costs

Express Scripts' innovative pharmaceutical and pharmacy solutions position Cigna to offer even greater value to our clients, public health program partners, and patients. The combined company integrates Express Scripts' pharmacy benefit management with Cigna's health care products and services.

For example, over seven million Americans diagnosed with diabetes use insulin. Total direct and indirect estimated costs from diabetes topped $327 billion in 2017, a 26 percent increase over a five year period.[2] Medical costs for people with diabetes are 2.3 times higher than for those

[1] http://lab.express-scripts.com/lab/drug-trend-report/2018-drug-trend-report
[2] American Diabetes Association. Economic costs of diabetes in the U.S. in 2017. *Diabetes Care 2018 May;* 41(5); 917-928.

without.[3] People with diabetes in the U.S. pay between 5.7 times and 7.5 times more than those in the UK for their insulin.[4] For some patients, the increasing price of insulin limits access and adherence. When Cigna and Express Scripts announced the merger, we clearly stated we would improve choice, affordability, and predictability. Within the first 100 days of our combination, we were able to launch a new **Patient Assurance Program** which will bring additional affordability and predictability to customers who rely on insulin to manage their diabetes. This program establishes a lower fixed out-of-pocket cost for covered insulins, ensuring customers will pay no more than $25 out-of-pocket when filling a 30-day insulin prescription at a retail pharmacy or through home delivery. This is just one example of private sector innovation and solutions aligning incentives in the financing and delivery of care.

Express Scripts uses clinical expertise and scale to negotiate lower drug costs with drug manufacturers, leveraging competition to help drive savings for clients, which include employers, labor unions, health plans, the federal government, and states. These negotiations serve to create competition in the market for prescription drugs. The discounts negotiated in the supply chain for our clients ultimately benefit patients in the form of lower premiums and reduced out-of-pocket costs. Additional savings are realized when clients take advantage of Express Scripts' clinical support services, which enable individuals to lead healthier and more productive lives.

When it comes to prescription drugs, our goal is to achieve improved clinical outcomes at lower costs. Express Scripts offers several innovative programs to help us achieve that goal:

- Our **SafeGuardRx℠** programs allow us to help our clients closely manage high-cost drug classes through a holistic approach that combines clinical care with advanced analytics, and patient engagement supported by technology. Through SafeGuardRx Solutions, we have leveraged value-based arrangements to take on some of the most challenging therapy classes, including hepatitis C, high cholesterol, cancer, inflammatory conditions, pulmonary conditions, and multiple sclerosis.

- One of our SafeGaurdRx programs – The **Diabetes Care Value Program** – improves pharmacy care while controlling plan costs for people with diabetes. Developed with drug makers and launched in 2017, the program has reduced diabetes drug spending by 19 percent—a total savings of $42.6 million. The program combines specialized diabetes pharmacist care with benefit strategies, such as utilization management and quality pharmacy networks, and improved compliance with recommended treatment guidelines.

- Our **National Preferred Flex Formulary** is a unique approach that provides employers and health plans with the flexibility to take advantage of the possibility of a drug manufacturer choosing to lower the price of a drug by offering an authorized generic alternative. Should the manufacturer offer an authorized generic, that product can be added to the formulary. In the end, we care most about the lowest net cost of a drug, not

[3] https://www.cdc.gov/diabetes/data/statistics-report/deaths-cost.html
[4] https://www.dailymail.co.uk/health/article-3269835/The-transatlantic-drugs-divide-Patients-pay-THREE-TIMES-drugs-UK.html

the rebate. We welcome manufacturers lowering their list prices so that patients can have greater access to medications. Eli Lilly recently announced it is reducing, by half, the price of its Humalog® insulin. We are proud more manufacturers are responding to our call to lower prices and increase affordable access to medicine. We are in discussions with Eli Lilly about a Humalog® authorized alternative, and if the net cost is lower, we will add it to our Flex Formulary.[5]

- **SmartShareRx℠** offers employers and plan sponsors more flexibility in how they use rebate savings. The program was established to share estimated rebate savings on eligible medications to combat patients' primary pain point: cost-sharing in the deductible phase. However, the program has evolved to apply estimated rebate value to eligible medications filled in all phases of the pharmacy benefit to reduce patients' out-of-pocket costs at the pharmacy counter. For more than 10 years, we have offered the option to clients to provide rebate value at the point-of-sale. To date, only a handful of clients have opted to apply rebates at the point of sale and instead use those discounts to offset premiums and benefit designs.

- **Inside Rx℠** is a prescription savings program launched in partnership with drug manufacturers and retail pharmacies to expand affordable access to brand and generic medications for patients with no insurance, high deductibles, or high out-of-pocket costs, by offering discounts to these patients at the point-of-sale. Since the launch of the program, in May of 2017, we've helped patients save an estimated $400 million. Insulins are among the brand drugs for which Inside Rx offers more affordable options to those in need. The average patient savings on brand insulin products through the Inside Rx savings program is $150 per claim. Savings on branded diabetes products averaged 47 percent in 2018, and savings on all diabetes products, brands and generics, averaged 52 percent.

Express Scripts builds products that fit a wide variety of use cases, working to uniquely partner across the health care ecosystem to uncover opportunities, take action, and deliver better outcomes. Express Scripts' **Real Time Prescription Benefit**, launched last November, helps to simplify the patient's experience with their prescriber and improve the transparency of drug costs. Real-time clinical alerts that reach physicians through electronic prescribing systems can turn data into actionable patient intelligence, helping people stay on their therapy and avoid dangerous drug-drug interactions. We provide patient-specific information and pricing information directly into the physician's Electronic Health Record (EHR) within seconds. Physicians using electronic prescribing can see the following information to inform prescribing decisions:

- Alternative drugs and associated details, such as generic vs. brand pricing;

- Coverage information, including electronic prior authorization requirements, step therapy requirements, or quantity limits; and,

[5] http://lab.express-scripts.com/lab/insights/drug-options/flexibility-to-make-insulin-more-affordable

- The patient's cost through each pharmacy dispensing channel: retail, home delivery or specialty pharmacy.

By providing drug cost information and reconciling coverage issues at the point of prescribing, we are eliminating confusion and pain points for patients at the pharmacy counter. A 2018 annual report by Surescripts on price transparency found that provider adoption of Real-Time Prescription Benefits has grown by 1,338 percent, with monthly benefit checks growing to over 6 million by December 2018.[6] Surescripts' data shows that Real-Time Prescription Benefit saved patients as much as $8,032 in out-of-pocket costs on a single prescription.[7] These systems are delivering measurable savings to patients at the pharmacy counter, while ensuring providers and patients are communicating to make better-informed medication choices. Electronic prior authorization capabilities are improving as well, allowing prescribers to switch the drug 28 percent of the time and eliminating over 158,000 hours of potential wait time in December 2018, according to Surescripts' report.

Increases in the List Prices of Insulin

Express Scripts welcomes lower list prices, known as a manufacturer's wholesale acquisition cost ("WAC"), and has gone on record favoring them. List prices are exclusively controlled by manufacturers. [8] Over the last several years, the list prices for insulin products have steadily increased. We've seen rates of growth in list prices of widely-used insulins increase more than 50 percent—and in some cases even higher—over the last five years. Cigna and Express Scripts share this Committee's concerns about the affordability of insulin, and we are working every day to lower the cost of this life-saving medication for the patients we serve.

We have not observed a manufacturer *decreasing* its list price for any insulins. It is important to note that nothing in our contracts with manufacturers addresses the maintenance of list prices, and certainly nothing in our contracts prohibit a manufacturer from *decreasing* the list price of a drug.

The Role of Rebates in the Prescription Drug Supply Chain

Approximately 90 percent of all prescriptions we fill are generics. The remaining 10 percent are branded drugs, which represent 70 percent of the spending on prescription drugs. We believe there are targeted solutions to address this 70 percent. We work to do this through sophisticated, evidence-based negotiations for clinically equivalent therapies.

Solutions for driving lower drug spending and fostering the use of lower net cost treatments often include negotiating discounts or rebates. The role of rebates in prescription drug pricing has been mischaracterized. Rebates are not the cause of increasing drug prices. Rebates are discounts paid by drug manufacturers after a patient receives a manufacturer's drug. In the system today, rebates are used to reduce health care costs for consumers. Today, employers and

[6] https://surescripts.com/news-center/press-releases/!content/new-data-from-surescripts-shows-that-patients-are-getting-more-affordable-prescriptions-faster-and-with-less-hassle
[7] https://surescripts.com/news-center/press-releases/!content/price-transparency-at-the-point-of-care-boosts-patient-savings-and-prescriber-efficiency
[8] https://www.businessinsider.com/express-scripts-responds-to-gilead-drug-pricing-comments-2017-3

others use the value of discounts to help keep premiums affordable, lower out-of-pocket costs, and offer workplace wellness programs, just to name a few ways they put discounts to work.

Most drugs do not involve a rebate structure. For example, rebates are not typically offered for generic medications, for drugs without market competition (*i.e.,* sole-source brand drugs), or for drugs administered by a physician. According to a study of drugs covered under Medicare Part D by the actuarial firm Milliman, 81 percent of all drugs analyzed do not offer rebates and 64 percent of brand drugs analyzed do not offer rebates.[9] Many sole-source, highly expensive specialty drugs, like drugs to treat cancer, do not offer rebates and continue to be priced higher and higher:

- In 2017, non-rebated drugs treating depression, high-cholesterol, infertility, and other conditions all registered price increases of more than 15 percent.[10]
- List prices for oral oncology medications, which are not rebated or discounted to any significant extent, doubled between 2011 and 2016, from $20 per unit to $40 per unit.[11]
- Looking at the 39 oral oncology medications on the market in 2010, six experienced 100-200 percent inflation between 2010 and 2016; one was greater than 300 percent and another one was greater than 800 percent.[12] Rebates are not available on these drugs, but the manufacturers continue to increase list prices.

Restricting or eliminating rebates does not assure improved affordability for patients or taxpayers:

- A study by the actuarial firm Oliver Wyman found that rebates reduced overall costs in Medicare Part D by $34.9 billion from 2014 to 2018, and eliminating rebates would have driven Part D premiums higher by 52 percent in 2018 alone.[13] From 2014 to 2018, the national average Part D premium increased less than two percent per year. Manufacturer rebates are one of the major contributors to holding premiums relatively flat over the last five years.
- The Centers for Medicare and Medicaid Services' (CMS) Office of the Actuary (OACT), in reviewing the Department of Health and Human Services' (HHS) recently proposed rule addressing rebates in Medicare Part D and Medicaid, estimates that Part D premiums will increase by as much as 25 percent and that federal spending will increase by $196 billion over ten years.[14]

---

[9] Milliman, Prescription Drug Rebates and Part D Drug Costs. July 16, 2018. The Milliman analysis focused on approximately 1,300 drug and therapeutic class combinations, reflecting 97 percent of 2016 Part D gross drug spending.
[10] Express Scripts, Let's Talk About Rebates, May 15, 2018. http://lab.express-scripts.com/lab/insights/industry-updates/lets-talk-about-rebates
[11] Express Scripts, The Cost of Hope: 5 Things to Know about the Cost of Cancer Drugs. May 30, 2017. http://lab.express-scripts.com/lab/insights/industry-updates/the-cost-of-hope-5-things-to-know-about-the-cost-of-cancer-drugs
[12] http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter
[13] Oliver Wyman, Premium Impact of Removing Manufacturer Rebates From the Part D Program. July 2018. https://www.pcmanet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf
[14] https://aspe.hhs.gov/system/files/pdf/260591/OACTProposedSafeHarborRegulationImpacts.pdf

- Data released by the Centers for Medicare and Medicaid Services (CMS) for 2019 Part D premiums, and national average plan bids, show a negative trend for the first time in more than a decade.[15] CMS cites drug manufacturer and pharmacy price concessions as a factor driving lower costs.
- A *Health Affairs* analysis of the most recent National Health Expenditures prescription drug forecast for 2017-2026 concluded that increased rebates "contributed to lower net prices for many prescription drugs in recent years and are expected to have dampened prescription drug spending growth in 2017."[16]
- The actuarial firm Milliman found that on average, the highest cost drugs have the lowest manufacturer rebates (as a percentage of gross drug cost), for brand drugs with rebates.[17]

In the Medicare Part D program, rebate savings are passed to Part D plan sponsors and are responsible for saving enrollees and taxpayers billions of dollars each year since the Part D program began. CMS requires plans to show how they are using rebates to deliver Part D coverage to their members. All Part D plan sponsors must submit to CMS detailed annual reporting of rebate amounts by drug and Part D plan. In addition to reporting individual drug rebates, plan sponsors must also report to CMS how much of the rebate amounts were retained by the pharmacy benefit manager (PBM) rather than being shared with the sponsor, rebate guarantee amounts, rebate amounts reflected at the point-of-sale, third-party payer claim rebate amounts, and any other rebate amounts not already reported. Not only are plan sponsors required to report these rebate amounts to CMS, but they must also report what the rebates are for, such as formulary or tier placement, market share targets, volume targets, inflation rebates, or rebate guarantees. Finally, plan sponsors must report any administrative fees charged to manufacturers.[18]

In the commercial market, rebates are an effective tool that employers and health plans use to generate more savings for prescription drugs. Employers and other plan sponsors that work with Cigna and Express Scripts choose how rebates are used. Some use them to lower premiums and cost sharing, others choose to expand access, fund wellness programs, or provide discounts to consumers at the point-of-sale. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates. Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers.

---

[15] 2019 Medicare Advantage ratebook and Prescription Drug rate information. https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data-Items/2019Rates.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending

[16] *Health Affairs*, National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth. February 14, 2018. https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1655

[17] Milliman, Prescription Drug Rebates and Part D Drug Costs. July 16, 2018.

[18] Final Medicare Part D DIR Reporting Requirements for 2017. Accessed 3/4/19 at: https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-May-30th.html

Cigna welcomes the opportunity to work with policymakers to bring down drug prices for patients at the pharmacy counter. There are a number of opportunities to address high list prices and patient exposure at the pharmacy counter that address competition, access to generics, and benefit designs. However, legislative or regulatory efforts to eliminate or restrict the ability of plan sponsors or PBMs to negotiate overall lower costs will lead to higher drug prices, not only for Medicare beneficiaries and taxpayers, but also for millions of individuals who access health benefits through their employers.

We believe there are more direct and effective ways to deliver relief to patients most in need without disrupting coverage for millions. For example, in addition to the policy opportunities discussed later, we believe a better way to address patient out-of-pocket costs is to allow payers and their PBMs to use the power of benefit designs to limit beneficiary exposure while ensuring payers continue to have all of the tools at their disposal to negotiate lower costs. For individuals in high-deductible health plans, this could include changes to the tax code to allow coverage of chronic care treatments and other services pre-deductible, for example. Additionally, many have discussed possible changes to the Medicare Part D benefit design to achieve lower patient out-of-pocket costs, and Cigna and Express Scripts welcome the opportunity to be a constructive participant in those efforts for both Medicare Part D beneficiaries and patients in the commercial market.

Rebates for Insulin Products

Express Scripts negotiates retrospective rebate discounts with manufacturers of all major insulin products. The amount of rebate discounts varies significantly based on utilization and a plan's benefit design. The overall value extracted from manufacturers through rebates has increased over time, as has the value shared with our clients.

Express Scripts also negotiates discounts from retail pharmacies that dispense insulin, although it generally does not negotiate rates specific to insulin products. Discounts realized by clients at pharmacies vary significantly based on the benefit design, pharmacy network, geography, and the type of pharmacy.

Express Scripts has published data regarding general trends around the net costs of drugs, and particularly the cost of medications used to treat diabetes. Our most recent Drug Trend Report showed a 4.3 percent decrease in spending for diabetes medication in 2018 for plans enrolled in our clinical solutions. For insulin, the same plans saw a 1.5 percent decline in unit cost. This net decline in insulin per unit cost occurred despite a growth in the average list price of insulin products during the same period. Express Scripts achieved this result by driving competition among manufacturers while also leveraging pharmacy discounts to drive savings.

Regarding clients' net prices for drug products, closely managed plans that adopt strong clinically-driven benefit designs generally experience slower growth in their net cost, or in some cases even a flat or negative trend in net cost, even when the list prices change. Comparatively, plans that offer broader benefits generally experience higher rates of growth in net cost. We have observed that, on average, and particularly over the last five years, the net cost to our clients for

insulins, like many other drugs, has generally increased at a lower rate than the rate manufacturers have increased list prices.

Opportunities to Improve Affordability and Patient Care

We believe that our national formularies drive clinical efficacy at lower costs. Insulins are considered highly interchangeable by our National Pharmacy & Therapeutics Committee, which is comprised of 15 independent physicians and one pharmacist. In fact, many competing insulin products contain the same active ingredient (e.g., Humulin® vs. Novolin®; Lantus® vs. Basaglar®) and we offer clients exclusions in certain categories. In August, we announced our 2019 NPF changes, of which there are 48 new formulary exclusions. Less than 0.2 percent of members will see a change in coverage for a medication. These changes will save plans an estimated $3.2 billion; cumulative savings for plans leveraging the NPF since 2014 is estimated to reach $10.6 billion.

As with formularies, copay tiers and other elements of benefit design are ultimately determined by Express Scripts' clients. 64 percent of high-deductible health plans used the preventive drug list offered by Express Scripts which includes first-dollar coverage of insulin. Clients may also select a narrower network of retail pharmacies where their members can fill insulin prescriptions, generally at greater savings. Further, Express Scripts offers clients various utilization management options to further reduce costs for members covered by their plans.

Value-Based Contracting for Insulin

As noted previously, Express Scripts also offers several value-based arrangements, including our Diabetes Care Value Program, and we continue to develop program offerings for insulin and other products that focus on value enhancement.[19] We believe that arrangements that tie reimbursement with patient outcomes is key to improving value and health outcomes for patients with diabetes.

Regarding potential value-based contracts for insulin, Express Scripts would recommend monitoring outcomes such as hemoglobin A1c/glucose goals, escalation of therapy, and hypoglycemic episodes for patients. Given the complexity of dosing and management for insulin, these alternative factors will provide appropriate indicators of a patient's response to insulin therapy over a short term period and subsequently appropriate pricing of insulin based on outcomes. We would provide blood glucose remote monitoring devices for patients on insulin that connect to a care manager to monitor when blood sugars are too high or low. Based on overall performance of the drug in connection with the monitoring, and whether the patient had any hypo/hyper episodes or emergency room visits as a result, we would receive value back from the manufacturer for lack of performance or to cover emergency room visits.

Improving Insulin Adherence

[19] See, e.g., http://lab.express-scripts.com/lab/insights/drug-options/flattening-the-trajectory-of-the-diabetes-epidemic

Despite industry demand for a uniform standard for measuring insulin adherence, no such standard exists due to wide variations in patients' medication administration directions and use. Typical industry methods of measuring adherence for other medications involve calculation of Medication Possession Ratio (MPR) or Proportion of Days Covered (PDC). Both of these measures are commonly used to determine whether a patient has sufficient supply of medication on hand to maintain adherence to their prescribed drugs. Due to variable dosing of insulin based upon individual blood glucose levels, the number of units a patient should be taking is very difficult to calculate for an accurate MPR or PDC.

Express Scripts saw an overall 1.9 percent improvement in *Adherence for Diabetes Medications,* the quality metrics tied to the 2017 CMS Star Ratings for clients in a Preferred Value Network. Express Scripts started measuring this variable in 2017 with the launch of our first Preferred Value Network. Due to the lack of an industry standard to measure insulin adherence, Express Scripts offers a number of solutions and attempts to identify adherence gaps through numerous methods: predictive modeling, late-to-fill logic, and proactive adherence opportunities. Our clinicians, who have therapy-specific specialized training, partner with pharmacies to identify and recommend programs to best address nonadherence.

Proprietary predictive modeling is used, in combination with personalized clinical services and interventions, to attempt to prevent or minimize nonadherence. Information is first gathered on patients' potential personal adherence obstacles, such as cost, clinical concerns, and/or personal behaviors or preferences. The predictive models are then used to assess which patients are at risk to be nonadherent in the future. Using this data, a tailored approach is made—through personal clinical services and interventions with licensed pharmacists—to attempt to prevent or minimize future nonadherence.

Late-to-fill logic takes an active approach to message patients who are late to fill a medication. Upon login to the Express Scripts' website, the individual will receive a message that prompts the individual to act to fill the medication, speak with a specialist pharmacist, arrange for a follow-up reminder, or indicate that the medication is no longer needed. Pharmacy records are automatically updated with the individual's selection. Individuals immediately react 45 percent of the time when receiving a late-to-fill message.

Express Scripts also utilizes a number of proactive adherence opportunities. Medication refill reminders are sent via mail, email, phone, the member website, and through mobile apps. Express Scripts also sends gap in care alerts and enhanced messaging to remind patients about managing their care through standard mail, email, mobile applications and electronic medical records.

Legislative and Regulatory Solutions to Lower Insulin Costs for Patients

We support efforts by Congress and the Administration to use market-based solutions that put downward pressure on prescription drug prices through competition, consumer choice, and open and responsible drug pricing. For example, last year we endorsed legislation championed by Rep. Buddy Carter and others to ensure patients are told the lowest cost option available to them at the pharmacy counter. We were pleased the legislation became law, and included a provision

authored by Rep. John Sarbanes and Rep. Bill Johnson to provide more transparency into so-called "pay-for-delay" agreements that prevent biosimilar drugs from entering the marketplace.

In our 2018 Drug Trend Report, Express Scripts indicated that no new widely used generics will be available until 2023, and that utilization and costs are expected to increase for diabetes medications.[20] We continue to hope that the recent appropriate reclassification of insulin as a biologic product by the Food & Drug Administration (FDA) provides an opportunity for other manufacturers to bring insulin products to the market with lower prices, which will drive down the prices brand name insulin manufacturers currently charge.

Express Scripts supports and continues to advocate for legislation that can reduce prescription costs for American families by bringing generic and biosimilar products to market as soon as possible. With an expected cost of 15 percent to 40 percent less than originator products, biosimilars create a significant savings opportunity across the U.S. health care system.

Looking to the future, we believe efforts to address out-of-control drug pricing through legislative and regulatory actions should include:

- **Speeding generics and biosimilars to market**:
    - Enacting the Creating and Restoring Access to Equivalent Samples (CREATES) Act, introduced by Rep. Peter Welch and Rep. David McKinley, among others, which aims to lower drug prices by ending restricted access to samples by manufacturers of brand-name drugs, and help to speed generics to market. We applaud the Committee for its recent passage. According to the Congressional Budget Office, its passage would save $3.9 billion over 10 years. [21]
    - Prohibiting patent settlements that include so-called "pay-for-delay" arrangements, which delay the availability of lower-cost generics and biosimilars. Legislation to address these arrangements was recently introduced by Rep. Bobby Rush, and we applaud the Committee for its recent passage. We hope Congress will enact authority to block these anti-competitive agreements, removing barriers to competition and expanding the availability of lower-cost generics and biosimilars. According to a Federal Trade Commission (FTC) study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.[22]
    - Encouraging the FDA to finalize guidance on biosimilar naming standards, improve the efficiency of the biosimilar product development and approval

[20] Diabetes trend will increase as no new widely used generics are coming to market until Januvia® (sitagliptin) generics become available in 2023. Greater utilization of diabetes medications is expected due to population aging and the obesity epidemic. *See* Express Scripts 2018 Drug Trend Report, pg. 17. https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf
[21] https://www.cbo.gov/system/files/2018-09/s974.pdf
[22] https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay

process, and develop effective communications tools to educate providers and patients about the safety and efficacy of biosimilars.

- Preserving the ability of the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office to invalidate patents that do not represent true innovation. Legislative and regulatory efforts to weaken this process will extend patent monopolies for pharmaceutical and biological products, resulting in higher prices for patients.
- Considering changes to provisions included in the United States-Mexico-Canada Agreement (USMCA) that would extend exclusivity for biological products in Mexico and Canada for ten years. These provisions will limit the ability of Congress to address the 12-year exclusivity period for brand-name biologics.

- **Advancing price transparency for patients and providers in public programs:**
  - We strongly support the concept of providing information about the price of drugs, therapies, and the cost of care to beneficiaries and their providers as a means of improving price transparency, educating consumers, and incentivizing the efficient use of care throughout the health care system. We support efforts by CMS to move toward a system in which Part D enrollees and their providers have access to real-time benefit check and electronic prior authorization tools, while ensuring an appropriate standardization and timeframes for implementation.
- **Advancing value-based arrangements in public programs:**
  - It is essential to bring the benefit of value-based payment to spending in public programs. Such arrangements may involve outcomes-based payments that cannot be determined until well after the plan year concludes. Changes to existing laws and/or regulations would allow for such arrangements in all settings and help improve the overall value of national spending for pharmaceuticals. The specific changes Cigna and Express Scripts believe are needed include:
    - Modifying Medicaid Best Price (MBP) rules to exclude outcomes-based pharmaceutical contracts from inclusion in MBP calculations in certain situations where failure to achieve a desired outcome leads a manufacturer to refund the full (or majority) cost of the drug, or where payment is contingent on the health outcomes of individual patients;
    - Creating additional flexibility under the Anti-Kickback Statute (AKS) to support value-based contracts and other innovative programs; and,
    - Revising Part D regulations to explicitly permit and provide guidance for how outcomes-based contracting should be accounted for in plan bids or between plan sponsors when the outcome measurement period spans plan years, or when outcomes can only be measured at the end of a plan year.
- **Prioritizing reforms to lower costs and protect patient access in Medicare:**

- Public programs must also have the ability to leverage the commercial market's successful utilization management tools that lower costs while protecting patient access. We also support efforts to modify the six protected "classes of clinical concern" in Part D, where all or substantially all drugs in a class must be covered, allowing drug manufacturers to name their price with little negotiation. CMS' plan to only moderate the effect of protected classes—not eliminate them—would save $2 billion over 10 years.
- There are also clear opportunities to achieve savings in the Medicare Part B program, including introducing Part D utilization management tools into Part B and potentially shifting some Part B drugs to Part D. Because of the complexity involved with identifying the "candidate" drugs for moving into Part D, along with assessing the consequences and impacts of doing so for both programs, we strongly recommend CMS engage stakeholders through a work group-type process where sample, de-identified data could be shared for mutual evaluation.
- We support efforts to ensure the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment Advisory Commission (MACPAC) have access to de-identified information submitted currently by PBMs, Part D sponsors, and Medicare Advantage plans to CMS. Legislation to address this issue was recently introduced by several members of this Committee, including Rep. Buddy Carter, Rep. Tom O'Halleran, Rep. Greg Gianforte, and Rep. Peter Welch. We applaud the Committee for its recent passage.

- **Stopping Orphan Drug Act abuses**:
  - Pharmaceutical manufacturers have been accused of abusing the Orphan Drug Act, which was introduced to incentivize drug manufacturers to prioritize the development of "ophan drugs," drugs used to treat an illness or disease that affects fewer than 200,000 people. We support efforts to ensure that this pathway is used for true orphan designation, and not, as some observers say, as a legal cover to seek specious orphan drug designations.[23]

Thank you for the opportunity to be here today, and for the consideration of our views. We look forward to working with you and others to improve the affordability and accessibility of insulin products. Many of the proposals highlighted in my testimony are achievable if we work collaboratively, throughout the system, to overcome the challenges facing public and private stakeholders, and the health of our nation.

I welcome the opportunity to discuss these issues with you and look forward to your questions.

[23] https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/

Ms. DEGETTE. Thank you.

Dr. Dutta, you are now recognized for 5 minutes.

STATEMENT OF SUMIT DUTTA

Dr. DUTTA. Chair DeGette, Ranking Member Guthrie, Chairman Pallone, Ranking Member Walden, and members of the subcommittee, good morning. I am Dr. Sumit Dutta, Chief Medical Officer of OptumRx, a pharmacy care services company whose dedicated employees ensure the people we serve have affordable access to the drugs they need. I'm honored to be here to discuss steps we can all take to reduce the cost of insulin.

The OptumRx team includes 5,000 pharmacists and pharmacy technicians who help patients learn how to take their medications, avoid harmful drug interactions, manage their chronic conditions. Our nurses infuse lifesaving drugs in patients' homes, our efforts have helped lower overprescribing in opioids. Our diabetes management program offers personalized patient-driven services to high-risk members to help them manage their diabetes.

OptumRx's negotiated network discounts and clinical tools are reducing annual drug costs on average by $1,600 per person for our customers. Our efforts start with a clinical assessment by our pharmacy and therapeutics committee comprised of independent physicians and pharmacists. They evaluate our formularies based on scientific evidence, not cost. These meetings are open and transparent to our customers. Cost only becomes a factor after this independent committee has identified clinically-effective drugs in a therapeutic class.

Because OptumRx promotes the use of true generics to drive costs lower through competition, about 90 percent of the prescription claims we administer are for generics. Unfortunately, in the case of insulin there are no true generic alternatives. Because many branded insulin products are therapeutically equivalent, we negotiate with brand manufacturers to obtain significant discounts off list prices on behalf of our customers.

Already, 76 percent of the people we serve who need insulin pay either nothing at the pharmacy or have a fixed copay, most commonly $35. For insulin users on high-deductible or coinsurance plans, we have taken action to help them directly benefit from the savings we're negotiating with manufacturers. Last year, we dramatically increased the discounts at the pharmacy counter for millions of eligible consumers who are now seeing an average savings of $130 per eligible prescription and the savings are even higher on insulin.

Last month, we announced the decision to expand this point-of-sale discount solution to all new employer-sponsored plans beginning January 2020. Nevertheless, the price of insulin remains too high. A lack of meaningful competition allows manufacturers to set high list prices and continually increase them which is odd for a drug that is nearly 100 years old and which has seen no significant innovation in decades. These price increases have a real impact on consumers in the form of higher out-of-pocket costs.

The most impactful way to reduce insulin prices is by opening the market to true generics and biosimilars. This is why we support efforts to reform the patent system and promote true generic

competition. For years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one brand to prevent competition. Others have engaged in multiyear patent disputes to delay the introduction of lower cost products.

Congress can increase competition and lower prices by passing the CREATES Act, prohibiting pay-for-delay deals and evergreening of patents, accelerating biosimilar options, and reducing the exclusivity period for drugs. We are committed to doing our part to make insulin more affordable. I would be pleased to answer any questions you have.

[The prepared statement of Mr. Dutta follows:]

Testimony of Sumit Dutta, M.D., Chief Medical Officer, OptumRx
Before the United States House of Representatives
Energy & Commerce Subcommittee on Oversight and Investigations
"Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin"
April 10, 2019

Chair DeGette, Ranking Member Guthrie, and Members of the Subcommittee, I am honored to be here today on behalf of OptumRx. Our company has 28,000 dedicated employees – including 5,000 pharmacist and pharmacy technicians – working every day to improve the quality of pharmacy care services, simplify the health care experience, and ensure that the individuals we are privileged to serve have affordable access to the drugs they need.

1. **OptumRx's pharmacy care services approach is achieving better health outcomes for patients, lowering costs for the system, and improving the health care experience for consumers.**

OptumRx helps deliver pharmacy care services to 250,000 patients each day. These services help improve health outcomes for patients and reduce costs in the system. Here are some examples:

- We communicate with patients and their physicians about how to take their medications, avoid harmful drug interactions, and access convenient home-delivery services.
- We provide drug infusion services directly in patients' homes, so that they do not need to visit a hospital to obtain the same, high-quality care. These in-home services help improve medication adherence and reduce costs.
- We have more than 450 pharmacies embedded in community mental health centers to serve the behavioral health medication needs of patients where they receive their care. Our ability to deploy those on-site services has helped improve medication adherence, reduced emergency room visits and hospitalizations and reduced overall costs by $700 per patient.
- We provide special assistance for patients who need help managing their chronic conditions, including real-time video consultations with pharmacists.
- We are helping to address the opioid crisis by implementing evidence-based programs that help prevent overprescribing by physicians and detect suspected opioid misuse, as well as offering medication-assisted treatment to patients with opioid use disorder. Our customers who have adopted our opioid management program have achieved a 96 percent adherence rate by prescribers with the Centers for Disease Control and Prevention's prescribing guidelines.

Our pharmacy care services approach is doing important work to improve health outcomes and lower costs. We are not stopping with those efforts. We are also developing consumer-friendly tools to make the health care experience more satisfying and effective for patients and providers. For example, one of these tools, PreCheck MyScript®, is a digital platform that simplifies the drug prescribing experience by showing the prescribing physician what the patient's true out-of-pocket cost would be while the patient is still in the physician's office. PreCheck MyScript® has helped lower consumer out-of-pocket costs by an average of $135 per prescription filled. This platform is just one of the ways we are working to simplify the system.

2. OptumRx negotiates better prices with drug manufacturers for our customers and consumers.

OptumRx delivers value for our customers and the consumers we serve through a number of services, including negotiating lower drug costs. And approximately 98 percent of the discounts we negotiate from manufacturers go to our customers. Historically, our customers have used these discounts to reduce the costs of drugs, help keep premiums stable and help ensure access to drugs for consumers.

We have heeded the call for change by taking direct action to ensure that the discounts we obtain directly lower consumers' out-of-pocket costs at the pharmacy counter. Last year, we implemented a point-of-sale discount solution at scale for fully insured group customers so that consumers receive the benefit of discounts at the pharmacy counter. This action has already made nearly six million consumers eligible for point-of-sale discounts. Eligible consumers filling prescriptions on discounted brand drugs are seeing average savings of $130 per eligible prescription. We believe it will also improve prescription drug adherence by as much as 16 percent. By the end of 2019 we expect more than nine million consumers will be eligible for these point-of-sale discounts. Last month, we announced a decision to expand this point-of-sale discount solution to all new employer-sponsored plans beginning in January 2020.

It is important to recognize that pharmacy benefit managers are the only stakeholders in the prescription drug supply chain working to reduce costs for their customers and the only ones able to effectively negotiate with drug companies.

OptumRx manages pharmacy benefits on behalf of customers, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and federal and state government employee plans. In that role, we promote use of clinically effective, lowest net-cost prescription drugs for consumers when medications are needed.

This work starts with an independent, clinically based formulary design process. OptumRx's Pharmacy & Therapeutics (P&T) Committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an unbiased and evidence-based way. The P&T Committee meets regularly, and its deliberations are open and transparent to OptumRx's customers and prospective customers.

A drug's cost plays no role in the P&T Committee's clinical review. Cost only becomes relevant after the P&T Committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered. If there is more than one drug in a particular class, OptumRx gives preferable placement on its formulary to the drug with the lowest overall cost to our customer. For about 90 percent of prescriptions processed, OptumRx can identify a low-cost generic drug in a particular therapeutic class, and give that drug preferred placement on its formulary over the more expensive branded (or "on-patent") drug.

Unfortunately with insulin, there are no true generic alternatives. Because branded insulin products within each class (short-acting and long-acting) are therapeutically equivalent, we have been able to negotiate with competing brand manufacturers to obtain significant discounts off list prices, allowing plans to place the drug with the lowest overall cost to the customer in a preferred position on the formulary. But the solution that will benefit everyone who uses insulin is true generic and biosimilar competition which will drive down list prices.

3. Insulin costs too much already, yet manufacturers keep raising prices.

Multiple independent studies have shown that the list price of insulin has skyrocketed in recent years. The Health Care Cost Institute (HCCI), for example, found that manufacturers doubled the price of insulin between 2012 and 2016.[1] The Journal of the American Medical Association (JAMA) published research that found insulin prices went up 197 percent between 2003 and 2013.[2] Addressing the high cost of insulin is a crucial part of reducing the overall cost of treating diabetes for our customers and consumers alike. We recognize that when the cost of insulin is too high for patients, they may be forced to make unhealthy choices like rationing their doses, or going without insulin altogether. This practice can lead to complicating health consequences and put patients at risk.

Manufacturers are increasing insulin prices for one simple reason: there is a lack of meaningful competition. In the absence of competition, manufacturers often set exceptionally high prices. Moreover, manufacturers appear to have raised the list prices of competing insulin formulations in tandem over the last decade or more.[3]

A driving factor behind this challenge is that manufacturers have been able to exploit loopholes in a U.S. patent system that is designed to reward investment in innovation. Insulin has been used to treat diabetes for nearly 100 years, and manufacturers have not introduced any significant new innovations in decades. Yet they continue to drive list prices higher and extend their patents.

For years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition.[4] Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products.

All of this legal maneuvering has led to a lack of competition from true generic alternatives, the introduction of which would have a significant and beneficial impact on list prices. This problem is particularly acute when it comes to insulin.

Manufacturers have blamed pharmacy benefit managers, health plans, and hospitals for high drug costs. They contend that the discounts or rebates we negotiate with them are the root cause of the problem. That is simply untrue.

In fact, drug prices are rising the fastest in the area of specialty drugs, where due to the importance of the drug and the lack of a clinical alternative, manufacturers are unwilling to negotiate a discount. It is no surprise, then, that the Centers for Medicare and Medicaid

---

[1] Binek & Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, Health Care Cost Institute, January 21, 2019 (available at https://healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices).

[2] Hua, Carvalho, Tew, Huang, Herman, and Clarke, Research Letter: *Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013*, Journal of the American Medical Association, Volume 315, Number 13 (April 5, 2016) (available at https://jamanetwork.com/journals/jama/fullarticle/2510902).

[3] Binek & Johnson, *supra* note 1 at 7-8; *see also* Ramsay, "There's something odd about the way insulin prices change," Business Insider, September 17, 2016 (available at https://www.businessinsider.com/rising-insulin-prices-track-competitors-closely-2016-9), citing data from Truven Health Analytics.

[4] I-MAK, *Overpatented, Overpriced Special Edition: Lantus*, October 30, 2018 (available at http://www.i-mak.org/wp-content/uploads/2018/10/I-MAK-Lantus-Report-2018-10-30F.pdf).

Services (CMS) recently reported that in 2016 and 2017 drug manufacturers raised prices the most on those drugs that have no discounts.[5]

Drug manufacturers also have responded to criticisms of the high prices they set for their products by introducing so-called "authorized generic" versions of their higher-priced brand products.

OptumRx promotes the use of true generics to drive costs lower through competition. That's why almost 90 percent of the prescriptions we administer are for generic drugs.

"Authorized generics" are not generic drugs. The marketing and production of "authorized generics" is exclusively controlled and directed by brand drug manufacturers. They do nothing to promote competition. In fact, drug manufacturers generally make more money per "authorized generic" script. In our experience, these "authorized generics" often result in net prices higher than the brand drugs they replace. "Authorized generics" are just another tactic for drug manufacturers to improve profitability.

For years, manufacturers have engaged in such tactics to extend their control over a drug, limit competition, and maximize profits at the expense of consumers. The promotion of "authorized generics" is of a kind with patent "ever-greening" and pay-for-delay deals that work to keep true generics – and real competition – out of the market.

As an example, consider a hypothetical brand manufacturer that has set the list price for its brand drug at $100. OptumRx has successfully negotiated a $70 discount off that list price, resulting in a net overall cost of $30 for the brand drug. If the brand manufacturer announces a so-called "authorized generic" at a list price of $50, the list price may be lower, but the overall net price of the "generic" is $20 higher than the brand drug. This situation may result in a lower cost-sharing obligation for some plan members in the short-term, but in the long-term it will be more expensive for plans and lead to higher overall drug costs for everyone, benefiting no one other than the manufacturers.

Finally, manufacturers assert that their net profits on insulins are going down even as list prices go up. For a drug that is 100 years old and has seen no significant innovation in decades, their profits should go down. At the same time, the FTC has recognized that in the PBM market, "competition for accounts is intense, has driven down prices, and has resulted in declining PBM profit margins."[6]

4. OptumRx is working on behalf of its customers and consumers to mitigate the impact of insulin manufacturers' price increases.

OptumRx is working to mitigate the impact of the high and rising price of insulin set by insulin manufacturers for our customers and consumers.

First, we negotiate substantial discounts from insulin manufacturers on behalf of our customers, and approximately 98 percent of those discounts go to our customers.

Second, we are leading the way to ensure that the discounts we negotiate on insulin directly benefit consumers.

---

[5] Sarah Karlin-Smith, Sarah Owermohle and Janie Boschma, "Drugs with a single manufacturer drive Medicare, Medicaid spending increases, CMS says." Politico, March 14, 2019.

[6] See, e.g., https://www.ftc.gov/sites/default/files/documents/public_statements/statement-federal-trade-commission-concerning-proposed-acquisition-medco-health-solutions-express./120402expressscripts.pdf.

- As noted above, for more than a year we have implemented a point-of-sale discount solution to ensure that consumers directly benefit from our negotiations with drug manufacturers. By the end of 2019 we expect more than nine million consumers will be eligible for these point-of-sale discounts, and beginning January 1, 2020, we will expand this point-of-sale discount solution to all new employer-sponsored plans.

- Seventy-six percent of the consumers we serve who need insulin pay zero at the pharmacy or have a fixed copay, most commonly about $35.

- OptumRx has placed insulin on its Preventive Drug List, leading by example for many of our customers to do the same. This approach takes insulin out of the deductible structure entirely for consumers in those plans.

- On average, out-of-pocket costs for the consumers we serve who need insulin are about $41 per month, which is about eight percent of the list price of the drug.

Third, we understand that paying for insulin is just one of the many hurdles diabetics must overcome to treat their disease. Comorbidities associated with diabetes like hypertension, obesity, and high cholesterol levels often also require treatment through medication. OptumRx works to reduce the costs of these drugs as well, encouraging the use of low cost generics or lower cost, therapeutically equivalent brand drugs when they are available. We also employ thousands of licensed pharmacists and pharmacy technicians who, in addition to being available by phone 24 hours a day, 7 days a week, provide face-to-face or virtual consultations and coaching to help consumers manage chronic conditions. And where possible, we use data and analytics to identify opportunities to engage consumers on health actions that help improve outcomes and lower total cost of care.

5. Sensible policy reforms will help make drugs more affordable.

The actions described above have significantly blunted the impact of rising list prices for many of the consumers we serve, and we will continue to find creative and fair solutions to this problem for those who might still be vulnerable to high list prices. But absent more competition in the insulin market, we expect to see manufacturers continue to increase their prices.

An effective intellectual property environment plays an indispensable role in both promoting drug discovery and ensuring innovations are affordable and sustainable. Today's intellectual property system does not work as intended. The most important step Congress can take to address the high cost of prescription drugs is to modernize the intellectual property system. Several reforms can help eliminate drug manufacturers' ability to manipulate the patent and regulatory system and thereby prevent lower-cost generics and biosimilars from reaching consumers more quickly. Specifically, Congress should:

- Pass the bipartisan CREATES Act to end the manipulation by drug manufacturers of the Risk Evaluation and Management Strategies (REMS) program to block timely entry of generic competition;

- Prohibit "pay-for-delay" settlements between manufacturers that delay the market entry of lower-cost alternatives;

- Restrict "ever-greening" of patents in which drug manufacturers make minor changes to their product, or to the delivery technology for their product, to extend the patent exclusivity period;

- Reduce the exclusivity period for brand and specialty drugs; and
- Continue FDA reforms to promote greater uptake of biosimilars, which is even more important with FDA's recent guidance to treat insulin as a biosimilar beginning in 2020.

If the Administration intends to finalize the Proposed Safe Harbor Rule, it should prevent the disruption of the existing and proven supply chain and ensure that pharmacy benefit managers are explicitly authorized to facilitate discounts at the point of sale for seniors. Today, pharmacy benefit managers administer point-of-sale discounts, including for Medicare Part D, through proven, stable, secure, and highly efficient systems that have evolved through three decades of investment, innovation, and partnership with key stakeholders. Unless pharmacy benefit managers facilitate point-of-sale discounts, existing, negotiated drug discounts will be jeopardized, net prices could increase, and consumers will experience disruption.

We appreciate the opportunity to address the Committee today, and share with you the meaningful solutions we are advancing to deliver value for patients and bring down the cost of insulin. We are committed to doing our part to make insulin more affordable for people and sustainable for the country. I would be pleased to answer any questions you have.

Ms. DEGETTE. Thank you, Dr. Dutta.

It is now time for the Members to ask questions and the Chair recognizes herself for 5 minutes.

I appreciate all of your testimony. What strikes all of us on this panel, which we have heard from all of the actors in the system, is how the list price is really high, but then there are all these workarounds that some people can get to get a lower price of insulin, and let me just give you an example. Eli Lilly increased the price of Humalog from $35 in 2001 to $275 today. Novo Nordisk increased the list of NovoLog by over 350 percent since 2001. And on January 8th of this year, the insulin products of Novo Nordisk went up by 5 percent. Sanofi increased the price of Apidra from $86 in 2009 to $270 last year. And so, since January 1st, the three main brands were 4.4 to 5.2 percent gone up this year.

And most everybody here now knows my daughter Francesca, who is 25, she is a type 1 diabetic. I am not going to put anybody on the spot, but she is on a newer kind of insulin and she has insurance. She is still on my insurance for eight more months—who is counting—and she renewed her prescription at the beginning of the year. And for this insulin it says on the receipt the retail price, $1,739.79, "Your insurance saved you 1,399.79." But for her type of insulin she is on, the list price is $347.80 per bottle. Now she didn't pay that because she is on insurance, but she still paid quite a bit because I have a pretty high deductible.

So here is the thing everybody is saying, "Well, sure the list price is high, but there are all these workarounds." But not everybody gets the workarounds, and the question is why is the list price so high? So, I am going to ask each one of you, and I have really limited time.

Mr. Mason, I am wondering if you can tell me in 30 seconds, how does Eli Lilly justify these huge increases in list prices in the past 10 or so years?

Mr. MASON. Thank you for the question. I hope your daughter is doing well.

Ms. DEGETTE. Yes, forget about that. Just, please.

Mr. MASON. Seventy-five percent of our list price is paid for rebates and discounts to secure access, so people have affordable access——

Ms. DEGETTE. That is what is making the price go up and up?

Mr. MASON. Two hundred and ten dollars of a vial of Humalog is paid for discounts and rebates.

Ms. DEGETTE. OK, Mr. Langa, same question.

Mr. LANGA. So as you heard last week from Dr. Cefalu from the ADA, there is this perverse incentive and misaligned incentives and this encouragement to keep list prices high, and we've been participating in that system because the higher the list price, the higher the rebate.

Ms. DEGETTE. So, you also think it is because the rebates that the prices have gone up so much in the last 10 years?

Mr. LANGA. There's a significant demand for rebates. We spend almost $18 billion.

Ms. DEGETTE. OK, I am sorry.

Ms. TREGONING. Yes, as part of how we set list prices, we have to look at the dynamics of the supply chain including the rebates.

We have at Sanofi limited ourselves to list price increases no greater than national health expenditures across every one of our products.

Ms. DEGETTE. OK.

OK, now, Mr. Moriarty, I bet you have a different perspective on why the list price of insulin is so high.

Mr. MORIARTY. Chairwoman, rebates are discounts. And as we've disclosed, more than 98 percent of those discounts go back to our clients.

Ms. DEGETTE. I understand, but why do you think the list prices are so high?

Mr. MORIARTY. I can't answer that. That is the pharmaceutical manufacturers' purview.

Ms. DEGETTE. But you don't think it is because of discounts?

Mr. MORIARTY. I do not, no.

Ms. DEGETTE. Ms. Bricker?

Ms. BRICKER. I concur. I have no idea why list prices are high and it's not a result of rebate.

Ms. DEGETTE. Dr. Dutta?

Dr. DUTTA. We see list prices rising double digits in non-rebated drugs, in generics where monopolies lost, or where manufacturers buy up and create monopoly, so we can't see a correlation just when rebates raise list prices.

Ms. DEGETTE. OK, so of course my time is almost up, but I think this is a good example of the problem that the Members of Congress are dealing with in trying to figure out how to solve this problem. Because it seems to me what is happening is that every component of the drug system is contributing to an upward pressure on the list price.

I know the members are going to have a lot of questions around that and we will do some follow-up at the end, so I would like to recognize the ranking member for his input, for 5 minutes.

Mr. GUTHRIE. Thank you very much. Thanks for being here. I am going to use a quick example just because I am trying to make it simple. I have been wrestling with this for about a month in trying to figure out what is happening.

If Chair DeGette was making this phone and I want to buy it and she said she is willing to take $100 for it, but she says, "I will sell it to you for 300," and give me 200 back, and that doesn't make sense. Or Chair DeGette is willing to take $100 and I say to her, "Hey, I am willing to pay 100, but charge me 300 and I will give you 200 back." The whole idea is that Brittany is the purchaser at the end and I am passing, I am giving that to her for $100 because she is the plan, she is saving the money and passing it on to her consumers, and what we are trying to figure out is where that delta is going. It is just hard to figure out and I have been spending a lot of time on it.

On February 6th, so the three manufacturers, I want to try to, because I have a few questions so try to go fast, you said that your list price has gone up, but your net price has gone down. What would happen if you just said, "Hey, I want to make my list price my net price, and put it out on the marketplace?"

So I'll let you three.

Mr. MASON. First of all, we are dropping our list price of Humalog by 50 percent with our launch of lispro insulin. For us there are many people who have access. The majority of people have access for insulin at affordable cost through their plans. That's not tied to list price, so we don't want to disrupt those by lowering list price. We think the best way is to provide in the short-term is to keep our list price at the way it is; so we don't disrupt those individuals, we don't harm the access that they have.

Mr. GUTHRIE. But if you are willing to take, I think you said you had, I don't know, whatever the net price is, I know net prices are different with different plans. There is not one net price, I get it. But if you are willing to take a net price for your product and three of you here, why wouldn't that be something out there for everyone to pay? I mean that is what you are willing to charge, right?

Mr. MASON. It's just more difficult to do that to disrupt that for a product that's on the marketplace today, because people have affordable access.

Mr. GUTHRIE. But you have had your net price and according to your testimony go up 207 percent while your list price dropped by 3 percent, according to the letter on February 6th on Humalog.

I think you all are similar too. I don't want to just do Lilly, all of you guys as well. I mean that is kind of, so we see the net price going—I understand what you are saying, but we see the net price rising. We want to know why it is doing it? Maybe there is a market reason for that and it is benefiting consumers, but we want to know.

Mr. LANGA. In the current system today, the most important thing for us is for the most number of patients to get our brands at the most affordable prices, and in the system today that is the current formulary positions. Just the three PBMs here today represent over 220 million covered lives.

Mr. GUTHRIE. OK, you said they were perverse. OK, I am running out of time.

Mr. LANGA. So that is 80 percent of the lives, so for us to lose one of those positions that would be a dramatic impact to patients in terms of the medicine that they are on, physicians in terms of their choice.

Mr. GUTHRIE. Your argument is——

Mr. LANGA. And there would be——

Mr. GUTHRIE [continuing]. You would lose your position on the formulary if you lowered your price?

Mr. LANGA. In the current system if we eliminated all the rebates, yes.

Mr. GUTHRIE. You are shaking your head, the same way?

Mr. LANGA. We believe that we would be in jeopardy of losing those positions.

Mr. GUTHRIE. You said there were perverse incentives. What are the perverse incentives?

Mr. LANGA. Well, we're spending almost $18 billion a year in rebates, discount, and fees, and we have people with insurance with diabetes that don't get the benefit of that.

Mr. GUTHRIE. What are the perverse incentives for that 18 billion in rebates? You said they are perverse——

Mr. LANGA. They're going into the system and they're misaligned, right, so that's, we believe that they should go back to the diabetic patient.

Ms. TREGONING. The issue here, Congressman, is not one of negotiation. The PBMs are very effective negotiators. It's what happens with the results of that negotiation. Those rebates are not necessarily going all the way through to patients. They're being used for other parts of the system, and we don't have visibility to how those rebates get used. Those rebates are part of how we secure formulary placement and cost sharing for the patients that are covered by those plans.

Mr. GUTHRIE. So you say, "I am willing to take X for a product, but for me to get on their formulary, I know I am going to have to raise my list price because they then want rebates," is that what you are arguing?

Ms. TREGONING. The rebates are how the system has evolved. The rebates are part of the negotiation to secure formulary placement and associated——

Mr. GUTHRIE. I went too long on that side because I am not giving you—you already talked to that, I guess. I had other questions, but I would rather hear your responses to that.

Ms. BRICKER. So as mentioned previously by my colleague to my left, of course we're looking at the clinical attributes of a product and I know you want to get to the economics. The way we make formulary decisions is based on net price. If every one of the manufacturers to my right wanted to reduce their list price, there would be no implication to the rebate status so long as the net price remained the same.

Mr. GUTHRIE. So on my example, if she is willing to sell for me a hundred and I sell to Brittany for a hundred, and you are saying rebates keep the price down, but in the end because you are selling to her at the net price, so why wouldn't the net price be—what we are trying to figure out is it seems like there is a price that is marked through the system that seems to be based on something, but there seems to be an inflation and another higher price that just seems to be caught up in the system.

But what really affects people as we have talked about, when they are going to the point of sale when they haven't hit their deductible. I know you have these plans in place and those are great, but we need to figure out the economics behind it; so if we need to do something here to help people out, we need to understand that.

I wish we had more than 5 minutes. I yield back.

Ms. DEGETTE. The Chair recognizes Mr. Kennedy for 5 minutes.

Mr. KENNEDY. Thank you. I want to thank the witnesses here and I want to thank the Chair and ranking member for holding this hearing.

I am going to follow up on some of the questions that have already been asked. I want to submit for the record though a Boston Globe piece from last November. I have done this before in other hearings about individuals, two mothers that brought ashes of their children in front of Sanofi in Boston, in Cambridge, back in November trying to protest these prices.

You all have, you know why we are here, and you know what the challenges are. I can tell you even from being here for a couple minutes how frustrating it is to be on this side of the dais, and watch everyone do this. So I also, I hope, and I expect that you will also understand that if that is the result of this hearing that we are not, you are hearing bipartisan frustration on this. You are not going to—the status quo is not going to continue, it can't.

We heard testimony last week from patients that were literally rationing, putting their lives on hold, or taking serious risks for themselves and their children, to be able to get access to medicine that was patented and sold for a dollar.

And, sir, Mr. Mason, you began by saying about the 75 percent of that increase over the course of the past several years increase in list price goes to PBMs. The data that I have indicates that over the past—since 2002 to 2013, Endocrine today estimated the average price went from $231 in 2002 to $736 in 2013, inflation adjusted. Seventy-five percent of that is roughly $375. That means 127—50 percent of that baseline price is not PBMs.

Where is the other 50 percent? What justifies the other $127 increase?

Mr. MASON. You know, our net prices have gone down since 2019, so the—or since 2009. We haven't taken a price increase until since 2017.

Mr. KENNEDY. Sir, have you ever lowered a price off of your formulary?

Mr. MASON. We are launching a lower priced Humalog that's 50 percent off.

Mr. KENNEDY. It took 15 years and global outcry on this to do it? What factors go into—have you ever lowered the price off of a formulary?

Mr. MASON. We have lowered our net price over the last 10 years.

Mr. KENNEDY. What factor goes into lowering that price? What evaluation do you take to lower that price?

Mr. MASON. What evaluation, you know, a decade ago we were on formularies, all formularies, now we're on formularies about, you know, half, about half of formularies, patients in America have our insulins because we're moving to strictly formularies. We have to provide rebates in order to provide and compete for that so people can use our insulin.

Mr. KENNEDY. Mr. Langa, have you ever lowered a list price?

Mr. LANGA. We have not.

Mr. KENNEDY. Why not?

Mr. LANGA. For two reasons, as I said the biggest vehicle today for the most majority of patients in this country——

[Simultaneous speaking.]

Mr. LANGA. No, it's formulary position. So that's the best way for us today to reach the most amount of patients in an affordable way and anything that risks that is something that we have to strongly consider. Everything's on the table right now for Novo Nordisk. We want to be part of the solution.

Mr. KENNEDY. If it takes us hauling you in after people are telling us that they are rationing the lives of their children, how does this work? I understand that part of this comes back on us. You

guys are responding to incentives that Congress sets and a lack of regulation, a lack of oversight to allow this to happen. But from my position at the moment, trying to figure out what levers to push and pull, we are asking what goes into the factors to set that list price, we don't get an answer. To lower risk price, it either hasn't happened or we don't know. You place the blame on the major of the hike of it to going on the PBMs and the PBMs are putting it back at you.

If you were in my position, what do we do to try to make sure that patients in this country get access to lifesaving medication, that was initially discovered for a buck and sold to a university, to ensure that every person could get access to it? What do you suggest?

Mr. LANGA. I suggest that we all come together to come up with solutions, get together with Congress to make sure that rationing never happens again. As I mentioned in my opening statement, one patient is too many. And as an organization that's for 90 years been committed to patients with diabetes, it's tragic and it should never happen.

Mr. KENNEDY. Ms. Tregoning?

Ms. TREGONING. Congressman, no one should be rationing insulin. No one——

Mr. KENNEDY. And they do every day.

Ms. TREGONING. We need to make those patients more aware of the programs that are available.

Mr. KENNEDY. What do you do—the programs, ma'am, there were people here last week that said those programs take weeks to get into that there are not transparency on it. They can't wait six weeks to get an insulin shot.

Ms. TREGONING. Congressman, our copay assistance programs can be accessed in a matter of minutes online, and so, people with high-deductible health plans——

Mr. KENNEDY. Do you have any patients that don't have access to internet?

Ms. TREGONING. We also have phone numbers where patients can call.

Mr. KENNEDY. How long does it take for them to be able to access those programs? What percentage of folks do you deny?

Ms. TREGONING. For copay assistance and for—we have, it's literally a matter of moments for the VALyou Savings Program that we accessed, that we announced today, the expansion——

Mr. KENNEDY. That you announced today when you are in front of Congress?

Ms. TREGONING. It's an expansion of a program that we started last year, $99 for the insulin that they need in any combination at the pharmacy counter; people can get access to that. It's for uninsured patients. For those with high-deductible health plans, they can access copay assistance that's no more than a $10 copay.

Mr. KENNEDY. I am way over time.

But for the folks that are uninsured that are paying your full list price——

Ms. TREGONING. For the folks that are uninsured paying full list price——

Mr. KENNEDY. I yield back.

Ms. TREGONING [continuing]. They now have access as of June, $99 at the pharmacy counter for the insulin that they need per month.

Ms. DEGETTE. The Chair recognizes the ranking member of the full committee, Mr. Walden, for 5 minutes.

Mr. WALDEN. Thanks again, Madam Chair, for having this hearing. Thanks again to our witnesses for being here.

Ms. Tregoning, in 2018, Sanofi launched Admelog. Now I understand that is a follow-on biologic to Eli Lilly's Humalog. Now according to press articles, Sanofi launched Admelog at a list price that is about 15 percent less than the list price for Humalog. Is that pretty close?

Ms. TREGONING. Yes. It's the lowest rapid-acting list priced insulin.

Mr. WALDEN. OK. Typically, when a generic medicine enters the market, we expect for the price of the generic to be less than the branded; and many patients to switch from the brand medicine to the generic medicine. You have told us, however, that Admelog is not on the formulary for any commercial plans. I believe that is correct?

Ms. TREGONING. No. Yes, correct. It's only available through Managed Medicaid.

Mr. WALDEN. Given that Admelog was launched at a lower list price than Humalog, what barriers are preventing patients from this alternative and are there issues gaining formulary access for Admelog?

Ms. TREGONING. Congressman, we were unable to secure formulary access through rebating with Admelog. As to exactly why those decisions were made, I'd have to defer to my colleagues on the other side of the panel.

Mr. WALDEN. Has Sanofi faced these barriers for launching any other products?

Ms. TREGONING. Yes, Sanofi has brought a number of products to patients at lower prices including Kevzara, which is a lower list price of a rheumatoid arthritis medicine, and we similarly face challenges.

Mr. WALDEN. Given Sanofi's experience with Admelog, do you think more follow-on biologics and biosimilars of insulin will help reduce the list price of insulin, or does the biologic market function differently than introduction of a generic of a small molecule drug?

Ms. TREGONING. There is already competition in the insulin market as I believe one of the colleagues referenced. Eli Lilly introduced a follow-on biologic version of Lantus several years ago and so there is competition. CVS in its testimony spoke to the fact that they were able to leverage greater rebates and negotiate through that.

Mr. WALDEN. Now, I want to switch to Mr. Mason and thanks again for being here. We have heard that sometimes a branded biologic manufacturer may tell pharmacy benefit managers, PBMs, and health insurance plans that they will no longer provide rebates for their branded product, if the PBM or health insurance plan puts a follow-on biologic or biosimilar on the formulary. Has Eli Lilly told any PBMs or health insurance plans that it will no longer

provide rebates for Humalog if the PBM or health insurance plan puts Admelog on its formulary?

Mr. MASON. No, we haven't.

Mr. WALDEN. All right.

Ms. Tregoning, similarly did Sanofi tell any PBMs or health insurance plans that it would stop providing rebates for Lantus if the PBM or health insurance plan put Basaglar on their formulary?

Ms. TREGONING. No, nothing.

Mr. WALDEN. Mr. Moriarty, has a manufacturer ever said they would stop providing you rebates for a product if you put a competing product on your formulary?

Mr. MORIARTY. Not that I'm aware of, sir.

Mr. WALDEN. OK, so that has never happened.

Mr. Moriarty, Ms. Bricker, and Mr. Dutta, why isn't Admelog included on your formulary?

Ms. BRICKER. The challenge that we have with Admelog specifically is one of net cost. And so through the mechanisms that we use today, which are rebates or discounts, it was more expensive than competing product. Manufacturers do give higher discounts for exclusive position, so I think that was your question to my counterpart here on the right.

Mr. WALDEN. Yes, if each of you could answer that.

Ms. BRICKER. Yes, so to the extent that we have recognized one product as exclusive, other manufacturers will—that exclusive product will receive less discount if additional products are added.

Mr. WALDEN. Why not include both?

Ms. BRICKER. We'll receive less discount in the event that we do that.

Mr. WALDEN. What?

What about the others on the panel, Mr. Dutta and Mr. Moriarty, can you speak to this?

Dr. DUTTA. The lowest cost product gets preferential position on our formulary. So, for example, generics which are very low cost have preferential position.

Mr. WALDEN. OK.

Mr. Moriarty?

Mr. MORIARTY. Similarly, we drive to lowest available cost, lowest cost product. And with the example of Basaglar we were able to move that follow-on biologic to preferred status and actually have most, if not all, patients now on that one.

Mr. WALDEN. We keep hearing the manufacturers should just lower their list prices, but a lower list price doesn't necessarily guarantee that a manufacturer will have access to patients, or that that patient will pay a lower price at the pharmacy counter. Do you take the list price of a medicine into consideration when making formulary decisions?

Mr. MORIARTY. We do not. We focus on the lowest available cost, the lowest net cost.

Mr. WALDEN. All right.

Ms. Bricker?

Ms. BRICKER. The same, yes, lowest net cost.

Mr. WALDEN. Mr. Dutta?

Dr. DUTTA. Lowest net cost, and for the member we consider their cost by using point-of-sale discounts and in order to lower their cost out-of-pocket.

Ms. DEGETTE. I just want to follow up on the ranking member's questions for Mr. Moriarty and Dr. Dutta. Why then if you look at generics and the lowest cost, why aren't either of your PBMs putting Admelog on these plans?

Mr. MORIARTY. Madam Chair, we have gone with Basaglar as the follow-on biologic alternative and the preferred status for that category.

Ms. DEGETTE. OK.

Dr. Dutta?

Dr. DUTTA. It would cost the payer more money to do that.

Ms. DEGETTE. Why?

Dr. DUTTA. Because the list price is not what the payer is paying. They're paying the net price.

Ms. DEGETTE. The Chair now recognizes Dr. Ruiz.

Mr. RUIZ. Thank you, Chairwoman.

The rising cost of drugs is such a big problem that it has reached kitchen table, family conversations across America. Those families are struggling, worried about having to decide between paying for insulin or paying their bills. There has been a lot of rhetoric today, and finger pointing in the drug pricing debate; and oftentimes the conversation is based on theoretical arguments about what will work for manufacturers, or PBMs, or insurance companies, with little regard to what works for patients.

As a doctor, I put my patients' needs above all else and our solutions should do the same and reduce out-of-pocket costs for patients. In my district, according to the Health Assessment & Research for Communities 2016 survey, one out of four adults diagnosed with diabetes in the Coachella Valley are living below the Federal poverty line; and over 10 percent of adults diagnosed with diabetes do not have health insurance that covers some or all of the cost of their prescription drugs. This is not just a problem for the uninsured or underinsured either.

Just this week I heard from Tamara Smith and David Richard, two constituents who had to go on a specialized form of insulin that isn't covered by their insurance. That means hundreds of dollars more out-of-pocket every month. So reducing the list prices of drugs or increasing the number of generics does not solve the problem, if these savings are not lowering out-of-pocket costs for people like Tamara and David. The CEO of Diabetes Patient Advocacy Coalition drove home this point in her testimony last week in stating, "Somebody's making a profit and it's not the patients."

So, Mr. Mason from Eli Lilly, who is making a profit from these increases in insulin prices?

Mr. MASON. You know, I think, first of all, we don't want anyone not to be able to afford their insulin.

Mr. RUIZ. Who is making a profit with these increases in insulin prices that patients have to pay for?

Mr. MASON. Our net price is the price that we receive are going down.

Mr. RUIZ. Are you?

Mr. MASON. No.

Mr. RUIZ. Are you making a profit? Are the CEOs of your companies making these profits?

Mr. MASON. Our net prices, the price that we receive has gone down since 2009.

Mr. RUIZ. Well, somebody is making a profit. Somebody is getting richer on the backs of our patients.

Mr. Langa from Novo Nordisk, what entity in the supply chain is prioritizing affordability and access of insulin for patients?

Mr. LANGA. Well, we'd like to think we are. I mean we participate in as many formularies as we can. As I've mentioned that is critically most important. We have Patient Assistance Programs as well as copay assistance programs.

Mr. RUIZ. Who is making a profit then?

Mr. LANGA. Well, our nets are going down as well, but there is a small profit that——

Mr. RUIZ. Your nets, but your overall profits for the company and CEOs have been going up, haven't they?

Mr. LANGA. No. Our profit has been——

Mr. RUIZ. Take-home pay from CEOs?

Mr. LANGA. Our profits have been relatively stable.

Mr. RUIZ. From CEO pay hasn't gone up in the past several years?

Mr. LANGA. His pay has increased, yes.

Mr. RUIZ. OK.

So last week, Dr. Cefalu from the American Diabetes Association noted that PBMs' primary customers are the health plans and insurers not the patients. He testified, "We don't know whether those transactions are actually benefiting the patient at the point of sale."

Ms. Bricker from Express Scripts, does Express Scripts pass any savings on to beneficiaries; and how do we know what the difference is if there is not that transparency?

Ms. BRICKER. So yes, thank you for the question. For over 20 years, Express Scripts has supported point-of-sale rebates. We do have clients and plan sponsors that are——

Mr. RUIZ. How do we know what the percentage of that cost savings to patients, is if we don't have transparency of what the savings are? Are they going to your clients' profit or are they going to reducing out-of-pocket costs? How do we know?

Ms. BRICKER. So we support transparency for our plan sponsors, those that hire us. They absolutely have the ability to look at all of our rebate negotiated contracts as well as our retail contracts. We believe in transparency for patients.

Mr. RUIZ. So we need to look into what you say, and what is actually being done with implementation and that is what the purpose of this is for.

Mr. Moriarty from CVS Health, are these barriers to passing discounts on to patients at the point of sale and, if so, what are they?

Mr. MORIARTY. Sir, we have over ten million lives covered in a point-of-sale rebate program today. We also, as you heard in my written testimony and oral testimony, we really advocate a zero copay for insulin and other preventive medications. The cost savings associated with adherence is significant.

Mr. RUIZ. OK, I got 20 seconds so let me ask this question directly. What are each one of you willing to give up to make sure that every patient who needs insulin will get insulin? Mr. Mason?

Mr. MASON. We are willing to provide solutions, and we are providing solutions that close the gap to anyone paying out-of-pocket——

Mr. RUIZ. What are you willing to give up?

Mr. MASON. We're willing to give up—we gave up $108 million last year.

Mr. RUIZ. Mr. Langa, what are you willing to give up?

Mr. LANGA. Last year we invested almost $18 billion in rebates, discounts, and fees; and we also spent 200——

Mr. RUIZ. But yet the prices are still going up, so the status quo isn't working.

Ms. Tregoning, what are you willing to give up?

Ms. TREGONING. We are willing to contribute to solutions to allow patients to access, and that's why the program that we have allows $99 at the pharmacy for the insulin——

Mr. RUIZ. Those solutions aren't working if we are seeing doubling, tripling, cost of insulin and our patients are having to ration and not afford their insulin.

Ms. TREGONING [continuing]. And that costs are going down.

Ms. DEGETTE. The gentleman's time has expired.

The Chair now recognizes the gentleman from Virginia, Mr. Griffith, for 5 minutes.

Mr. GRIFFITH. Thank you, Madam Chair.

Mr. Mason, Ms. Tregoning, and Mr. Langa, we have heard that there are numerous fees and discounts in the prescription drug supply chain that are calculated based on insulin prices. According to what I have read, you all have fees with your supply chain partners that are based on a percentage of the list price of insulin. Why are they structured this way?

You are up first, Mr. Mason, let's go. Time is running.

Mr. MASON. We don't—the PBMs kind of own the paper of the contracts and that's what we have to work with.

Mr. GRIFFITH. All right.

Mr. Langa?

Mr. LANGA. It's the current system.

Ms. TREGONING. Agreed, it's the current system.

Mr. GRIFFITH. All right. Have any of your companies tried to negotiate flat fees with your supply chain partners?

Mr. MASON. Yes, we have.

Mr. LANGA. We have tried a variety of different avenues with contracting.

Mr. GRIFFITH. But you have not been successful, why?

Mr. MASON. No, our efforts were pushed away.

Mr. LANGA. I think it's because it's the current system and again in this demand for rebates today.

Mr. GRIFFITH. Ms. Tregoning?

Ms. TREGONING. Yes, again it's the system under which we operate.

Mr. GRIFFITH. So other than just it's the system, what reasons did the other participants in the supply chain provide to justify a fee based on the list price of the medicine rather than a flat fee?

Mr. MASON. It's the current system.

Mr. GRIFFITH. Just the current system, everybody agree with that? All right, because I will move on.

Mr. Moriarty, in the February 6th letter that we sent to CVS Health, we specifically asked CVS Health to list all the contractual terms in your existing contracts that are impacted by the list price of a medicine. CVS Health did not directly answer whether there were any fees charged by CVS that are calculated as a percentage of a list price.

While reviewing the standard contract template commonly utilized between CVS Caremark and a health plan client for several lines of business that the committee received in response to a letter that we sent to CVS Health last August, we saw that there was a section in the template on disclosure of manufacturer fees, that are disclosed that Caremark Part D services may also receive administrative fees from pharmaceutical companies that are based on a percentage of the list price of the medicine. It therefore appears as though CVS Health may use administrative fees that are based on a percentage of the list price of a medicine. This is correct, isn't it?

Mr. MORIARTY. Congressman, over 98 percent of all the fees, rebates that we obtain across our services and 100 percent in Medicare go back to the plan sponsors.

Mr. GRIFFITH. That is not what your contract says. Your contract says you all can charge a one percent fee, an administrative fee based on the price of the medicine. The question that I have is, it doesn't cost your company any more to process a $4 drug than it does a $40,000 drug; isn't that correct?

Mr. MORIARTY. It represents the costs associated with that processing, sir.

Mr. GRIFFITH. Well, wouldn't it make more sense from a consumer's standpoint that you came out and be more transparent, but that you came out with a flat fee and worked with these folks over here to come up with a flat fee? Because I understand in Part D on Medicare you are just charging the one percent, but across the board according to your information you sent us you are charging two percent. As a part of the rebate you are getting two percent of that, and I don't know whether you are charging those folks an administrative fee or not, but wouldn't it make more sense just to have a flat fee for doing what you all do?

Mr. MORIARTY. If the flat fee represents what the current net pricing, the lowest pricing it is in the market, yes, we will do that.

Mr. GRIFFITH. You are willing to do a net, even if it costs your company some profit you are willing to do a flat fee?

Mr. MORIARTY. Here's the issue. I think what's been proposed before actually results in not lower costs, actually higher costs. If it results in lower costs, we will implement that.

Mr. GRIFFITH. I mean because one of the problems we have is if you are not in one of the magic companies you are paying the list price and you are not able to afford it, or you are paying the high deductible in order to get there because you haven't reached your deductible yet. And lots of people have opted for these plans, and so the consumer is having to pay that higher list price, they aren't getting all those rebates all the time, and as a result of that their

net price has gone up substantially. That is what we're hearing from our constituents who are having to pay that. It just seems to me that it ought to be something that we all can look at, the whole system needs to be more transparent; and that you all ought to be paid for processing that prescription whether it is a $4 drug or a $40,000 drug, you ought to be charged a set standard fee that doesn't have the drug companies coming in here saying, "We are raising our list price," so they can get more.

By the way, how many billions of dollars, or at least hundreds of millions of dollars is represented by that one or two percent?

Mr. MORIARTY. We pass back as I said over 98 percent, and we had disclosed publicly what the retained number is.

Mr. GRIFFITH. What is the dollar number?

Mr. MORIARTY. The total number across is $300 million.

Mr. GRIFFITH. I yield back.

Ms. DEGETTE. Thank you.

Mr. Kennedy offered an article for the record and, without objection, it shall be entered.

[The article appears at the conclusion of the hearing.]

Ms. DEGETTE. The Chair now recognizes the chairman of the full committee, Mr. Pallone, for 5 minutes.

Mr. PALLONE. Thank you, Madam Chair. I missed a lot of the hearing because we had other hearings, and we were on the floor today with net neutrality. But I just want to say this. All I hear from my constituents, they are just totally disgusted, right. They figure particularly for insulin it has been around a long time, you know, they don't even believe in a market-based system anymore.

I mean, frankly, I believe in a market-based competitive system. I think that, you know, that is what the country is all about. But what they tell me is, just set the price. They will literally say to me, "You in Congress or some Government agency should just set the price and that is it." They just don't believe in a competitive model anymore. So, you know, you keep saying the system, the system, the system doesn't work, well, I guess part of what I would like to know is why this marketplace competitive model doesn't work anymore. What has happened?

So, you know, last week the committee heard from Dr. Lipska, who is a clinician and researcher, and she said, and I quote, "Drug makers make excuses for why prices have gone up. They say it's the fault of PBMs, or wholesalers, or the high deductible insurance plans, but the bottom line is that drug prices are set by drug makers. The list price for insulin has gone up dramatically and that's the price that many patients pay. That is what needs to come down. It's as simple as that." Now, many of my constituents say, very simple, set the price. Have the Government set the price and not have the company set the price. But I mean that is not the competitive model obviously. So let me just start.

Mr. Mason, you set the list price for your insulins, not the PBMs or anyone else in the supply chain. Why are we talking about high drug prices when it is within your power to bring the list prices down? Why don't you just bring the list price down, or do you want us to set it? Because that is what my constituents say. Don't have Mr. Mason set it, you set it. Let the government set it. Why not, if you are not going to do anything?

Mr. MASON. OK, so we—well, we actually buy down everyone in a high-deductible plan down to $95, so we're doing that today. Everyone who has, on a Lilly insulin at the pharmacy we buy every prescription down to $95, so we are reducing the list price. We're paying rebates in order to get access and——

Mr. PALLONE. Are you willing to reduce it more?

Mr. MASON. We right now reduce, you know, no matter how much their—you mean, they can use multiple vials, multiple pen packs. We've brought it down to——

Mr. PALLONE. All right. What would be the problem if the Government lists the price and just brings it down and says that is what you have to charge?

Mr. MASON. I mean right now we have—the competition is fierce. I mean our net prices are lower today than——

Mr. PALLONE. So you think competition is working; the marketplace is working.

Mr. MASON. I think it's working, yes. Yes.

Mr. PALLONE. I don't hear that from my constituents.

Mr. Langa, it is unconscionable that these essential drugs have seen dramatic price increases. Why isn't Novo Nordisk reducing its list price? Again, my constituents say force them do it.

Mr. LANGA. Well, we do believe in a market-based system. I would also say if we reduced our list price, we would put all of our formulary positions in jeopardy. Just here at the table, these three PBMs represent 220 million covered lives, and for us the risk that——

Mr. PALLONE. So you are going to blame the PBMs again.

Mr. LANGA. It's not the blame. We don't want to put those lives at risk, but we are willing to——

Mr. PALLONE. All right, so then let's get rid of the PBMs and we will just set the price, the Government will set the price and you don't have to worry about the PBMs. What do you think?

Mr. LANGA. It's not what we believe in. We take a market-based approach and it is competitive.

Mr. PALLONE. I agree with you, but nobody thinks it is competitive anymore.

Mr. LANGA. So if you look at our rebates, the average rebate for Novo Nordisk in 2014 was 48 percent. The average rebate just 4 years later in 2018 was 68 percent. That's a 40 percent increase. We spent up to $18 billion last year in rebates, discounts, and fees to provide formulary access, so.

Mr. PALLONE. All right, let me—I think you are just passing it on to the PBMs.

Ms. Tregoning, same question is people being forced to ration their insulin because they can't afford it. What is stopping Sanofi from lowering its list price? Why don't we just set the price ourselves?

Ms. TREGONING. Congressman, unfortunately, under the current system simply lowering list price as I believe some of the witnesses last week attested to might not help patients and actually could cause some patients, who are on their formularies where we've secured position with rebates, to lose access. If we could get——

Mr. PALLONE. But if we set the price there would be no PBMs anymore.

Ms. TREGONING. Congressman, I believe that the market-based system is very important for continued innovations. We don't——

Mr. PALLONE. I agree, but you guys have got to convince us that it is working and that the, you know, the problem that we have is we always end up having to interfere with the market when it becomes monopolistic, when it is not working, and my constituents say it is not working. "What are you doing, Pallone? It is not working."

Ms. TREGONING. Congressman, competition is working. The net prices are coming down. The issue we have is that the results of that negotiation are not finding their way to patients, and that's the issue at hand. We at Sanofi are working, where patients are exposed to those high list costs, we are effectively de facto having a lower list price and covering through copay assistance or VALyou Savings Programs. But we don't control the out-of-pocket costs.

Mr. PALLONE. I mean the problem is, Madam Chair, I know my time is up, but everybody just blames, you know, the PBMs blame the companies, the companies blame the PBMs, and our constituents say they are all no good, just get rid of the system. I am reluctant to do that because I believe in a market-based system. But this is, you know, this is what I hear. Thank you.

Ms. DEGETTE. Thank you, Mr. Chairman.

The Chair now recognizes Mrs. Brooks from Indiana, for 5 minutes.

Mrs. BROOKS. Thank you, Madam Chairwoman.

I think everyone is focused and the answers all seem to be focused on the system which I think we all are acknowledging and are very frustrated. It seems to be very broken. In the February 6th letter that we sent to the manufacturers we heard it is becoming increasingly common for insurers and PBMs to only offer one insulin manufacturers' line on their formularies.

I want to ask some questions about formularies and because it sounds like everyone in this finger pointing is having to do with formularies. And so, I am curious, why are, and not, you know, being involved in, but we are all learning a lot more about this system, why is it that you might have one insulin on a formulary? Why wouldn't you want all of them to be on your formularies?

I also have a question because if you are, say, an employee's daughter or son and you are used to one insulin then the company switches their insurance program and then that child has to go to different insulin, why would we not offer as many options as possible?

I will start with you, Dr. Dutta. If you could, you know, why do we make this change and then the rebates get in the middle of it and the discounts, and can you just help us? The system seems really broken and it sounds like that is part of it.

Dr. DUTTA. Thank you for the question. The first assessment is purely clinical. It is about whether a product is unique or if there are therapeutic alternatives. So when you have a unique product, price is high. It's put on our formulary, there is no competition. Then as manufacturers produce more products that are therapeutically equivalent, in the case of insulins rapid-acting insulins, long-acting insulins, in a category then there's an opportunity when they're equivalent to negotiate price down off of list price. However,

to your specific question, if there's a patient that requires a medication that is not our preferred product or not formulary, we offer a process for the patient and their doctor to request and provide rationale for their product. If there's a good reason like an allergy or something like that, then they would be allowed to have that product.

Mrs. BROOKS. Thank you.

Ms. Bricker, what would happen in the market for you to stop, for you, not just your company, but all of the PBMs here, what would happen if you stopped excluding certain insulin products from the formularies, if you allowed all of them in the different categories of insulins as I understand, if you allowed all of them to compete and be on each of your formularies?

Ms. BRICKER. Yes, thank you for the question. We don't have one formulary. We have many, many, many formularies. The formulary that provides the greatest savings for our clients actually limits through exclusivity or exclusive placement insulin options. We do that because we're able to secure the deepest discount from the manufacturer once we award that placement. And so, they're offering discount in exchange for market share and in exchange for access.

But to your point, we have other options and we believe that choice to our plans is critical and they absolutely can select formularies that have all insulin on the formulary.

Mrs. BROOKS. What if we removed exclusivity from formularies?

Ms. BRICKER. Prices would go up.

Mrs. BROOKS. Why do you believe prices would go up? Mr. Moriarty, why would prices go up if all of the companies were able to be a part of your formulary? Mr. Moriarty?

Mr. MORIARTY. Because the drug companies would not offer the discounts that currently exist in the system.

Mrs. BROOKS. And so, if we were to remove all exclusivity from formularies, Mr. Mason?

Mr. MASON. You know, our rebates went up during the period were removed from kind of dual access to exclusive formularies. That's what caused the list prices to go up.

Mrs. BROOKS. Mr. Langa?

Mr. LANGA. Our rebates have been competitive for years. Year over, year over year they're competitive. We believe in choice, choice for the physician, and choice for the patient. Someone that—a physician should be able to use their clinical experience to make decisions, not a formulary.

Mrs. BROOKS. What if we got rid of rebates and discounts, Ms. Tregoning?

Ms. TREGONING. We would support moving to a system in which you had fixed fees for PBMs and that we removed rebates. As long as patient access and affordability could be guaranteed, we would be more than happy to move to that system.

Mrs. BROOKS. Do you think if we had systems like that you all would lower your insulin prices that would be offered?

Ms. TREGONING. If we could be assured that patient access and affordability would be maintained, we would certainly be willing to lower our list prices, if we moved away from a rebate system.

Mrs. BROOKS. Mr. Langa?

Mr. LANGA. Yes, we support the rebate rule and we also support that if as long as there's access and affordability we are open to that option.

Mrs. BROOKS. Mr. Mason?

Mr. MASON. Same answer.

Mrs. BROOKS. Thank you. I yield back.

Ms. DEGETTE. The Chair now recognizes the gentlelady from New Hampshire, Ms. Kuster, for 5 minutes.

Ms. KUSTER. Thank you.

Thank you very much for your testimony today and as we unravel this whole process of rebates and volume discounts the high cost that patients and families are facing for insulin. In New Hampshire we have 121,000 Granite Staters, just give or take ten percent of our population, actually, have either type 1 or type 2 diabetes. These are the people that I have in mind, the families that we have been hearing from.

But I want to understand, the frustration that the diabetic Americans come not just from the dramatic increases in the out-of-pocket costs, but the mind-numbing complexity of how the drugs are priced and a belief that insulin manufacturers and pharmacy benefit managers may have lost focus on who they are truly meant to be working for, the patient. So that is really where we are coming from is to try to understand as we unravel this.

You have heard some of the ideas here, which I would imagine would be a dramatic change in the way you do business on certainly from the conversations I have had with the PBMs, but also from the manufacturers' point of view. I mean, I don't think anyone really comes to this with totally clean hands because you are chasing the profits of the quarterly earnings as well as anyone else.

I think part of what is difficult for us to understand is these are medicines that have been around for a long, long, long time without a great deal of innovation, without a change in the chemistry and the medication itself. Maybe there has been a change I understand in the delivery mechanism, you know, maybe there is a medical device change in having a longer lasting impact on patients, and certainly for patient convenience and patient health that is important.

But we are trying to get to the bottom of why this has gone up so much. It is one thing for us to consider that in a field of medicine that has dramatic new innovations and the R&D costs, but it is all the more complex for us to sort that out with something like insulin.

I want to get at two areas, if I could. Just, Mr. Mason, what efforts would you recommend to Congress to improve price transparency for patients? You obviously have taken a stand on getting rid of rebates or those types of things, but what is it that should be happening in terms of the patient understanding the pricing?

Mr. MASON. We're open for transparency to help patients. We think the biggest issue that we're hearing right now—we want the same thing. We're not defending the system, we're just explaining the system up here. We want reform. We want, you know, anything that provides better access to patients. The heart of what we're hearing from patients is those with high-deductible plans, about half of those high-deductible plans will take the rebates that are

given to them and they use those to afford chronic, or affordable care for those with chronic disease. About half of them decide to actually put that back and actually lower premiums for the general population.

So what we hear and what you're probably hearing is for those individuals who are in those high-deductible plans where that employer has decided to say, "I'm going to pick the plan design that gives me lower premiums," because they're prioritizing that. They're making that conscious plan decision and that leaves individuals with chronic medication paying this price. That is a gap in the system right now that is leading to what we're hearing the most from diabetes patients.

Now we're providing now a stop-gap measure to buy all those people down to $95, but that's a short-term fix. Long-term fixes should really be focused on what can we do with these high-deductible plans so that they have affordable coverage from day one and that decision is universal.

Ms. KUSTER. So you would agree that there is a discount for volume purchasing, and are you saying they fall outside—and I can ask Ms. Bricker to explain this.

But—well, let me go to you, Ms. Bricker. What he is saying, how do we get to transparency for the patient, and how do we get all the patients to benefit from a mechanism that makes sense to me that you have described which is a volume discount, essentially? That is what the rebates are.

Ms. BRICKER. A couple of things, if I may, so believe strongly in having real-time benefit check at the time of prescribing that the physician has at his or her fingertips, what product is covered under the formulary, and what it will cost the patient, absolutely critical to ensuring that there isn't friction at the counter. Transparency, also, to plan sponsors so that they fully understand the value that we've negotiated for them by way of rebates and discounts.

And so of course we've got to continue to do more. We've, as mentioned previously, announced a program for $25 insulin for all of our commercial patients. But clearly where we're still faced with challenges in the Part D benefit and we are absolutely in support of continuing to modernize that benefit such that patients, you know, have caps and don't have, aren't exposed to these high list prices, essentially.

Ms. KUSTER. My time is up, but thank you.

Ms. DEGETTE. Thank you. The gentleman from West Virginia is now recognized for 5 minutes.

Mr. MCKINLEY. Thank you, Madam Chairman. I apologize. I have been back at two other committee meetings going on, so I have missed some of your—but I heard enough of it.

Mr. Langa, I probably would focus most of my remarks towards you on this. I was here, so just begin, for my records the only thing that we have some information that we were—a vial of insulin in '67 cost a dollar. If just the CPI went up $17, but yet your NovoLog is now with a list price of 237, not $17.

So many times, when we have our meetings back in the district in our roundtable discussions they talk about how people in West Virginia, probably no different than around the country, having

three and four hundred dollars a month. I just talked with that fellow this morning, he said he just wrote a check for a thousand dollars for his insulin in excess of his insurance.

What I was hearing not only similar dollar increases like this, but I was hearing all of you say it was caused by innovation, in part by innovation. I am curious what kind of innovation have we implemented over the last few years that would cause such a drastic increase in the price of insulin, the innovation part of it? Because let me just, I am a strong, strong supporter of innovation, so help me out a little bit. Why is innovation causing the increase in price?

Mr. LANGA. Sure, so innovation is very important to us as an organization, we're an innovator company. I would tell you that what's most important, and I think it was mentioned earlier, is that we keep the patient in mind. Because even that word "incremental," it's not incremental to patients.

So when you think about going from 4 to 6 injections a day to one, if you think about being able to take a mealtime insulin at or right after you eat versus an hour to an hour and a half before, if you think about basal insulin or long-acting products today that give you the support of hypoglycemia, maybe the best way I could describe it is: we have patients that want to work for Novo Nordisk because of the mission that we're on to defeat diabetes, and we have these patients sometimes speak at our company meetings.

Mr. MCKINLEY. I am just trying to understand the innovation part of it.

Mr. LANGA. But I am going to, I think, get to it.

Mr. MCKINLEY. Please get to it because we have run out of—I don't need someone to filibuster here on me.

Mr. LANGA. It's not filibustering, it's this individual talk about what he lives with; night terror. Night terror is something called low hypoglycemia at night and actually makes him do things that are out of what he normally does. And because he got on a product called Tresiba that reduces hypoglycemia 40 percent——

Mr. MCKINLEY. You are saying, you are saying the innovation that——

Mr. LANGA [continuing]. He has not had a night tremor since.

Mr. MCKINLEY. I am saying if—were prior to having the innovation that prices were lower, now they are skyrocketing up to 237. Can we just stop the innovation? If it worked before, why in the last five years through innovation we have gone from 17 or $20 up? I don't want to go there, because as an engineer I believe very much in research and to do that, but if we are driving the price up—innovation is supposed to drive the price down, not up.

I am really troubled with it. But I think it is——

Mr. LANGA. Innovation is for today, and tomorrow I think it's important because we're innovating for the future and the future of people living with diabetes. So it's a partnership with MIT. It's our partnerships with the University of California San Francisco.

Mr. MCKINLEY. I want to respond back to why that in the past, until the last few years that I am sure you were innovating back in the '70s and '80s, the innovation and it wasn't skyrocketing like it is right now. So it is just counterintuitive that why innovation is driving the price up now in the last few years.

Let me go back to the list prices because I am not going to—we are going to run out of time. But I don't understand that—I come from the construction industry, but also in life I need to see some examples of why we have these list prices set up for discounts I have heard you talk about. If we don't have rising list prices for cars and appliances and construction material, why is it that pharmaceuticals are jazzing up the list price so they can offer discounts? Why is that unique to the pharmaceutical field?

Mr. LANGA. Again, I know you've heard a lot about this today, but it is about these misaligned incentives in the system. The higher the rebate—excuse me. The higher the list price, the higher the rebate.

Mr. MCKINLEY. Yes.

Mr. LANGA. The rebates are used within the system. And that is—and again, and those rebates don't get passed through to the people living with diabetes and that is there that lies the challenge.

Mr. MCKINLEY. Should we eliminate or discourage the rebates?

Mr. LANGA. Well, certainly we're supportive of the rebate rule, and we're supportive of the pass-through of those rebates to benefit patients, and we think that would be something that would be healthy for patients.

Mr. MCKINLEY. OK, I have run out of time. I am sorry. I yield back.

Ms. DEGETTE. The Chair now recognizes the gentlelady from Florida for 5 minutes.

Ms. CASTOR. Well, thank you, Chair DeGette for holding this hearing to tackle the skyrocketing insulin prices.

I recently met with a family from back home in Tampa. Nine-year-old Brooke and her father Todd explained to me how she was diagnosed when she was three days old in the hospital and how they have struggled with her diabetes since then. But it is not just—the big struggle hasn't really been on the health side. It has been with affording insulin and drugs. They have had to change their lifestyle a little bit and Todd told me at one point they had run out of insulin two weeks before the end of the month and had to borrow a vial from an adult friend of ours who was using Humalog and had numerous vials stockpiled.

That is how, he said, "That is how we do it now. We tell our endocrinologist that we use more insulin than we need in a month, so she writes prescriptions for slightly more than we use. Since the vials are good for two years, we have extra in case anything happens. At the end of the day, we count ourselves blessed that both my wife and I work, and our insurance sufficiently helps pay for all of Brooke's type 1 diabetes supplies, but the beginning of the year is still very difficult until we pay our deductibles. We choose to pay more for our insurance out-of-pocket to make those deductibles." But he says, "I cannot fathom how a family can choose to limit or ration insulin for their children. The system needs to be fixed."

Then I asked Brooke, I said, "What would you as a 9-year-old having to deal with this, what would you want me to ask?" She says, "Why do we have laws that protect kids' safety like bike helmets, seatbelts, and indoor smoking bans, but not laws that would allow them to get the medicines they need to stay alive?"

So this, things have got to change. So let's start with manufacturers' list prices and how we get them under control. It seems to be that just about everyone in the supply chain except the patient is benefiting from increasing list prices.

Mr. Mason, if rebates and fees tied to list price were to be restricted or eliminated, do we have any guarantee from Eli Lilly that prices would go down and patients would pay less?

Mr. MASON. We would definitely consider it.

Ms. CASTOR. Mr. Langa?

Mr. LANGA. Yes. We would consider that, yes.

Ms. CASTOR. Is there a guarantee?

Mr. LANGA. Well, what's important to us again is that the majority of patients can have access at affordable pricing and as long as there was that in place then, yes, we would consider that.

Ms. CASTOR. Ms. Tregoning?

Ms. TREGONING. Yes, as long as we can ensure patient access and affordability in formularies then we would certainly lower list price with the elimination of rebates.

Ms. CASTOR. OK. There is another hitch in the system here and that is kind of the gaming of charitable contributions. It has been reported that some manufacturers use the Patient Assistance Programs to reduce their own tax burden. That by donating drugs to these Patient Assistance Programs, the company is able to deduct the value of the donated drugs from its taxes.

In 2015, I understand Lilly donated 408 million worth of drugs to the Lilly Cares Foundation. Mr. Mason, should manufacturers be able to benefit financially from the Patient Assistance Programs?

Mr. MASON. We do it only to help patients. We don't want anyone not to afford——

Ms. CASTOR. But boy, that is a big—408 million, then I would think we would see some commensurate reduction of the list price that would be tied to that.

Mr. MASON. Our net prices are going down, and then what you're not seeing is we spent $108 million last year on savings offers that helped 525,000 people. Those aren't a tax write-off. Those are——

Ms. CASTOR. I think there is an issue here though with these kinds of charitable contributions. You seem to be benefiting on both sides and patients aren't.

So turning to the PBMs, Ms. Bricker, if fees paid to PBMs and wholesalers are standardized and entirely delinked from the list price, what impact would it have on what the patient ultimately pays?

Ms. BRICKER. Over 50 percent of our clients receive all fees that are collected from manufacturers and 95 percent of all fees and discounts and rebates are passed on to our plan sponsors. And so, ultimately when you delink the fee from the list price, there really is nothing that prevents the manufacturer from continuing to increase the price.

Ms. CASTOR. So, Mr. Dutta, the mission of PBMs is to get the lowest price possible for drugs for their clients, but that clearly isn't happening. How can we change the system to better align out-of-pocket patient cost to negotiate a net cost instead of the list prices?

Dr. DUTTA. Well, 76 percent of our members today either pay zero-dollar copay or most commonly a flat copay of $35. And for that other percentage that you're asking about that are on a coinsurance or a high-deductible plan we advocate for point-of-sale rebates as well as preventive drug lists such that insulins would not apply to the deductible.

Ms. CASTOR. I yield back my time, thank you.

Ms. DEGETTE. Thank you. The Chair now recognizes Mr. Mullin for 5 minutes.

Mr. MULLIN. Thank you, Madam Chair, and thanks for holding this meeting. It is not too often we get together and actually agree on issues, but we are all talking about the same thing; and we are all scratching our head trying to figure out how we got to this point.

Real quickly, I want to go back to what was just asked about YOUR tax advantage for taking the rebates. Is there a tax advantage for YOUR companies for those rebates, yes or no?

Mr. MASON. No.

Mr. MULLIN. No.

Mr. LANGA. No.

Ms. TREGONING. No.

Mr. MULLIN. Well, what about the charitable contributions? Is that not a tax advantage?

Mr. MASON. We only give insulin and what people use.

Mr. MULLIN. Well, because if it is at $300, and I am just using generic numbers, if the list price is 300, you put your rebates in and you get it all the way down to 100, who absorbs those rebates?

Mr. MASON. That's not why we're doing it. We're doing it for——

Mr. MULLIN. No, who absorbs those rebates?

Mr. MASON. Those——

Mr. MULLIN. Who absorbs those rebates? Do you guys absorb those rebates? If you are giving the rebates and the list price is at $300, you are getting it to $100, who absorbs those rebates?

Ms. TREGONING. The rebates go to the PBMs with whom——

Mr. MULLIN. It doesn't go to the patient though, right?

Ms. TREGONING. That's based on the—that's the concern that we have.

Mr. MULLIN. Do you write that off as a charitable contribution?

Ms. TREGONING. That's different than a charitable contribution. The free drug program which are run through Patient Assistance Programs——

Mr. MULLIN. OK.

Ms. TREGONING [continuing]. That's different. That's providing free drug to patients below a certain income threshold. That's separate from rebate——

Mr. MULLIN. You know what Mr. Griffith asked back here in the back, the innovation—no, I am sorry—McKinley asked about the innovation. When you are talking about the innovation side of things, are you using insulin today to help pay for future drugs? Is that the innovation that you guys are using for research? Does the price of insulin help offset the cost of research for future drugs?

Ms. TREGONING. Revenues from all of our business, in part, go back to fund research and development across all areas. For diabe-

tes in the United States, I would point out our revenues have gone down.

Mr. MULLIN. But I can understand price. A lot of you guys come in and you talk to me in my office and you say, "Look, the price of the drug is so we can recoup our cost to develop it. That was the cost so that is why it is set at where it is because we are trying to recoup the cost of it." I totally get that. You have got to recoup the cost especially when you start having patents that are going to run out and you need to recoup your costs in time.

But the cost is already recouped in this, so you are using insulin today, the cost of insulin today to pay for future drugs that are outside of insulin; is that correct?

Ms. TREGONING. We continue to invest in research——

Mr. MULLIN. That is why you are seeing it go up so much?

Ms. TREGONING. No, because our revenues from diabetes are going down. The net prices are going down. Our revenues from——

Mr. MULLIN. But you don't have any costs associated with it because it has already been developed. It has already been paid for.

Ms. TREGONING. But again, the revenues for Sanofi's diabetes business in the U.S.——

Mr. MULLIN. OK.

Ms. TREGONING [continuing]. Have gone down by half over the last four years because net prices have gone down so dramatically.

Mr. MULLIN. I have some quick questions I need to get to. If a patient qualifies for YOUR programs, how much does it cost? How much does their insulin cost at that point?

Mr. LANGA. Patient assistance is free.

Ms. TREGONING. For copay assistance they'll pay no more than a $10 copay.

Mr. MULLIN. OK.

Ms. TREGONING. But if they qualify for the charitable then it is free drug.

Mr. MULLIN. OK.

Mr. MASON. Patient assistance is free.

Mr. MULLIN. Is free.

Ms. Bricker, with the Express Scripts you guys came up with no more than a $25 charge to customers. You just rolled that out recently, right? How long did it take you to develop that?

Ms. BRICKER. We've been working on it for a few months.

Mr. MULLIN. For a few months. Have the companies here on the panel, have they agreed to participate in that with you?

Ms. BRICKER. Yes, they have.

Mr. MULLIN. It took you two months to come up with that. How are you guys able to offer that?

Ms. BRICKER. In collaboration with the manufacturers as well as in collaboration with the plan sponsors.

Mr. MULLIN. When a patient qualifies for YOUR programs, how long do they typically stay on those Patient Assistance Programs? Either one.

Mr. LANGA. It varies. It varies, really, by patient program. So they have renewal periods, but it could be 1 year, 3 years.

Mr. MULLIN. Do you know what average the patient stays on the program?

Mr. LANGA. I'd have to get back to you on the average. I don't know what that is.

Ms. TREGONING. I don't have that information.

Mr. MULLIN. Mason?

Mr. MASON. Our separate foundation does that, so we don't have that data.

Mr. MULLIN. OK, I will yield back.

Thank you so much for your time.

Ms. DEGETTE. Thank you. The Chair now recognizes the gentleman from New York, Congressman Tonko, 5 minutes.

Mr. TONKO. Thank you, Madam Chairwoman.

I would like to begin by asking our panel a number of simple yes or no questions. During our hearing last week, patient advocate Gail DeVore testified that against her doctor's orders she had rationed and diluted a bottle of insulin because she couldn't afford to pay the $346.99 it cost her per month. Are you aware of stories like Gail's, and we will start with you, Mr. Mason, and go across, but yes or no, are you aware?

Mr. MASON. Yes.

Mr. LANGA. Yes, we are.

Ms. TREGONING. Yes, we're aware.

Mr. MORIARTY. Yes.

Ms. BRICKER. Yes.

Dr. DUTTA. Yes.

Mr. TONKO. Have any of you personally ever had to ration a vial of insulin?

Mr. MASON. I have not.

Mr. LANGA. I have not personally.

Ms. TREGONING. No, I have not.

Mr. MORIARTY. I have not.

Ms. BRICKER. I have not.

Dr. DUTTA. No, and no one should.

Mr. TONKO. Similarly, I hear stories from my constituents frequently about the struggle to afford lifesaving medications including having to make tough choices about putting food on the table or simply buying medication. Have any of you ever personally had to choose between feeding your family or buying a life-sustaining medication?

Why don't we start with you, Dr. Dutta, and go the opposite way?

Dr. DUTTA. No, and no American should.

Ms. BRICKER. No, I have not.

Mr. MORIARTY. I have not.

Ms. TREGONING. No, I have not, and agree no one should.

Mr. LANGA. I have not and no one should.

Mr. MASON. I have not and no one should.

Mr. TONKO. In a broader sense, have any of you ever struggled to afford a medication that was recommended to you by your doctor?

Mr. MASON. I have not.

Mr. LANGA. There once was a time when one of my children had to be on a growth hormone product and we were not able to get reimbursement. At that time, it was going to be several thousand

dollars and that was going to be a challenge for us. So yes, there was a time in my life.

Mr. TONKO. Thank you.

Ms. TREGONING. I'm fortunate not to have faced that situation.

Mr. MORIARTY. I have not.

Ms. BRICKER. I have not personally, but yes, my family members have struggled.

Dr. DUTTA. No, I have not and no one should.

Mr. TONKO. Well, I thank you for your candor. I want to be clear that I am not asking these questions as a gotcha moment, but as a reminder that we need to approach this issue with empathy and compassion. We never know what the person next to us might be going through. These stories we have all heard and are sharing today are from real people.

Modern medicines like insulin save lives, but when we dangle these life-sustaining medications just out of reach from those who need them, we are engaging in a most cruel form of torture. According to Dr. Lipska's testimony last week, one in four individuals reported using less insulin than prescribed over the past year specifically because of cost. Let's put ourselves in their shoes for the day.

We can get bogged down here in Washington with the blame game and talk about esoteric issues like rebates and list prices and Patient Assistance Programs, but the reality is that when I go this weekend back to my hometown to Amsterdam, New York, there will be people in my community that are in the hospital putting their lives at risk, because they are so desperate for this medication that they are priced out of that they deliberately let their blood sugar crash just so they can get free samples of insulin on their way out of the door. Regardless of where you pin the blame, the system as it exists now is horrendously broken; and the companies represented at the witness table are benefiting while patients across the country are losing. That is unacceptable and we need answers.

Last week, in testimony before the committee we heard from the Endocrine Society that in 2017 expenditures for insulin in the United States reached some $15 billion. They also told us that three of the top ten medication costs were for a type of insulin. Where is all this money going?

Let's start with you, Mr. Mason.

Mr. MASON. Our net prices are going down. Why we hear so much of why people can't afford their insulin today, it's those individuals in about half the high-deductible plans that don't benefit from the rebates and have high out-of-pocket costs because the rebates are being used to buy down the premiums.

Mr. TONKO. Do those net prices need to go down further?

Mr. MASON. Our net prices are going down.

Mr. TONKO. No, you said they are, but do they need to go down further? In order for people to—we hear about CEOs getting an increase in their salary and we—tell us, well, the response is our net prices are going down. Do they need to go down further or do we need to take from the CEO?

Mr. MASON. All I'm saying is our net prices are going down. The price that plans pay, payers pay to get insulin is going down, but

those costs are not being used to help people who have diabetes in about half of the high-deductible plans. Those rebates are used in order to buy down premiums for the general population leaving those with chronic medications like insulin exposed to a deductible. That's what we're hearing. That's the point that we need to focus on solutions. That's the gap in the current system. The current system's not working. We agree a hundred percent. That is the heart of the issue.

Mr. TONKO. Well, I see my time is up, I will yield back. But again a crisis that we need to resolve as soon as possible, quickly here. Thank you and I yield back.

Ms. DEGETTE. The Chair now recognizes the gentlelady from New York, Ms. Clarke, for 5 minutes.

Ms. CLARKE. Thank you very much, Madam Chair, and I thank our ranking member. This is a very important hearing today and I wanted to ask a couple of questions.

We have heard a number of examples of the dramatic rise of insulin prices this afternoon and I am still not clear on the flow chart. You know, we have heard a whole lot of different things about net pricing, list pricing, and that net pricing is going down.

Is that what you are saying, Mr. Mason? OK, now is that subject to ebbs and flows? In other words, if you are saying that price is going down as we sit here, is there a point where that price gets settled at a lower price or is there the possibility that it rises again? Is it like oil?

Mr. MASON. No, it's not like oil. I mean this has been pretty flat over the last 10 years. We can provide the, I think we provided the data as part of our written testimony.

Ms. CLARKE. Well, how is it then if they are going down over the past 10 years that it is still unaffordable? That is the flow chart that I am talking about. If you are going down—first of all, it spiked for some strange reason, I guess the change in the system or the, you know, modernization of the system that included this rebate, you know, shenanigan, because that is what it is at the end of the day, if you have a 100-year-old product that increased in value because all of these other dynamics got involved and, you know, it is the same product.

Can you give me a sense of what happens when you produce this product, what the cost is, and then how it gets to the point where the average American can't afford, who needs it, can't afford to access it? That is the crux of this for, I think, the listening public. Because we have talked about a lot of terms of art here, but Americans need to know how you got to where you are given what we know. Can you explain? Can you explain, or is there anyone on the panel that can explain it in layperson's terms?

Ms. TREGONING. Congresswoman, first, the insulins of today are very different than the insulins of the past, so I think that's also very important to keep in mind. That the insulins today——

Ms. CLARKE. We understand that.

Ms. TREGONING. In terms of the list versus net prices, the net prices have been going down steadily. We talked about our insulins. Our list price has gone down 25 percent over the last five years, or since 2012, and that is expected to continue. The issue here is that the savings——

Ms. CLARKE. What precipitated that?

Ms. TREGONING. It's additional competition and rebating——

Ms. CLARKE. Are you sure it wasn't the outcry of the public that could no longer afford it that are watering down their insulin?

Ms. TREGONING. Unfortunately, Congresswoman, the lower net prices are not finding their way to patients, exactly to your point. That the rebates that exist in the system that gap between the list and the net prices is being used to subsidize other parts of the system and so, unfortunately, patients——

Ms. CLARKE. So the system became far more complex over time. Is that what you are——

Ms. TREGONING. I think the system became complex and rebates generated through negotiations with PBMs are being used to finance other parts of the healthcare system and not to lower prices to the patient.

Ms. CLARKE. If we extract rebates from the system, what happens?

Ms. TREGONING. If we moved to a system of fixed fee, we support the rebate rule then we would be able to lower our list prices, but we would need to ensure that the formulary position——

Ms. CLARKE. No. I just want to know if we removed the rebates.

Ms. Bricker, I think you had——

Ms. BRICKER. If you remove the rebates, the discounts, there is no one that's advocating then for the patient and the plan sponsor to drive discounts and affordability. The rebates are discounts. They sound mysterious. It's just a discount and it's a volume discount.

Ms. CLARKE. Right.

Ms. BRICKER. And so PBMs serve a critical function in ensuring affordability. Are there people that slip through the cracks? Absolutely, and we're absolutely committed to figuring out how to serve each and every patient. But I would caution, doing away with rebates will only increase costs.

Ms. CLARKE. OK.

Ms. TREGONING. We support having rebates pass through to patients, pass through to the patients who use the drugs upon which the rebates have been negotiated. That's——

Ms. CLARKE. This is a circular issue, because you want that passed on to the patient.

Mr. LANGA. Yes.

Ms. CLARKE. So that you can continue to push up the price.

Ms. TREGONING. We don't receive list price. We receive the net price. We don't receive the list price.

Ms. CLARKE. You don't receive the list price.

Ms. TREGONING. No. The price that is paid to manufacturers is ultimately the net price.

Ms. CLARKE. Right.

Ms. TREGONING. So the rebates now are being used to offset other costs in the system. What Sanofi would advocate for is ensuring that those rebates are provided to patients who are using the drugs; upon which those rebates are negotiated to lower their out-of-pocket costs.

Ms. CLARKE. Are you saying that the PBMs' demand for increased rebates is the reason you are forced to keep raising your list prices?

Ms. TREGONING. It is one component of how we consider and at Sanofi we have limited our list price increases. But one component of that decisionmaking is the dynamics of the supply chain.

Ms. CLARKE. What are the other components?

Ms. TREGONING. The other components include the need to continue to invest in R&D and the competitive environment.

Ms. CLARKE. I yield back. I think it is more P&G. That is profit and greed. I yield back, Madam Chair.

Ms. DEGETTE. The Chair now recognizes the gentleman from Maryland, Mr. Sarbanes, for 5 minutes.

Mr. SARBANES. Thank you.

Is the rebate, Ms. Bricker, is the rebate system transparent right now would you say?

Ms. BRICKER. The rebate system is 100 percent transparent to the plan sponsors and the customers that we service. To the people that hire us, employers of America, the Government, health plans, what we negotiate for them is transparent to them.

Mr. SARBANES. So we can track the list price, then we can see the rebate, then we can see the net price, then we can see the savings that you pass along to the consumer; that is all completely transparent to the public?

Ms. BRICKER. It's not transparent to the public unless they are our patient.

Mr. SARBANES. Should it be?

Ms. BRICKER. We don't believe so.

Mr. SARBANES. Should it be a trade secret, is that the problem, like proprietary——

Ms. BRICKER. The reason I'm able to get the discounts that I can from the manufacturer is because it's confidential.

Mr. SARBANES. It is a secret.

Ms. BRICKER. Because it's confidential.

Mr. SARBANES. Yes, because it is a secret. What about if we made it completely transparent? Who would be for that?

Ms. TREGONING. We would support transparency along the entire chain. That's the important thing is if we have transparency all along from the list price all the way through to patients.

Mr. SARBANES. Do you all support that?

Ms. BRICKER. Absolutely not, but——

Mr. SARBANES. No, you can't, because then it will end up hurting the consumer.

Ms. BRICKER. It will hurt the consumer.

Mr. SARBANES. Yes, it will hurt the consumer to have transparency, you know?

Ms. BRICKER. It will hurt the consumer, Congressman, because——

Mr. SARBANES. I don't buy it.

Ms. BRICKER [continuing]. Prices will be held high.

Mr. SARBANES. I am not buying it. I think a system has been built that allows for gaming to go on and you have all got your talking points.

Ms. Tregoning, you have said you want to guarantee patient access and affordability at least ten times, which is great, but there is a collaboration going on here. I know there is this going on too, but the system is working for both of you at the expense of the patient.

Now I reserve most of my frustration for the moment in this setting for the PBMs, because I think the lack of transparency is allowing for a lot of manipulation. I think the rebate system is totally screwed up, that without transparency there is opportunity for a lot of hocus-pocus to go on with the rebates. Because the list price ends up being unreal in certain ways except to the extent that it leaves certain patients holding the bag, then the rebate is negotiated, but we don't know exactly what happens when the rebate is exchanged in terms of who ultimately benefits from that.

I think we need more transparency and I do not buy the argument that the patient is going to be worse off, the consumer is going to be worse off if we have absolute transparency. I think just to get the lobbyists in the room to shudder a little bit, I think the PBMs should be utilities or converted to nonprofits or something. I know when you started out, I understand what the mission was originally with the PBMs. It is a complicated industry. You need an intermediary to assemble all the information on both sides, to weigh in, to assemble the bargaining position so that you can get the best price, and in the early days that was a good argument.

But now things have gotten out of control. You are too big, and the lack of transparency allows you to manipulate the system at the expense of the patient. I don't buy the argument that the patient and consumer is going to get hurt if we have absolute transparency. If we can't get it from a for-profit entity like the PBM, then we ought to look at other ways of doing it, including having the Government get into this space and compete in providing that important function. With that I will yield back my time.

Ms. DEGETTE. The Chair now recognizes the gentlelady from Illinois, Ms. Schakowsky, for 5 minutes.

Ms. SCHAKOWSKY. Thank you, Madam Chair, for holding this hearing.

I don't know if I have any questions at all, but I want to tell you something. In the 2018 election, the number one concern of Americans, the high cost of prescription drugs. We have the names of people who have died because they couldn't get their insulin. A young man who was trying to control it himself after going off his parents' policy, dead. We know that a huge number of people are not taking the insulin that they need because they can't afford it. So then they get sick, they get sicker, and maybe they die because of it. I don't know how you people sleep at night.

Between 1996 and now, when you have Eli Lilly from $21 a vial to $275, you heard Mr. McKinley—am I saying that right—who went through all that, interesting by the way. So for Eli Lilly it is now $275. For Sanofi it is $270. For Novo Nordisk it is $280. Curiously close in price and way too high. I want to tell you something. That will not stand in this Congress. I heard Ms. Brooks say the system is broken and I think on both sides of the aisle there is a commitment. We have even heard the President of the United States talk about price gouging. Yes, we need transparency. I have

a strong transparency bill that is going to hold you guys accountable and make you notify how you justify raising those prices. You talked about another—Mr. Langa, you talked about another drug that you are developing and that somehow that is an excuse because it helps diabetics and that is the research and development that you do. You are in trouble. And the lobbyists out here, or maybe that is you, need to understand that this is a commitment on the part of the Congress to get drug prices, particularly lifesaving, life necessities, to get those prices under control. If you think you can, you know, just out-talk us without any transparency, without any accountability, I just want you to know your days are numbered.

You know, when Mr. Azar became the Secretary of Health and Human Services, I wanted to remind him that he came from Eli Lilly at the very time that those insulin prices went through the roof, and we are seeing that on drugs that have been like yours on the market for decades. If you want to try and explain—I totally agree, isn't that a good thing that now people may be able to take one vial and not have to shoot up all the time because, you know, and the delivery system. But we had no clue if that means that you can raise those prices a thousand percent.

And you think you can get away with that kind of secrecy or just blaming the PBMs. I am not holding them unaccountable here, we need to do that. But don't excuse yourselves from this and don't tell us about the wonderful charity prices that you give and then you do get tax breaks, I am assuming—contradict me if I am wrong—when you give charity care to people. I believe that that is a tax-deductible kind of item for you, I am not hearing anybody contradict that. I resent that very much, because then everybody else is still paying those very, very high prices. So just know something is going to happen here if you don't decide in your own interests to lower those prices so people don't have to die. I yield back.

Ms. DEGETTE. The gentlelady yields back. The gentleman from California, Mr. Peters, is recognized for 5 minutes.

Mr. PETERS. Thanks. I have heard a lot of this discussion and it has been very edifying for me. Actually, I don't want to blame you for a system that we have set up here that encourages these bizarre incentives. The fact is that it is a system that incentivizes people to charge higher list prices so they can give rebates that give them access to customers.

I am pretty much a believer in markets. Someone called this a free market. This is really not. I don't think that we should suggest that this is the kind of competition that is going to take care of our problems. What we have here is what economists call a "market failure" at best. That is when it is appropriate for government to take action in a capitalist system. I think most people agree with that, and I think that is what we are going to see.

We are going to have to take out the incentive, this crazy incentive to charge higher prices so that you can get the customers and no one knows what the real prices are. I mean it is impossible for us to understand, you know, we have access to all this information, this is a really, really opaque system and so we are going to have to change that.

I appreciate the input. I don't ever suggest that companies aren't going to make money when they are allowed to do it. I just think that this is a perverse system that has to be changed so that if we want competition, we get real competition. But this system of rebates is really encouraging an anti-competitive behavior.

Also, I know that—I will just express a concern and this is in the courts. But, you know, now we have companies owning PBMs and plans without any assurance of the relationship between the sister companies, the PBMs and the plans. Again, I think there is a real risk of anti-competitive behavior.

I mean, I think you have come here and done the best job you can answering these questions. It is a system that no one should have to apologize for, but it is a system that we are going to have to change here in Congress; and I think that is what you will see going forward. I yield back.

Ms. DEGETTE. The gentleman yields back.

We now have several members who are not on this subcommittee but who have been gracious enough to be here for most of all of the hearing, and I appreciate their attendance and input. I would like to first recognize Congressman Bucshon for 5 minutes.

Mr. BUCSHON. Thank you, Madam Chairwoman.

I was a physician before I was in Congress, so these types of issues are extremely important to me. For me it is all about people and taking care of people, making sure especially when it is a life-sustaining drug. I appreciate all of your input. It is a system that needs changed.

We did a hearing last Congress and we had eight stakeholders in the entire supply chain and we pretty much got this, you know, the whole time, and I get that. I am not blaming anybody. I am just saying I think it is just, we have developed a system over time that is going to need changed. I am going to have questions for both the PBMs and the companies.

Dr., is it Dutta, yes, I understand that representatives from your company testified in front of the Senate Finance Committee yesterday. My understanding is that your company was asked questions about contracting practices and relationships with manufacturers. I would like to just follow up on those and then Ms. Bricker and Mr. Moriarty can comment also.

Can you talk about the following: Has your company ever proposed in contract or otherwise demanded that manufacturers give advance notice of list price decrease? I remind you, everybody, we are all under oath here, so, and we have access to information potentially that could counteract a questioned answer that isn't accurate.

Dr. DUTTA. Yes.

Mr. BUCSHON. OK. And then the manufacturers pay a higher fee, a rebate, if list prices do not increase above a certain percentage in that contract year? So, for example, if they don't increase their list price above a certain percent that they may have to pay a higher fee or rebate for that drug?

Dr. DUTTA. I'm not aware of that.

Mr. BUCSHON. OK. And that manufacturers pay a certain rebate amount even if they decrease their list price?

Dr. DUTTA. I'm not——

Mr. BUCSHON. My point is if you have a list price here and the company says, "We are going to go down to here," and the rebate was based on the higher list price, does that amount stay the same?

Dr. DUTTA. I'm not aware of that.

Mr. BUCSHON. OK.

Same questions, Ms. Bricker, is do you have contractual or otherwise demanded that manufacturers give advance notice of list price decrease?

Ms. BRICKER. No, we welcome lower list prices.

Mr. BUCSHON. OK, great. And that manufacturers pay a higher fee or rebate if list prices do not increase above a certain percentage in that contract year?

Ms. BRICKER. No.

Mr. BUCSHON. OK. The manufacturers pay a certain rebate even if they decrease their list?

Ms. BRICKER. No.

Mr. BUCSHON. OK. We hear that they do.

But, Mr. Moriarty, same thing, I mean do you have contractual relationships that otherwise demand that the manufacturers give you advance notice of decrease in the list?

Mr. MORIARTY. No.

Mr. BUCSHON. OK, great. The manufacturers pay a higher fee or rebate if list prices do not increase above a certain percentage in a contract year?

Mr. MORIARTY. No.

Mr. BUCSHON. OK, great. The manufacturers pay a certain rebate amount even if they decrease the list?

Mr. MORIARTY. No.

Mr. BUCSHON. OK.

Mr. MORIARTY. We are all about net price.

Mr. BUCSHON. Understood.

I am going to focus on the 340B program real quickly. I have been an advocate for reforming that program. Information that Novo Nordisk provided to the committee indicated that many of Novo Nordisk's insulin products are at penny pricing in the 340B program. Moreover, information Novo Nordisk provided the committee showed that for one of these insulin products at penny pricing the number of packages provided to 340B entities increased from just over 270,000 packages in 2014 to over 735,000 packages in 2018. That is more than 172 percent increase in the number of packages supplied to 340B entities, and many of the Novo Nordisk other insulin products also saw a significant increase in the number of packages sold in the 340B program during this period.

Can you explain the impact that the 340B program has had on Novo Nordisk's pricing in the private and commercial markets?

Mr. LANGA. We have over 18,000 facilities, I believe, at this point roughly and it is at penny pricing. So it's literally 99.9 percent, and the packaging is, I believe as you reference it so; and has been going up. Is the question its influence on the commercial market?

Mr. BUCSHON. Yes, I mean because of that, because of its penny pricing and the volume has gone up dramatically, has that had an effect on the overall pricing structure in the rest of the marketplace, essentially?

Mr. LANGA. I think the challenge has been the 340B entities and who actually gets the designation and not. I think that's been more of the complexity and the challenge than it has been the spillover.

Mr. BUCSHON. OK.

Mr. Mason, same thing. I mean 340B has dramatically expanded as we all know, right?

Mr. MASON. A similar question, I mean obviously it does take away our net sales. If those are legitimately helping, you know, individuals that need that help we're fine that our product is going——

Mr. BUCSHON. I understand that. I mean, but, and quickly. I am out of time.

Ms. TREGONING. Yes. I think the issue is the heavily discounted products that go into the 340B system. But are those heavily discounted prices making their way to patients.

Mr. BUCSHON. Yes. I am going to just quickly say, with your indulgence, Madam Chairwoman, that in the 340B program I firmly believe based on this subcommittee's report that was released last Congress that we need to seriously look at and reform the 340B program; so that it continues to exist for the hospitals and patients that need it, but add a degree of transparency because it is spiraling.

Thank you, I yield back.

Ms. DEGETTE. I thank the gentleman. The Chair now recognizes the very, very patient woman from California, Ms. Barragán, for 5 minutes.

Ms. BARRAGÁN. Thank you very much.

You know, I am sitting here, and I have been hearing this back-and-forth for the last couple of hours, and the way I think I would summarize this is it sounds like we are playing a middleman. It just sounds like we are playing a middleman for prescription drugs to be on a preferred list. That is not just to put all the blame here, but then these list prices have just been skyrocketing and then when we ask about pricing. What we are hearing back from the drug companies is, well, the net price is actually declining. Last time I checked I think Lilly was doing pretty good. Wouldn't you say so, Mr. Mason? Why don't you tell me what the revenue was for this coming year? What is Lilly's revenue this coming year?

Mr. MASON. $21 billion.

Ms. BARRAGÁN. OK, I saw $25.3 billion for the coming year. Your CEO in 2014 was making 14.5 million in a pay package. That was in 2014. The new CEO, 2018, is making $17.2 million in a pay package. You guys are doing okay. I would think so. The American people sees that, and they say, "Why can't we just get pricing for insulin, a lifesaving drug that we need? Not that we want, but that we need." And they say Congress has to do something.

When you see what, when you hear what is happening here today that is exactly what is going to have to happen. I don't see anything happening here. I mean, look, I represent a congressional district that is a majority minority. People of color are disproportionately impacted by diabetes, Latinos and African Americans. I happen to represent a district that includes Compton and Watts, very low-income, working class families who are struggling. My re-

port says there is over 80,000 uninsured there, a lot of people who probably can't afford to pay for their insulin.

Do you all recognize that YOUR pricing policies and this system is causing people to die every day? Do you all recognize that? Mr. Mason, do you recognize that? Let me just go down the list here, yes or no, do you all recognize this?

Mr. MASON. We don't want anyone not to be able to provide their insulin. We——

Ms. BARRAGÁN. I understand that. But do you recognize that this pricing system and model is causing people to die?

Mr. MASON. We need to do something about it collectively.

Ms. BARRAGÁN. OK, that is a yes.

Mr. Langa?

Mr. LANGA. We recognize the model is certainly a challenge, yes.

Ms. BARRAGÁN. You are playing a role in that model. Let's not mince any words here, is these companies and the PBMs are playing a role in this model and that is why we are having this hearing is because we are trying to get to the bottom of it.

Ms. BARRAGÁN. Ms. Tregoning.

Ms. TREGONING. Yes, we recognize that's happening and that's why we put in place the programs, to address the inadequacies of the current system so that that doesn't happen, so people aren't forced into rationing their insulin. We don't want to see that.

Ms. BARRAGÁN. Mr. Moriarty?

Mr. MORIARTY. There's no question there's a portion of the population where this needs to be addressed very directly, no question.

Ms. BARRAGÁN. Ms. Bricker?

Ms. BRICKER. Absolutely there are patients falling through the cracks. We exist only to make medication more affordable and——

Ms. BARRAGÁN. OK. I am not obviously going to get you to tell me that you are a part, because I mean, and the reality is what we heard today that that is what is happening here. You know, I wish that you all would just come together and collaborate.

A moment ago, Ms. Bricker, I believe you are the one who said that the way you were able to get the $25 plan and the deal that you were able to get for the insulin, the new program that you just rolled out, was that you collaborated together, that you worked together. So if you could do it there, how come you all can't do it for others, right? And so, this is where Congress has to step in and do something. It is because of profits. It is because of greed. The American people are tired. And when people die, when people die and that is what is happening, make no mistake about it, we hear about it. The country hears about it and it is outrageous. It is completely outrageous.

I want to end quickly on the Medicare Part D. You know, in 2018, more than 43 million seniors enrolled in Part D plans. Currently, the Government is prohibited from negotiating directly with the drug manufacturers on behalf of Medicare Part D enrollees. If this prohibition were lifted the Government would be able to provide the leverage needed to bring down prescription drug pricing.

On a yes or no real quick because I only have 10 seconds, starting on the end, yes or no, do you support Medicare being able to negotiate drug prices under Part D?

Mr. MASON. Prices are getting better in Part D——

Ms. BARRAGÁN. Yes or no, would you support negotiating drug prices under Medicare Part D?

Mr. MASON. Just don't think they're needed.

Ms. BARRAGÁN. OK.

Mr. LANGA. I think everything we would consider, if it helped the patient.

Ms. BARRAGÁN. So that is a yes?

Mr. LANGA. I think we'd consider everything. I think the fair market, the free market that's playing right now is working because we have some of the heaviest discounts in Part D.

Ms. BARRAGÁN. It is not working because people are dying, and they can't afford it.

But next?

Ms. TREGONING. The PBMs are very effective negotiators. The question: is what do we do with the results of those negotiations?

Ms. BARRAGÁN. You don't have an answer on whether you support Medicare being able to negotiate drug prices under Part D?

Ms. TREGONING. Don't support direct negotiation because the PBMs are effective negotiators.

Ms. BARRAGÁN. You do not. OK.

Mr. MORIARTY. We do not. We drive very effective discounting.

Ms. BARRAGÁN. OK.

OK, Ms. Bricker?

Ms. BRICKER. Similarly, yes. The Government——

Ms. BARRAGÁN. You do not?

Ms. BRICKER. Do not support.

Ms. BARRAGÁN. OK.

Mr. Dutta?

Dr. DUTTA. We do not.

Ms. BARRAGÁN. OK. I can understand why that might be the case. It is unfortunate, but my time is up. I yield back.

Ms. DEGETTE. Thank you. I thank the gentlelady.

I am now pleased to recognize the gentleman from Georgia, Mr. Carter, for 5 minutes.

Mr. CARTER. Thank you, Madam Chair, and thank you for allowing me to participate in this.

Ladies and gentlemen, thank you for being here today. Just a full disclosure, currently I am the only pharmacist serving in Congress. I practiced pharmacy, community pharmacy, independent community pharmacy for over 30 years. You know, I remember and just FYI, I started when I was ten. But I can remember that—I can remember when PBMs evolved. I can remember when PSC was nothing more than a processor. That is all they did was process claims before PBMs got involved in setting up formularies. I can remember ordering directly from drug companies and not going through a wholesaler or anyone, just getting a shipment every week, a delivery every week from Eli Lilly or any other of the companies, Upjohn, or any of the number of companies that we ordered from.

You know, my colleague, Mr. Tonko, mentioned earlier about patients having to make choices between eating and between paying for their medications. I have seen it firsthand. I have witnessed it firsthand.

Ms. Bricker, you said you were a pharmacist and practiced in community forums. I don't know what your experiences were. You are obviously a lot younger than me, but at the same time I can tell you I have seen it. I have seen patients at the counter having to make a decision between buying medicine and between buying groceries. I have seen mothers in tears because they couldn't afford their medications. I have witnessed it firsthand. I was the boots on the ground there. That is why I am so passionate about that.

I wanted to start with you Mr. Langa. During a briefing with committee staff, I don't know if it was you or a member, or a representative of your company; but they said that list prices started to increase more rapidly around the same time that there started to be more consolidation throughout the drug pricing supply chain, and that there have been increasing demands on rebates. Has consolidation impacted the list price of medications?

Mr. LANGA. I think it was a factor. I think that as the PBMs today, as I mentioned the three here today represent almost 220 million covered lives or 80 percent of the lives, so.

Mr. CARTER. And that is probably, the three here today I believe represent over between 70 and 80 percent of all the PBMs in America.

Mr. LANGA. Correct. I think that as the consolidation that purchasing power got bigger, the rebate challenges got heavier.

Mr. CARTER. Absolutely.

Mr. Mason, would you agree with that? And in fact, I believe that you responded to a letter and said the same thing.

Mr. MASON. Yes.

Mr. CARTER. OK.

I would like to ask you, Mr. Moriarty, you are with CVS Health. CVS is a drugstore, right?

Mr. MORIARTY. That's correct.

Mr. CARTER. Caremark is the PBM.

Mr. MORIARTY. That's correct.

Mr. CARTER. And that is owned by CVS, the same company?

Mr. MORIARTY. That's correct.

Mr. CARTER. Aetna Insurance is the same company?

Mr. MORIARTY. That's correct.

Mr. CARTER. OK, so we got Aetna the insurance company, we got Caremark the PBM, and we got CVS the drugstore, all the same company, right?

Mr. MORIARTY. That's correct.

Mr. CARTER. OK.

Ms. Bricker, I believe that Express Scripts, you are here today representing the PBM?

Ms. BRICKER. Yes, I am.

Mr. CARTER. You are also—you just bought out CIGNA Insurance. That is right?

Ms. BRICKER. CIGNA acquired Express Scripts.

Mr. CARTER. CIGNA acquired Express Scripts, and you also have your own mail-order pharmacy; is that correct?

Ms. BRICKER. We do have a mail-order pharmacy.

Mr. CARTER. OK.

Dr. Dutta, same thing with you. Optum is the PBM, United Healthcare is the insurance company, and you also have your own mail-order pharmacy; is that correct?

Dr. DUTTA. Optum and United Healthcare are sister companies, yes.

Mr. CARTER. You do have a mail-order pharmacy that you own as well?

Dr. DUTTA. OptumRx has a mail-order pharmacy.

Mr. CARTER. Yes. okay, that is a long yes answer. Nevertheless, when you have been saying during these hearings that you are returning money to the plan sponsors, can you define plan sponsors for me? Is that the insurance companies?

Mr. Moriarty?

Mr. MORIARTY. It is the employers, State and Federal——

Mr. CARTER. The insurance, are you sending the money back to the insurance company?

Mr. MORIARTY. As well as health plans, but it's much more than just health plans. Yes, sir.

Mr. CARTER. You are sending it back to—and, Ms. Bricker, you are sending it back to the insurance companies?

Ms. BRICKER. So we send back to the clients that hire us. Those are employers——

Mr. CARTER. At the end do you send it back to the insurance—please remember you are under oath here. Let's get on. Do you send it back to the insurance companies?

Ms. BRICKER. In the event that the plan sponsor is an insurance company, yes.

Mr. CARTER. Right.

Ms. BRICKER. But that's not the only——

Mr. CARTER. OK.

Dr. Dutta, same thing with you?

Dr. DUTTA. In the event that the plan sponsor is the insurance——

Mr. CARTER. OK, same thing. So essentially you are the PBM managing money and you are sending the money back to another company that you own. In some cases that could be the case; isn't that right, Dr. Dutta?

Dr. DUTTA. So we have many health plans that——

Mr. CARTER. I understand that. But it is possible you could be sending it back to the—owned by the same company. So this vertical integration that we are talking about here that I have been on the FTC and the Department of Justice about, that is something that certainly we need to be aware of.

Boy, 5 minutes flies, let me tell you. But before I relinquish my time, I want to congratulate all of you because you have done something here today that we have been trying to do in Congress ever since the 4 years and 3 months that I have been here and that is to create bipartisanship, because what you have witnessed here today is bipartisanship.

This is going to end. I have witnessed it. I have seen what you have done with the PBMs. I have seen what you have done with DIR fees. I see what you are trying to do now with GER fees and BER fees. Let me tell you, what the CMS is proposing in the way of doing away with DIR fees and the way of having discounts at

the point of sale, that is going to happen. We are going to make sure that happens and that is going to bring more transparency to the system, and we are not going to stop there.

Thank you, Madam Chair, and I yield back.

Ms. DEGETTE. Thank you, Mr. Carter. I was just saying I never thought I would see the day when Buddy Carter was channeling Jan Schakowsky. Congratulations.

I now want to recognize Mr. Guthrie for closing questions and a statement.

Mr. GUTHRIE. I just want to close and when the Chair and I were discussing having the hearing we thought insulin was a proper one to have. One, I know it is different than 100 years ago today. But we had a lady before, a doctor, physician from Yale that said that there was—held up an insulin and said this is the same insulin from the 1990s as it is today and the price has moved forward.

We wanted to—because we wanted to look at the entire system, but we thought if we looked at one drug that affects almost—like I said, I have two nieces with diabetes—it affects almost every family, that we could look at what is going on and then we could extrapolate to bigger.

I will tell you, and you were talking about Ms. Schakowsky, my friend Ms. Schakowsky from Illinois, she also talked about President Trump in saying that this is important to him. My experience with him in meeting with him is that drug pricing is important to him, so it is everybody. It is uniting everyone.

I am going to be quick. I know 5 minutes went fast before, I didn't get all my questions. I am not going to ask a question because that is not what I have been recognized for. But innovation is important. I saw a film yesterday of a father talking about his daughter, I don't know if "cured" is the right word, but not having any symptoms from sickle cell. I mean it is just—Hepatitis C, you can take with, and you talk about medical devices. You can do the artificial pancreases here.

So innovation and having a market-based system and a free enterprise system is absolutely important and—but what we are trying to get at with this is, and hopefully you can see our frustration, is that we see the pharmaceutical companies say, "Our net price is going down." We see the list price going up. I have friends here from Bardstown that are in the Buddy Carter situation, are community pharmacists, and they see, have described to me situations that he just described and they have to pay the list price to sell to somebody who is not through the—when they sell, so it is a cash flow to those kind of businesses.

What we are trying to figure out is if the net price is the net price, then why isn't that what is paid to the—if the idea is we are going to get the lowest price for our insurance companies, then why isn't selling something for $135 that is costing them $135 better than selling something 300 or $400 and getting 300 or $400 back, other than saying I saved you that money? Just trying to figure out where the money is going and so this has been informative.

I think one question I wanted to ask that I am going to do for the record is, so what you put on the formulary, is it better for a high list price with a lower net or that is better for the insurance company, but it is not as good for a—if it is just a lower net price

or just lower list price, it is actually lower for the consumer going to the counter at the pharmacy?

This is just hopefully the beginning of a series of hearings and it has been informative. We do appreciate you willing to come here and your testimony and trying to inform us because we do have to make some decisions. We don't want unintended consequences because you could get into—if you get into price controls you get into rationing and you get into shortages and that is not where we want to—that is not where I want to go. We want people to have a fair price that they can pay and if they can't pay to have the assistance to have that because it is lifesaving.

Thank you for your indulgence and I yield back.

Ms. DEGETTE. I thank the ranking member, and I do want to thank the witnesses. I know people asked you hard questions. It was important to us to get everybody in here, and I think we can all agree that the system is broken, and it has grown up in a way over time that people didn't anticipate. But here is the thing. The people who are suffering are the patients. In the case of insulin, the people who are suffering are people who need insulin every second of every minute of every day or they will die, and that is the issue that we have here.

I now, having done this investigation last year with my colleague from New York, Tom Reed, and now doing this investigation, I think I have a pretty good grip, and I think the members of this committee are getting a better and better grip of what is going on. And what is going on is the system has grown up in this country where we are continually—it is a smoke-and-mirror system where we are continually increasing the list price of insulin in order to try to do negotiations to somehow get the price of insulin down.

But let's look at the reality of the situation. The members of this panel kept saying over and over again net prices of insulin have gone down and one person even said that nobody pays list price, they all pay net price. But that is not exactly true.

So I just want to give you the example of Humalog, because Humalog is one of those insulins, it is not 100 years old, but it is over 20 years old and in 2001, Humalog cost $35 a vial. Today, no change to Humalog—it is not Tresiba, which by the way Tresiba is not an insulin, it is another drug to help absorption of insulin that is given to type 2 diabetics—so Humalog, it is still the same formulary. It is $275 today for a bottle of the same insulin that I bought for Francesca when she was six years old, and the generic Humalog that Lilly has come up with, good news, it is only $137 a bottle. So it is still way beyond where it was in 2001.

Well, now Sanofi has a new generic alternative, Admelog. I just sat here and looked and Admelog, it might not cost as much as Humalog, but it costs over $200 a bottle. So let's not kid ourselves that the generic equivalent of this is really any cheaper for that young woman in my district who doesn't have insurance who is desperately trying to find two bottles of insulin every month. That is $400 for her even if she bought that.

When you say nobody is paying list price, there are people paying list price. The people who are paying list price are the people who have high-deductible plans who have to pay for the list price when they go in to the pharmacy and they are on their deductible, the

people who are in the doughnut hole of Medicare Part D, and the people who are uninsured.

I know all of the, everybody here, the PBMs and the pharmaceutical companies all have these efforts to give cheaper insulin to people like this, but I am going to tell you, the lady I talked to in Denver, she didn't know how to get that insulin. She had no idea how to get it, and our witnesses last week said many people in that situation don't. It is not a solution to the problem, it is just a temporary Band-aid and it is one that we have to stop with a wholesale innovation.

Let me just say, finally, this. It is not like the pharmaceutical companies or anybody else in the system is doing this for a public interest reason. The pharmaceutical companies had $323 billion in profits last year. The PBMs had $23 billion in profits last year. And so everybody is making a profit and the people who are really suffering here are the people who either have to pay list price or even after their deductible have to pay an unacceptable price and nobody here in this room wants that.

What we are going to do, we are going to get together in a bipartisan way and we are going to work with all of you, plus everybody else in the distribution center, to figure out how we can provide insulin to diabetics at a cost that they can afford and we are going to do that as quickly as we can. So as you heard we are having an ongoing investigation here. We are prepared to talk to you now and we are prepared to bring you all back in July or in September to talk about the progress that we have made, because this is not optional and it is going to happen. I want to thank you all again for coming today and we are not going to have any more testimony, but I really want to thank you for coming and I want to thank you for being part of the solution and not a continuing part of the problem.

In closing, I will remind members that pursuant to committee rules they have 10 business days to submit additional questions for the record to be answered by witnesses who have appeared before the subcommittee. I ask that the witnesses agree to respond promptly to any such question should you receive any, and with that the subcommittee is adjourned.

[Whereupon, at 2:37 p.m., the subcommittee was adjourned.]

[The article appears at the conclusion of the hearing.]

Protesters at Sanofi in Cambridge decry high price of insulin

By **Allison Hagan** Globe Correspondent, November 16, 2018, 5:17 p.m.

Two mothers Friday tried to deliver the ashes of their two diabetic children to the Cambridge offices of drug giant Sanofi to protest the high price of insulin, which the company manufactures. The women said their adult children died while rationing the drug to save money, after losing their health insurance.

Antroinette Worsham of Cincinnati, Ohio, and Nicole Smith-Holt from Richfield, Minn., were joined by about 75 protesters. According to the Brookline-based Right Care Alliance, a patient advocacy coalition that organized the protest, Paris-based Sanofi is one of three insulin manufacturers that in recent years have marked up prices by as much as 5,000 percent.

The protesters stayed across the street while the two mothers attempted to walk through the Memorial Drive parking lot with small containers holding the ashes, but company security officials ordered them off the property, said Aaron Toleos, a spokesman for Right Care. Toleos said police on the scene told the women that "if you choose not to leave, you will be arrested." No arrests were made.

"We continued with the protest and letting them know the price of their product is killing people when it's intended to save their lives," said Smith-Holt, whose 26-year-old son, Alec Raeshawn Smith, died last year.

Nicole Smith-Holt of Richfield, Minn., held a vial with the ashes of her son, Alec, who died at the age of 26 from insulin rationing. (JOHN TLUMACKI/GLOBE STAFF)

Worsham's daughter, Antavia Lee Worsham, 22, also died in 2017. Right Care said they, and one other diabetes patient, lost their lives because they were forced to cut back on their medication to save money.

Antroinette Worsham held a vial of ashes from her daughter, Antavia Lee Worsham, who died last year. (JOHN TLUMACKI/GLOBE STAFF)

Nicolas Kressmann, a spokesman for Sanofi, said the company is exploring innovative ways to reduce out-of-pocket costs for patients. He said the company's security prevented the protesters from entering the company's office because of safety concerns.

"We want to ensure everything works as well as possible for employees and the protesters. We don't want any accidents or any situation," he said.

Allison Hagan can be reached at allison.hagan@globe.com. Follow her on Twitter @allisonhxgan.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"

April 10, 2019

Mr. Mike Mason, Senior Vice President, Lilly Connected Care and Insulins Global Business Unit, Eli Lilly and Company

The Honorable Joseph P. Kennedy III (D-MA)

1. **At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.**

   Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

   a. **Where can patients find information on eligibility and criteria for the programs?**
   b. **What are the eligibility criteria for the programs?**
   c. **What information and documents must patients submit in order to qualify for the programs?**
   d. **What number of patients apply for the programs each year, what number are approved, and what number are denied?**
   e. **What are the ten most common reasons your company denies a patient's application?**
   f. **Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?**
   g. **How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for insulin in 2018?**

Eli Lilly and Company ("Lilly") understands the importance of ensuring that our various insulin products are both accessible and affordable to individuals with diabetes. We have a number of programs in place to increase affordable access to our insulins. Information about these programs, their eligibility criteria, their utilization, and Lilly's efforts to make them widely available is set forth below.

Promoting affordable access begins with ensuring that our insulins are available to patients with insurance, which includes both private insureds and those covered by Medicare

Part D. Like other manufacturers, Lilly competes for placement on insurance formularies on the basis of product attributes like efficacy and safety, and by providing rebates to reduce the cost of insulin to pharmacy benefit managers ("PBMs"), payers, and patients. In 2018, for Basaglar, Humalog, and Humulin, Lilly paid approximately $4.4 billion[1] in rebates, discounts, and other price concessions, or over 50% of the $8 billion in gross sales of those products. By paying these rebates, Lilly ensures that its insulins are available to patients with insurance, who typically have low out-of-pocket costs.

We recognize that despite the rebates Lilly pays to ensure formulary access, some individuals remain exposed to high prescription drug costs. These patients have a real and pressing need for immediate solutions—particularly those who rely on medications to treat life-threatening, chronic conditions like diabetes. For this reason, Lilly has instituted multiple programs designed to reach each of the segments of people who need assistance affording their insulin. These programs work in a variety of ways. The Centers for Medicare and Medicaid Services ("CMS") narrowly define pharmaceutical manufacturer-sponsored "patient assistance programs" as those that "provide financial assistance or drug free [sic] product (through in-kind product donations) to low-income individuals to augment any existing prescription drug coverage."[2] Lilly provides in-kind product donations to charitable organizations, including Americares, Direct Relief, Dispensary of Hope, and Lilly Cares, separate non-profit organizations that conduct "patient assistance programs" for low-income individuals.

To fill additional gaps in coverage, Lilly has implemented other programs to promote access and affordability that may be relevant to your inquiry but do not fall within the CMS definition of a "patient assistance program." Below, we provide information on the range of initiatives undertaken by Lilly in addition to product donations.

- Insulin Lispro Injection: We recently launched the authorized generic ("AG") version of Humalog, Insulin Lispro Injection ("Insulin Lispro"). Insulin Lispro has a 50% lower list price than its identical medicine, Humalog U-100 and is available in both vial and KwikPen form. We sought to bring a lower-priced version of our product to the market because we recognized that Lilly's other solutions, though important, still left some people vulnerable to high out-of-pocket costs for insulin. We expect the introduction of Insulin Lispro to particularly benefit individuals in the deductible phase of their coverage period, as well as those enrolled in Medicare Part D who are in the coverage gap. The patients who benefit from Insulin Lispro in these periods should see their out-of-pocket costs cut in half. Because of government restrictions, the over 500,000 individuals taking Humalog who are enrolled in Part D do not have access to as many of our other solutions as people covered by commercial insurance plans. By introducing this AG version, Lilly can provide a lower-

[1] This figure includes: rebates for formulary access, value-based agreements, price protection penalties, patient adherence support programs, and incremental rebates associated with product bundling. This figure also includes administrative fees, which PBMs require and which are categorized as price concessions for purposes of government price reporting. These figures do not include discounts associated with mail order or cash card programs facilitated by a PBM, since they neither contribute nor are tied to conditions affecting coverage of a product.

[2] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html.

priced insulin quickly while maintaining access to branded Humalog, on which well over one million people currently depend.

- Automatic Discounts[3]: Lilly also offers savings directly to people in the high-deductible phase of their insurance plans by capping their prescription cost at $95 at a retail pharmacy. When a person in a high-deductible insurance plan fills a prescription for a Lilly insulin, the individual generally will pay no more than $95 out of pocket at the pharmacy, and Lilly will pay the remainder of the cost.[4] The discount is automatically applied at the point of sale, and therefore has an immediate impact on the cost paid by the insured person. This occurs when the insurance claim is processed and does not require the individual to enroll in any programs or request that the savings offer be applied.

- Co-Pay Cards and Cash Savings Cards (collectively, "Savings Card Programs"): Lilly provides various Co-Pay Cards and Cash Savings Cards that allow patients to obtain Lilly insulins at lower prices during the high-deductible phase of a commercial insurance plan or when they are paying cash because they do not have insurance coverage. These cards typically are used when the Automatic Discounts discussed above are not available at a particular pharmacy or for patients paying cash. A Co-Pay Card is a physical or virtual card presented at the time a prescription is filled where the patient discount is adjudicated as a secondary payer in addition to the patient's insurance. Cash Savings Cards are physical or virtual saving cards for patients without commercial insurance where Lilly provides a discount to the patient that is adjudicated at the point of sale with Lilly serving as the primary payer.

- Point-of-Sale Savings Programs: Since 2017, Lilly has participated in Blink Health (www.blinkhealth.com) and Inside Rx (www.InsideRx.com) savings programs that offer savings of up to 40% off the list price of Lilly's most commonly prescribed insulins. These programs are available to people through smart phone applications and offer savings at the point of sale. Our participation in these programs was an initial step to provide discounts to people on Lilly insulins who have commercial insurance or are uninsured.

- Lilly Diabetes Solution Center: Recognizing that some of the solutions described above will not help people unless they know about them, Lilly launched the Lilly Diabetes Solution Center ("LDSC" or the "Solution Center") in August 2018. The Solution Center is a patient-focused helpline staffed by medical professionals that connects people living with diabetes to any of Lilly's various resources and solutions based on their individual needs. These solutions include savings cards (requiring no paperwork and no application), an immediate emergency supply of insulin, or information about one of the clinics that can offer free insulin that Lilly has donated. The LDSC also can connect patients to Lilly

[3] Consistent with HHS OIG guidance on copayment coupons (OIG Special Advisory Bulletin—Manufacturer Copayment Coupons September 2014), the automatic discount and Co-Pay Assistance Programs are not intended to be utilized where payment may be made, in whole or in part, under a federal health care program.

[4] Significantly, the portion that Lilly pays is counted towards the patient's deductible.

Cares. Lilly has publicized the LDSC through press releases, social media channels, and advertising campaigns—including direct-to-consumer print ads—that directly target people with diabetes, the general public, and specific communities of color with a higher risk of diabetes.

To access information on Lilly's affordability programs, including eligibility requirements, patients can visit www.insulinaffordability.com, a Lilly website that provides information on the LDSC, Point-of-Sale Savings Programs (referred to on the website as "Discount Programs"), and Savings Card Programs. They can also call the LDSC, which provides information on many programs. The number for the LDSC is (833) 808-1234. In addition to helping patients enroll in these programs, the LDSC will also connect eligible patients with the separate non-profit Lilly Cares. Information regarding Lilly Cares and its requirements can be obtained from its website: https://www.lillycares.com/resources.aspx.

Lilly's affordability programs, including the Automatic Discounts, Savings Card Programs, and the Point-of-Sale Savings Programs, are readily available to patients. They require no applications and have only limited eligibility requirements. As noted above, the Automatic Discounts take place when the insurance claim is processed and do not require the individual to enroll in any programs or request that the savings offer be applied. In fact, individuals may not even be aware of these "buy-downs" or may be surprised by them. Our Savings Card Programs are broadly available to patients with commercial insurance or paying cash. To qualify for these programs, the patient must be a U.S. resident, be 18 or older, have a prescription for a Lilly insulin, and not have government insurance. There is no income cap. Similarly, a patient with commercial insurance may gain access to the Point-of-Sale Savings Programs simply by signing up. Lilly makes these programs as broadly accessible as possible. While patients with government insurance are excluded from the Automatic Discounts, Savings Card Programs, and the Point-of-Sale Savings Programs, this exclusion is imposed by the government, not by Lilly.[5]

Access to the LDSC is also broadly available to patients without an application and without satisfying any additional eligibility requirements. When a patient calls the LDSC, she is connected with a healthcare professional who assesses which assistance program may be the best fit. If the patient expresses an urgent concern about accessing medication, the Lilly representative's first step is to identify ways of addressing that need. For instance, the representative may be able to offer a free month's supply of insulin. Once the immediate need has been addressed, the healthcare representative moves to a conversation about longer-term solutions. Patients who meet the minimal eligibility requirements noted above are provided with assistance through Lilly's Savings Card Programs or Point-of-Sale Savings Programs. A patient who has Medicare Part D insurance is connected to Lilly Cares, since (as noted) Lilly may not, consistent with applicable government guidance, help these patients through its Automatic Discount, Savings Card, or Point-of-Sale Savings Programs. Additionally, if a patient volunteers income information indicating that the patient may be eligible for free insulin from Lilly Cares,

[5] Federal guidance has prevented Lilly and other manufacturers from subsidizing prescription costs for people insured through government programs such as Medicare Part D. OIG Special Advisory Bulletin—Manufacturer Copayment Coupons September 2014.

the LDSC representative refers the patient there. The LDSC can also provide patients with a list of clinics that provide free medication in or near her zip code. Finally, LDSC representatives are also able to provide information about Insulin Lispro. There are no separate income requirements that a patient must meet to obtain assistance from the LDSC, and no paperwork is required.

Only Lilly Cares requires patients to submit an application form.[6] (As previously noted, Lilly Cares is a non-profit organization separate from Lilly, but for convenience, we provide publicly available information from Lilly Cares herein.) The Lilly Cares application is available at: https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf. The form explains the separate Lilly Cares eligibility requirements, one of which relates to income. To access insulin drugs through Lilly Cares, a patient's household income may be no more than 400% of the federal poverty limit ($100,400 for a family of four).[7]

We want people to use our solutions, and our intent is to make these solutions as easy to access as possible. In 2018, Lilly spent more than $108 million on Automatic Discounts and Savings Card Programs, plus an additional $3 million on Point-of-Sale Savings Programs. The amount spent on Automatic Discounts and Savings Card Programs in 2019 is expected to rise to at least $200 million. Information from our vendors indicates that in 2018, the Automatic Discounts and Savings Card Programs served 525,403 unique patients, for a total of 1,636,797 redemptions. The Point-of-Sale Savings Programs are independently administered, and Lilly does not maintain enrollment data on those. Because Lilly's Automatic Discounts, Savings Card Program, and Point-of-Sale Savings programs do not require applications, Lilly does not have "denial" information for these programs. Utilization or denial data related to Lilly's donations of free insulin is not readily available because product donations are distributed by separate charitable organizations. The chart below, however, shows Lilly's donations of insulin from the Humalog, Humulin, and Basaglar product families from 2014 – 2018:

[6] Other free clinics to which Lilly donates medicines may also require application forms.

[7] https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf.

Organization	Quantity of Pens[8] and Vials
2014	
AmeriCares	380
Catholic Medical Missions Board	7,200
Diabetes Camps	34,504
Direct Relief	12,344
Lilly Cares Foundation	980,352
Lilly Medicare Answers	3,488
MAP International	200
Partners in Health	6,512
Project HOPE	43,000
2015	
Catholic Medical Missions Board	12,700
Diabetes Camps	39,807
Direct Relief	17,696
Lilly Cares Foundation	748,540
Lilly Medicare Answers	189,449
2016	
Catholic Medical Missions Board	19,050
Diabetes Camps	40,284
Direct Relief	23,693
Lilly Cares Foundation	1,038,710
2017	
AmeriCares	23,910
Catholic Medical Missions Board	4,700
Diabetes Camps	50,587
Direct Relief	164,325
Project HOPE	1,500
Lilly Cares Foundation	928,664
2018	
AmeriCares	24,600
Catholic Medical Missions Board	14,900
Diabetes Camps	46,812
Direct Relief	153,900
Dispensary of Hope	23,200
Lilly Cares Foundation	1,233,096
Total (2014-2018)	**5,888,103**

Approval or denial data for the separate non-profit entity Lilly Cares is available through that organization's 2018 Annual Report, which states that 88% of people who applied were approved for up to a year of coverage.[9] According to that Report, more than 52,000 patients were provided with $320.3 million in diabetes medication in 2018.[10]

[8] This table refers to the number of pens donated—not the number of boxes of pens donated.

[9] http://www.lillycares.com/_Assets/pdf/Lilly_Cares_2018_Annual_Report.pdf.

[10] *Id.*

Lilly's various programs to promote access and affordability have different requirements for requalification. Because there are no eligibility requirements for Insulin Lispro, there are no requalification requirements. Similarly, the Automatic Discounts take place automatically and require no patient action at any time. The Savings Card Programs typically last for a year and must be reauthorized on a yearly basis. The criteria for reauthorization are the same as for initial eligibility: the patient must be a U.S. resident, be 18 or older, have a prescription for a Lilly insulin, and not have government insurance.

The last subsection of this question asks how much Lilly spent on public awareness campaigns to promote its patient assistance programs in 2018 and how much Lilly spent on advertising for insulin in 2018. Lilly has implemented a comprehensive public awareness campaign for the LDSC that uses its sales force, social media, direct healthcare provider and pharmacy communications, and outreach to elected officials and patients. Our primary efforts are focused on healthcare providers and pharmacists providing care for people living with diabetes. Our national sales force proactively promotes awareness about our LDSC offerings. They are trained to provide information about how patients can connect with the LDSC and the various affordability solutions that are available. They also encourage healthcare providers to distribute LDSC flyers, patient cards, and office magnets, which list the call center's phone number and hours.

For 2018, Lilly also spent approximately $5.3 million on advertising the LDSC, which launched in August of that year, directly to patients. This is more than one-fifth of the amount Lilly spent on consumer awareness programs (including advertising) for its insulin products that year (approximately $23.4 million).[11] And about 50% of that $23.4 million was spent on a patient education campaign for patients who may have questions about how to start using Lilly insulin or how best to adhere to the treatment going forward.

In addition to paid advertising, Lilly promotes the LDSC through social media. Since August 2018, Lilly has published eight blog posts about the LDSC on LillyPad,[12] Lilly's official blog, and more than 145 social media posts on our corporate Twitter, Facebook, and LinkedIn accounts.[13] For example, during the federal government shutdown in 2018 – 2019, we published a blog post[14] and ran a paid LinkedIn advertising campaign to inform federal employees that they were eligible for discounts. We have directed more than 1,000 questions about insulin

---

[11] Consumer expenses reflect promotional activities designed to support patients initiating insulin treatment whom already received an insulin prescription from their Health Care Provider. Examples include branded paid search advertising and printed materials for patients. Also, included are unbranded disease state education digital content sponsored by Lilly USA, LLC. This may also include branded advertising presented alongside unbranded content. These expenses, including the unbranded content, are classified as promotional advertising by Eli Lilly and Company.

[12] https://lillypad.lilly.com; *see, e.g.*, Mike Mason, *Helping People with Insulin Affordability*, LILLYPAD (Aug. 1, 2019), https://lillypad.lilly.com/entry.php?e=11030.

[13] Lilly's corporate divisions each maintain their own social media accounts; these numbers include posts by Eli Lilly & Company and by Lilly Diabetes.

[14] *Help for People, Including Federal Employees*, LILLYPAD (Jan. 16, 2019), https://lillypad.lilly.com/entry.php?e=11221.

affordability to the LDSC via these social media channels in response to private direct messages and public posts. We also have issued three press releases about the LDSC since its launch.

In addition, we have reached out individually to hundreds of elected state officials to alert them of the LDSC, including governors and representatives in states such as California, Delaware, Idaho, Kentucky, Maryland, Massachusetts, New Jersey, New York, Pennsylvania, and Tennessee. Moreover, during the federal employee shutdown earlier this year, we sent similar notices to reach employees who may have needed assistance during the furlough.

The costs of advertising the LDSC are only a portion of the overall costs of operating the Solution Center. In 2018, Lilly spent approximately $3 million to staff the LDSC with healthcare professionals who answer individuals' questions. We opened the LDSC with four dedicated agents, but due to marketing efforts and increased awareness, we have had to increase our headcount by nearly 400% since our launch in August 2018, and that growth continues. Additionally, the $3 million spent in 2018 does not account for unallocated Lilly expenses, such as training and support from Lilly employees. These expenses are in addition to the $108 million noted above spent in 2018 on Automatic Discounts and Savings Card Programs and the $3 million spent on Point-of-Sale Savings Programs.

Overall, our solutions are working to reduce out-of-pocket costs. Today 95% of prescriptions for Humalog in the United States cost consumers less than $95 at the retail pharmacy, 90% cost less than $50, and 43% cost $0.[15] These figures reflect the cost for Humalog at the retail pharmacy regardless of the phase or term of the patient's health plan. Now that Insulin Lispro has launched, we hope it will be added to more formularies. At the same time, we continue to educate the diabetes and medical community about our Lilly Diabetes Solution Center so that even more people will pay less for their insulin.

2. **Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.**

    a. **Where can patients find information on eligibility and criteria for the programs?**
    b. **What are the eligibility criteria for the programs?**
    c. **What information and documents must patients submit in order to qualify for the programs?**
    d. **What number of patients apply for the programs each year, what number are approved, and what number are denied?**
    e. **What are the ten most common reasons your company denies a patient's application?**
    f. **Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?**

[15] Based on IQVIA data, FIA data (August 2018 – December 2018).

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for medication in 2018?

Lilly manufactures a variety of medications in the oncology, cardiology, immunology, endocrinology, and other spaces. As defined by CMS, Lilly's patient assistance programs center on donations to Lilly Cares and other charitable organizations. The following medications are available for free from Lilly Cares: Alimta, Cialis, Cymbalta, Cyramza, Emgality, Erbitux, Evista, Forteo, Glucagon, Humatrope, Lartruvo, Olumiant, Portrazza, Prozac, Strattera, Symbyax, Taltz, Trulicity, Verzenio, Zyprexa, Zyprexa Relprevv, and Zyprexa Zydis.[16] Approval or denial data for Lilly Cares is available through that organization's 2018 Annual Report, which states that 88% of people who applied were approved.[17] According to that Report, more than 52,000 patients were provided with $320.3 million in diabetes medication in 2018.[18]

The Lilly Cares application is available at: https://www.lillycares.com/_Assets/pdf/LillyCares_Group_ABApplication_EmgalityProgram_Eligibility_Update.pdf. The Lilly Cares oncology patient assistance program application is available at: https://www.lillycares.com/_Assets/pdf/LillyCares_oncology_application_Program_-Eligibility_Update.pdf. These applications set forth the eligibility and documentation requirements for the Lilly Care programs. Other third-party charitable organizations to which Lilly donates medication each distribute product to their network of clinics subject to their own patient eligibility requirements.

3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.

All of Lilly's insulins are covered by the programs discussed in response to Question 1. Please see Lilly's response to Question 2 for information about the non-insulin drugs available through Lilly Cares, a separate non-profit organization. Lilly Cares does not provide Adcirca, Gemzar, Glyxambi, Jardiance, Jentadueto, Synjardy, and Tradjenta. These drugs are either: (1) off patent and have competition from approved generics; or (2) are products we co-promote but do not manufacture or set associated prices.

4. Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does

---

[16] http://www.lillycares.com/content/lillycaresgroupa_druglist.html; https://www.rxassist.org/pap-info/company-detail?CmpId=16.

[17] http://www.lillycares.com/_Assets/pdf/Lilly_Cares_2018_Annual_Report.pdf.

[18] *Id.*

your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.

As discussed above, Lilly donates medicines to Lilly Cares, a separate charitable entity, and other charitable organizations that provide free insulin to patients. Lilly is eligible for a charitable tax deduction related to those donations computed in accordance with the relevant Internal Revenue Code and Treasury Regulations. The costs of Lilly's other patient access and affordability programs are recorded as sales reductions or operating expenses and are not eligible for a charitable tax deduction.

The Honorable Brett Guthrie (R-KY)

1. **In March 2019, Eli Lilly announced that it was launching an authorized generic version of Humalog. In a staff briefing, Eli Lilly said that it anticipated providing supplemental rebates for the authorized generic version of Humalog.**

    a. **Will Eli Lilly request that Pharmacy Benefit Managers (PBMs) include both the authorized generic and the brand version on their formularies? If so, why? Does Eli Lilly anticipate that one version of the product will be preferred on the formularies over the other version of the product?**

Lilly will offer and has offered all PBMs access to Insulin Lispro, the AG version of Humalog, at the same or better net price as Humalog. We believe having both options available to patients at the same formulary status (or, potentially, to have a better status for the AG) is appropriate so that individuals in a deductible phase or individuals with co-insurance would have a lower-cost option available. Our experience to date, however, is that most PBMs continue to prefer branded Humalog even when the net cost is comparable because that option offers more total rebate dollars, and many of their health plan and employer clients value the total rebate dollars that they receive when their members purchase prescription medications. As described further below, those health plans and employers use the rebate dollars they receive to marginally reduce premiums for all of their insureds, rather than using them to reduce patients' out-of-pocket costs for insulin at the pharmacy counter. As a result, most PBMs have indicated that they are considering several approaches for Insulin Lispro, such as excluding Insulin Lispro entirely from formularies, offering the AG only on "niche" formularies, or placing the product on formulary but at a higher cost-sharing tier.

    b. **Will the introduction of the authorized generic have any impact on the list or net pricing for the branded version of Humalog (*e.g.*, will the rebates Eli Lilly offers to PBMs for Humalog change)?**

We have not increased the list price of Humalog with the launch of Insulin Lispro. Launching a lower-priced product does have other costs to Lilly, especially to branded Humalog. Since we announced Insulin Lispro, some PBMs have demanded more generous rebates on

Humalog in exchange for formulary access. For example, where the net price of Humalog after the rebate is higher than the net price of the AG, PBMs have requested that we increase their Humalog rebates so that the net price of Humalog is at least equal to the lower AG net price. As detailed further below, PBMs' clients include health insurance plans and employer groups who value the total rebate dollars that they receive. Thus, even with the net prices the same, most PBMs appear to prefer Humalog, the product that generates more rebate dollars.

2. **There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of the medicine. Has Eli Lilly received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Eli Lilly lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Eli Lilly and describe the requirements set forth in the letter.**

   a. **Does Eli Lilly have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.**

No. Lilly received the communication referenced above but did not agree to the request.

   b. **Has Eli Lilly provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.**

No.

   c. **What happens to Eli Lilly's rebate obligations with PBMs if Eli Lilly lowers the list price of insulin or any other medicine?**

Theoretically, the dollar amount Lilly must pay in rebates should decrease if Lilly lowers the list price of a medicine, because rebates are calculated as a percentage of, and thus fixed to, a product's list price. It is possible, however, that channel partners will seek to renegotiate agreements to increase rebate and discount percentages because their financial forecasts would have been based on a product with a higher list price.

   d. **Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Eli Lilly's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.**

The above-referenced letter, coupled with the commercial responses to our authorized generic Insulin Lispro, illustrates the challenges and barriers to lowering list prices. As noted above, many health plans and employers value the greater total rebate dollars that they receive

from those medications. Consequently, some PBMs have indicated that manufacturers must maintain the total dollar amount of rebates paid to them even if the list price of a prescription medication is reduced. Indeed, the above-referenced letter proposed an alternative rebate calculation whereby Lilly would be required to pay the same amount of rebate dollars on a prescription drug with a lower list price. Such demands make it difficult for Lilly to reduce list prices and retain comparable levels of patient access on PBM formularies.

These market dynamics underscore the need for systematic reform. One proposal, which is sometimes called "first dollar coverage," is described in more detail below.

3. **We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Eli Lilly's testimony, Eli Lilly described how the net price of its most broadly used insulin product decreased by 8.1 percent while the list price increased by 51.9 percent. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price. Please explain.**

Lilly has always sought to make its insulin medications affordable for patients who depend on them. For years, Lilly was able to accomplish this by providing significant discounts off of the list price in the form of rebates to PBMs and other payers. These rebate payments ensured that Lilly's insulin products were covered on PBM formularies under terms that provided affordable access for patients. In recent years, PBMs have begun to offer only one manufacturer's insulin products on their formularies, while blocking patients' access to competing products. PBMs have used this leverage to negotiate with manufacturers for larger rebates, placing downward pressure on Lilly's "net prices," *i.e.*, the amount that Lilly receives on each prescription. At the same time, increasing numbers of patients have been moved to insurance plans with larger deductibles and cost-sharing obligations, such that they do not directly benefit from the larger rebates paid by Lilly and other manufacturers. These developments have created affordability challenges for a growing number of patients, even as net prices for Lilly's insulins have stayed flat or declined.

Unfortunately, this affordability challenge cannot be addressed simply by lowering list prices. While the PBMs' clients, which include health insurance plans and employer groups, may prefer products that have a low net cost, they also value the total rebate dollars that they receive when their members purchase prescription medications. Many plans and employers use these rebates to subsidize lower premiums for all members. This has had the effect of increasing out-of-pocket costs for patients with significant cost-sharing obligations, especially those with chronic illnesses like diabetes. For example, Lilly pays substantial rebates even for patients who are responsible for the full cost of their insulin prescription during the deductible phase of their

health plan. Rather than using the rebate dollars to reduce those patients' out-of-pocket costs, many health plans use the rebate dollars to marginally reduce premiums for all of their insureds.

Lilly's recent launch of Insulin Lispro, a lower-priced authorized generic version of its most popular insulin product Humalog, illustrates this dynamic. Insulin Lispro is available at a list price that is 50% less than Humalog, and the rebates Lilly has offered on Insulin Lispro would provide PBMs a net cost that is comparable to branded Humalog. However, because the list price of Insulin Lispro is substantially lower than the list price of Humalog, the total rebate dollars offered on Insulin Lispro are lower. Unfortunately, after months of contract negotiations, Lilly has only been able to gain limited formulary access for Insulin Lispro. We expect that it will be covered for less than 15% of patients with commercial health insurance and less than 25% of Medicare Part D patients.

One proposal that Lilly believes is worthy of consideration is adding insulin to preventive medications lists, which would lower out-of-pocket costs by, for instance, exempting insulin from deductibles (sometimes called "first dollar coverage"). Because of how the private health care system works today and the complexity of high deductible health plans, some people have full coverage for treatments to manage their chronic conditions while others must meet out-of-pocket and deductible requirements for the same treatments. Making people with chronic diseases like diabetes pay high prices for their medications does not make sense as a matter of public policy. While billions of dollars are spent in the United States each year on medical expenses directly related to diabetes, only 6% of that is spent on insulin.[19] The vast majority is spent to treat the serious and costly complications of diabetes. When people with diabetes take their medications, they live healthier lives, reducing overall health care costs. As a result, insurance design that makes insulin and other medications for chronic conditions available at low out-of-pocket costs is a matter of sound public policy. Independent actuarial analyses have shown that adding first dollar coverage for insulin patients would increase policyholders' premiums by just 43 cents per month while enabling insulin patients to affordably maintain their insulin therapy.[20] This would be a significant step toward a more sustainable model that addresses the unacceptably high out-of-pocket costs faced by some patients.

4. **During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are sometimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.**

    a. **What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?**

---

[19] Am. Diabetes Ass'n, *Economic Costs of Diabetes in the U.S. in 2017*, at 8 (Mar. 22, 2018), http://care.diabetesjournals.org/content/diacare/early/2018/03/20/dci18-0007.full.pdf.

[20] E. Anne Jackson, Matthew Berman & David M. Liner, *Mitigating Out-of-Pocket Costs for Prescription Drugs*, MILLIMAN (Dec. 2016).

b. Does your company support moving to a system where administrative fees are based on a flat fee instead?

As this question notes, manufacturers are often required to pay a specified administrative fee percentage, rather than permitted to freely negotiate the amount. Often, agreeing to these fee percentages is characterized as a "bid condition" by the PBMs—failure to acquiesce to this condition will result in an offer being rejected as "non-compliant." Since these are non-negotiable terms, manufacturers have no choice but to accept them.

We do not believe there are any advantages to setting PBM administrative fees as a percent of product's list price (WAC). Indeed, calculating administrative fees as a percentage of the list price can create uncertainty among manufacturers, PBM clients, and policymakers regarding the economic substance of such transactions. To the extent that such administrative fees are passed on to customers, as some PBMs have stated, it may be more appropriate to classify them as rebates.

The Honorable Jeff Duncan (R-SC)

1. **One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.**

   Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

   So, which is it? Is there innovation in the insulin market or not?

Yes, there is innovation in the insulin market as well as in the treatment of diabetes generally. Today's modern insulins have improved substantially since 1923. That year, Lilly pioneered the manufacturing and distribution of Iletin, the first animal-based insulin. Iletin was the first real hope for treating diabetes, a fatal disease then with no effective treatment options. But Iletin was created through processes most would view as crude today—extracting insulin from animal pancreases—leading to purity and quality concerns. Decades later, modern innovation led Lilly to introduce the first recombinant DNA insulin and, eventually, the first

human analog insulin. These improvements have been part of a dramatic change in the way diabetes is treated.

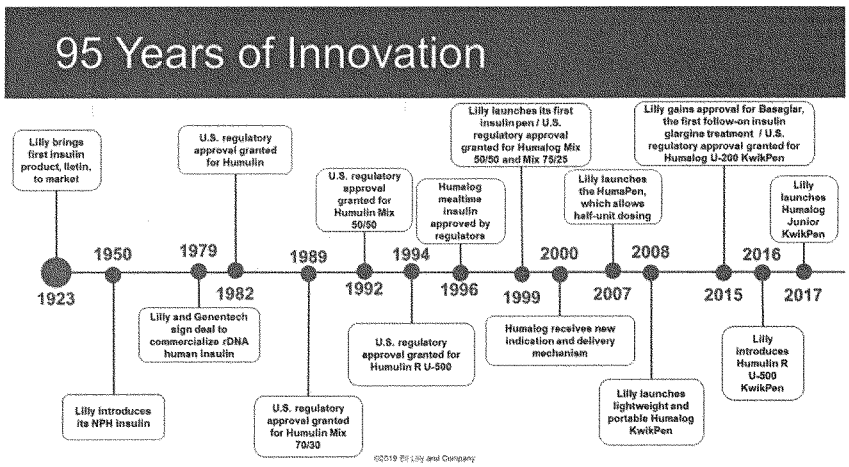
Lilly brought the first genetically engineered medicine, Humulin, to market in 1982, ending concerns about whether there would be enough animal-based insulin to serve the growing number of people with diabetes. This product saved lives by allowing the use of a biosynthetic form of human insulin. In 1996, Lilly launched another biotech insulin, Humalog, which mimics the body's own rapid insulin response and has made it easier for people with diabetes to manage their blood glucose. For evidence of the importance of this innovation, one need look no further than how much more often physicians prescribe modern insulins, like Humalog, compared to older human insulins, like Humulin. While human insulin is cheaper and widely available,[21] the vast majority of prescriptions for Lilly insulins are for Humalog. Moreover, not every new insulin product is widely adopted. The continued preference for Humalog demonstrates that this product was truly innovative and is still effective at helping people control their diabetes.

In 2015, Lilly obtained approval for the first follow-on insulin biologic, Basaglar. This product currently has a list price that is 23% lower than the list price of the most commonly prescribed basal insulin, Lantus. We also have developed a wide range of other diabetes treatments in oral and easy-to-use injectable forms that help people control their glucose levels. The wide range of therapies we offer is essential for physicians and patients to create individualized treatment plans for diabetes.

[21] For example, although not a Lilly product, the availability of ReliOn—human insulin sold by Walmart at a price to the patient of approximately $25—provides another option for patients unable to otherwise obtain access to affordable insulin. See https://corporate.walmart.com/_news_/news-archive/2012/07/24/walmart-launches-effort-to-save-diabetes-patients-up-to-60-million-annually.

Mr. Mike Mason
Page 16

A timeline showing some of Lilly's significant insulin advancements is set forth below:



Before the discovery of insulin, a child diagnosed with Type 1 diabetes at age 10 typically died within 2.3 years of diagnosis. Insulin was literally life-saving: It expanded the life expectancy of the average person with Type 1 diabetes into the early 40s, and eventually to where it is today in the late 60s. But our work is not done. The life expectancy of a patient diagnosed with Type I diabetes is still 11-12 years lower than that of the average American. Our hope is that one day the life expectancy for a person diagnosed with diabetes will be no different than that for any other American.

As an innovation-based pharmaceutical company, Lilly continues to push the boundaries of science today to bring better treatments to people with diabetes and other conditions tomorrow. Only about half the people living with diabetes and using insulin are able to fully control their condition. Increased innovation is needed to make diabetes easier to manage, and Lilly is committed to driving new innovative treatments to ease the burden of living with diabetes. For example, later this year, we expect to introduce an easier-to-use nasal glucagon treatment for life-threatening hypoglycemia. In 2018, Lilly announced its investment in a drug discovery partnership that we hope could move people with diabetes away from insulin altogether by developing cell therapies that would allow insulin-producing pancreatic beta cells to be delivered through implanted devices.[22] And in 2020, if approved, we expect to introduce an even faster-acting version of insulin. Lilly is also active in the space of digital health

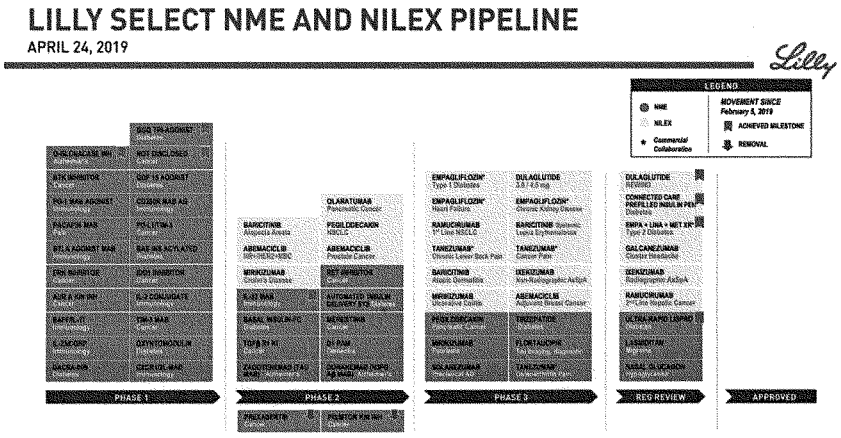
[22] *Lilly and Sigilon Therapeutics Announce Strategic Collaboration to Develop Encapsulated Cell Therapies for the Treatment of Type 1 Diabetes* (Apr. 4, 2018), https://www.prnewswire.com/news-releases/lilly-and-sigilon-therapeutics-announce-strategic-collaboration-to-develop-encapsulated-cell-therapies-for-the-treatment-of-type-1-diabetes-300624199.html; Alex Keown, *Eli Lilly Plunks Down $63M Upfront in Deal With Startup Sigilon* (Apr. 4, 2018), https://www.biospace.com/article/eli-lilly-plunks-down-63m-upfront-in-deal-with-startup-sigilon.

Mr. Mike Mason
Page 17

solutions and is developing a connected diabetes system consisting of devices that we hope will improve adherence, outcomes, and convenience.

Lilly is not merely an insulin manufacturer, nor is our focus limited to insulin or diabetes. In 2018 alone, Lilly spent more than $5.3 billion on research and development, accounting for more than 20 percent of total revenues, in multiple therapeutic areas other than diabetes, including oncology, immunology, Alzheimer's disease, and chronic pain. The revenues we earn on our portfolio of products, including insulins, directly support research and development for tomorrow's life-saving medicines. Any one, or all, of our potential treatments still in development could fail during clinical trials. Indeed, risk and uncertainty are inherent to drug discovery. A recent and heartbreaking example of the risk that our company undertakes can be seen in solanezumab, a potential treatment for Alzheimer's disease that did not succeed in its last stage of clinical testing. Had it succeeded, solanezumab would have been the first disease-modifying drug to treat Alzheimer's. Nevertheless, Lilly remains committed to Alzheimer's research, and our portfolio includes other potential approaches, including a BACE inhibitor in clinical trials.

Below is a visual representation of Lilly's pipeline for new molecular entity ("NME") and indication or line extension ("NILEX") drugs.



2. **One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."**

Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

So, which is it? Are there patents preventing innovation and competition or not?

We do not believe OptumRx was talking about Lilly.[23] No patents prohibit competitors from launching products similar to Lilly insulins. In fact, none of our insulin active ingredients are currently protected by patents. Additionally, although Lilly has filed or holds patents on certain delivery systems used with some of our insulins (e.g., U.S. Patent Number 7291132 covering "medication dispensing apparatus with triple screw threads for mechanical advantage"), this is not a barrier to insulins delivered in a variety of other ways. In fact, Sanofi launched a follow-on insulin lispro product to compete with Humalog in April 2018, and no patent litigation or other regulatory impediment inhibited Sanofi's launch of its product. The general absence of patents covering Lilly insulins is verifiable in the FDA Orange Book, which is available and searchable on the FDA's website at https://www.accessdata.fda.gov/scripts/cder/ob/index.cfm.

[23] OptumRx's written testimony from the April 10, 2019 hearing before the House Energy & Commerce Committee cites a study on Lantus, an insulin manufactured by Sanofi. https://docs.house.gov/meetings/IF/IF02/20190410/109299/HHRG-116-IF02-Wstate-DuttaS-20190410.pdf.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"

April 10, 2019

Mr. Doug Langa, Executive Vice President, North America Operations, President, Novo Nordisk Inc.

The Honorable Joseph P. Kennedy III (D-MA)

1. At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.

   Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

   a. Where can patients find information on eligibility and criteria for the programs?

Answer: There are many ways patients can access details on Novo Nordisk's patient assistance programs in order to increase the likelihood that they can obtain the information they need in a timely manner. Information about Novo Nordisk's Diabetes Patient Assistance Program (Diabetes PAP) can be found on the Novo Nordisk Patient Affordability and Access Support website-www.NovoCare.com, as well as Novomedlink (found at www.Novomedlink.com), which is directed towards healthcare providers. The NovoCare® site is also linked to Novo Nordisk U.S. diabetes branded and unbranded sites directed at healthcare providers and patients. In addition, multiple key consumer and patient-advocacy maintained sites, and related mobile applications, connect to NovoCare®, including the American Diabetes Association (ADA), American Association of Diabetes Educators (AADE), Needymeds, Inc., medicineassistancetool.org (managed by PhRMA), and Drugs.com. Patients may also gather information through their medical providers, or by calling the Novo Nordisk Customer Care Line (at 1-800-727-6500), or the Novo Nordisk Reimbursement Hotline (at 1-855-253-2414).

   b. What are the eligibility criteria for the programs?

Answer: The eligibility requirements for the Diabetes PAP are as follows: The patient must be a U.S. citizen or legal resident, and must be uninsured and ineligible for Department of Veterans Affairs prescription benefits, or any federal, state, or local program such as Medicare or Medicaid. There is an exception for patients with Medicare Part D coverage who meet the threshold out-of-

pocket spend on prescription medication, which is currently $1,000; patients who are Medicare eligible and do not have Medicare Part D coverage and have applied for and been denied the Extra Help/Low Income Subsidy (LIS); and patients who are Medicaid eligible and have applied for and been denied Medicaid. Finally, patients need to demonstrate that their income is at or below 400% of the federal poverty level—about $103,000 for a family of four and $49,960 for an individual. Although these criteria govern eligibility for the Diabetes PAP, Novo Nordisk also considers patients who exceed the income threshold in certain situations—for example, job loss or sudden financial hardship—on a case-by-case basis.

c. What information and documents must patients submit in order to qualify for the programs?

Answer: Patients must fill out one page of the Diabetes PAP application that seeks basic identifying information such as their name, address, and social security number, as well as information about their prescription drug coverage. Patients can provide proof of income by submitting copies of any of the following: two most current paycheck stubs or earning statements for all working members of the household; a federal income tax return from the prior year; Social Security, pension, or other income statements; W-2 or 1099 forms; or unemployment benefit statements. If applicable, patients must provide a Medicaid eligibility form or, for Medicare Part D patients, documentation (such as a letter from a provider, a statement or explanation of benefits, or a pharmacy printout) showing that the patient has spent $1,000 on prescription medicine for the relevant benefit year. It ordinarily takes seven to ten days from the time Novo Nordisk receives a completed application until products are sent to the patient's healthcare provider. In many cases, medicine is sent to patients in less time.

d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

Answer: For the Diabetes PAP, Novo Nordisk received 74,713 applications in 2018 for 105,220 products, as some applications requested multiple products. 16,477 (16%) of these product applications were either withdrawn or incomplete. Among the 88,743 completed product applications, 65,077 (73%), were approved while 23,666 (27%) were denied.

e. What are the ten most common reasons your company denies a patient's application?

Answer: Eligibility for Novo Nordisk's Diabetes PAP is governed by the criteria described above. If a patient does not meet those criteria, her application will not be approved. (As noted above, however, Novo Nordisk does make exceptions to the income criteria in certain situations decided on a case-by-case basis). In addition, if a patient does not complete the application process, including by verifying income eligibility, her application will not be approved.

Of the applications for the Diabetes PAP that are denied, about 70% are denied because the patient has insurance. A far less common reason is that the patient exceeds the income threshold, which occurs in 7%-20% of denials (varies by product). Other reasons include failure to meet the requirements for qualification with Medicare coverage (such as providing proof of out-of-pocket expenses) or failure to provide identifying information requested in the application (such as social

security number or healthcare provider information). If a patient appears to be eligible for Medicaid, Novo Nordisk requires that the patient apply for Medicaid before approving their PAP application.

f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

Answer: For uninsured patients, an approved application is valid for 12 months. For Medicare Part D patients, an approved application is valid for the calendar year in which they applied. Patients may be reapproved annually for as long as they meet the eligibility criteria.

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018?

Answer: Novo Nordisk invests in website design features that offer information about affordability options, including the Diabetes PAP, and has worked to improve those features each year. In addition, Novo Nordisk telephone representatives are equipped to answer questions about the Diabetes PAP when patients call the customer care line. Novo Nordisk sales representatives also educate physicians on the Diabetes PAP so that they may in turn educate patients needing assistance. Novo Nordisk works with patient organizations, such as the American Diabetes Association, to ensure that patients are aware of the affordability options available to them, including the Diabetes PAP. Because these efforts are adjunct to Novo Nordisk's general product promotion activities, it is not possible to quantify the dollars spent specifically on public awareness for the Diabetes PAP.

i. How much did your company spend on advertising for insulin in 2018?

Answer: Novo Nordisk spent $91.6 million on print and television advertising, as well as other consumer-facing marketing activities, for insulin medicines in 2018.

2. Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.

a. Where can patients find information on eligibility and criteria for the programs?

Answer: In addition to the Diabetes PAP, Novo Nordisk operates Patient Assistance Programs for growth hormone disorders (Growth Hormone Patient Access Program or Growth Hormone PAP), Hemophilia (Hemophilia Product Assistance Program or Hemophilia PAP), and hormone therapy (Hormone Therapy Patient Assistance Program or Hormone Therapy PAP). Information about those programs can be found on Novo Nordisk's website Novonordisk.us, as well as other web sources, and through health care providers.

b. What are the eligibility criteria for the programs?

Answer: For the Growth Hormone Patient Access Program, the following eligibility criteria apply: The patient must be a U.S. citizen or legal resident and must have a diagnosis that is an FDA-

approved indication for Norditropin®; the patient's total household income must be at or below 350% of the federal poverty level after inclusion of Norditropin® estimated cost deduction; and the patient cannot have or qualify for government insurance, including any federal, state, or local program such as Medicare or Medicaid. Patients who are eligible for Medicaid or VA prescription benefits must have been denied enrollment, including exhaustion of all appeals, in order to be eligible for the PAP. If the patient is Medicare eligible but does not have Medicare Part D coverage, the patient must have applied for and been denied the LIS.

For the Hemophilia Product Assistance Program, the following eligibility criteria apply: The Patient must be a U.S. citizen or legal resident and must be prescribed a Novo Nordisk factor product for an indicated condition; the patient must not have prescription coverage; and the patient's total household income must be at or below 400% of the federal poverty level. The patient cannot have or qualify for government insurance, including any federal, state, or local program, such as Medicare or Medicaid, and patients who are eligible for Medicaid or VA prescription benefits must have been denied enrollment, including exhaustion of all appeals, in order to be eligible for the PAP. If the patient is Medicare eligible but does not have Medicare Part D coverage, the patient must have applied for and been denied the LIS.

For the Hormone Therapy PAP, the following eligibility criteria apply: The patient must be a U.S. citizen or legal resident; the patient must not have private prescription coverage or state, federal, or local prescription coverage, such as Medicare, Medicaid, or VA benefits; and the patient's total household income must be at or below 200% of the federal poverty level. If approved, a 90-day supply is sent to the patient's health care provider.

c. What information and documents must patients submit in order to qualify for the programs?

Answer: For the Growth Hormone Therapy PAP and the Hemophilia PAP, patients must fill out the application form and provide certain documentation. For proof of income, they may provide any of the following: the two most current paycheck stubs or earning statements for all working members of the household; a copy of last year's federal income tax return (1040); a copy of Social Security income, pension, and other income statements, including interest or dividend statements; a copy of last year's (or most current) W-2 or 1099 form; or a copy of an unemployment benefits statement. Some patients must also provide a Medicaid, VA, or Extra Help/LIS denial letter (dated within 1 year of applying for the PAP). For the Growth Hormone Therapy PAP, some patients must provide a copy of their medical and pharmacy insurance cards. For the Hemophilia PAP, patients must provide their prescription with exact quantity and assay limits.

For the Hormone Replacement Therapy PAP, patients may demonstrate their income eligibility by providing their most recent federal tax return (1040), or Social Security income, Pensions, Interest, Retirement, and Child Support documentation.

d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

Answer: In 2018, for the Growth Hormone Therapy PAP, Novo Nordisk received 994 applications and approved 687. Of the applications that were not approved, 221 were withdrawn or incomplete. For the Hemophilia PAP (again, in 2018), Novo Nordisk received 28 applications and approved 7. Of the remaining applications, 6 were withdrawn or incomplete. For the Hormone Therapy PAP (also in 2018), Novo Nordisk received 63 applications and approved 39.

e. What are the ten most common reasons your company denies a patient's application?

Answer: As described above, each of Novo Nordisk's PAPs have eligibility criteria. If patients do not meet the eligibility criteria, including by verifying income, their applications may be denied. However, Novo Nordisk evaluates certain atypical financial situations on a case-by-case basis.

The most common reason that patients are denied approval for the Growth Hormone, Hormone Therapy, and Hemophilia PAPs is that their income exceeds the eligibility threshold. Other reasons include failing to meet other criteria or providing incomplete information or documentation.

f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

Answer: Approvals must be renewed annually. Patients may reapply as long as they remain eligible.

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018?

Answer: As explained in response to question 1, it is not possible to quantify the amount spent on public awareness campaigns for the Patient Assistance Programs because those efforts are adjunct to other corporate communications and product promotion activities.

h. How much did your company spend on advertising for medication in 2018?

Answer: In 2018, Novo Nordisk spent $274 million on print and television advertising, as well as other consumer-facing marketing activities, across all of its products.

3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.

Answer: All of Novo Nordisk's medicines that are currently marketed are available through Novo Nordisk's PAPs, with one exception. Saxenda®, which is used to treat obesity, is not available. Novo Nordisk considers obesity to be a separate disease space from diabetes and does not currently have an Obesity PAP.

4. Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When

your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.

Answer: Novo Nordisk does not use a private foundation to operate the Patient Assistance Programs described above. The company does not take a charitable tax deduction for the products it provides to patients through its PAPs, or for costs of administering the programs. NovoCare® is not a private foundation—it is an arm of Novo Nordisk dedicated to patient access and affordability support in the U.S.

The Honorable Brett Guthrie (R-KY)

1. There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of the medicine. Has Novo Nordisk received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Novo Nordisk lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Novo Nordisk and describe the requirements set forth in the letter.

Answer: Novo Nordisk received the letter from OptumRx requesting notice of any decision to lower list prices. Novo Nordisk did not agree to provide that information. Novo Nordisk is not aware of receiving similar letters from any other PBM.

a. Does Novo Nordisk have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.

Answer: No. As described above, OptumRx sought to include such obligations in its contracts with Novo Nordisk, but Novo Nordisk declined.

b. Has Novo Nordisk provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.

Answer: No, it has not.

c. What happens to Novo Nordisk's rebate obligations with PBMs if Novo Nordisk lowers the list price of insulin or any other medicine?

Answer: Novo Nordisk's contracts with PBMs hold the company to a certain rebate amount. That amount is expressed as a percentage of list price. Because rebates are a function of list price, if Novo Nordisk lowers list prices for its medicines, the amount of the rebate paid to the PBM will decrease. As such, PBMs will earn less in rebates for products where the list price is lowered.

d. Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Novo Nordisk's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.

Answer: Although Novo Nordisk did not agree to OptumRx's request, the letter indicates the importance of rebates to the PBMs, payers, and plan sponsors. Rebates are critically important to PBMs and other payers and can represent millions of dollars for a single contract in a single year. The role and importance of rebates to payers' business models is, of course, a consideration in pricing. Novo Nordisk always considers the entire market when setting list prices, including the rebate percentages and dollars that are required to secure and maintain formulary access.

2. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Novo Nordisk's testimony, Novo Nordisk said that the net prices for its insulins have declined year-over-year from 2015 through 2018—the net price of the NovoLog® declined by 21 percent from 2003 to 2018 while the list price of the product increased by 310 percent during the same period. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price. Please explain.

Answer: As outlined above, rebates are critically important to PBMs and other payers and can represent millions of dollars for a single contract in a single year. Novo Nordisk has had discussions with payers about the possibility of eliminating rebates and focusing instead on net price—in other words, lowering list price to the amount the company actually receives from payers. In those discussions, PBMs and other payers have expressed concern about the consequences of such a systemic change and have been unwilling to offer assurances that Novo Nordisk would maintain its formulary positions if it no longer offered rebates.[1]

Formulary access is crucial to ensuring that Novo Nordisk's products reach the patients who rely on them. Having products available on formulary is the way that the vast majority of patients can access Novo Nordisk products at reasonable co-pays. If Novo Nordisk products were excluded from formularies, patients would either have to pay much higher prices for their medicine or switch to another product that might not work as well for them. No two diabetes patients are alike, which is why it is so important that patients not lose access to the medicines that work for them.

Because of consolidation, the three PBMs who testified at the April 10th hearing manage the pharmacy benefit for over 80% of the patients in the United States. Accordingly, losing access to any of their formularies would materially impact Novo Nordisk's business and market share,

[1] The question correctly notes that there has been a decline in the net price of NovoLog® since 2003. It is important to recognize that the 21% decline reflects adjustments for inflation.

as well as Novo Nordisk's ability to deliver its medicines to patients. For these reasons, in the current system, Novo Nordisk must proceed cautiously with respect to reducing or eliminating rebates. Complicating matters, rebate pressures have been increasing year over year. Across all products and channels, Novo Nordisk paid 68% in rebates and other discounts and fees last year—up 40% from 2014. As long as this persists, Novo Nordisk must offset growing rebate demands with list price increases in order to remain a sustainable business capable of delivering its medicine to patients and continuing to invest in innovation to ultimately defeat diabetes.

Novo Nordisk supports the proposed rule from the Department of Health and Human Services, *Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees* (the Rebate Rule). Novo Nordisk believes that the Rebate Rule will benefit patients and supports its expansion to the commercial market. However, Novo Nordisk believes that the wholesale conversion of both markets simultaneously could cause confusion in the marketplace and disrupt patient access to medications. There are many new operational and system requirements necessary to ensure that the appropriate discount is applied at the pharmacy counter, that patient cost-sharing responsibilities are correctly calculated, and that pharmacies are fully compensated. Previous changes of this magnitude have been afforded years for implementation, and were themselves not without challenges at the outset. Therefore, Novo Nordisk supports a focus on ensuring a successful implementation in the Part D market before moving on to other channels.

Novo Nordisk also supports other legislative or regulatory changes that would ensure that the rebates pharmaceutical manufacturers pay to secure and maintain formulary access are passed on to the patients who use those medicines.

3. Are any of Novo Nordisk's insulin drug substances currently protected by patents or are all of the current patent protections on Novo Nordisk's insulin products for the delivery systems? Please describe how a patent on the delivery system limits the ability of a competitor to make a generic version of the product.

Answer: Several of Novo Nordisk's insulin drug substances are protected by patents, while several are not. Novo Nordisk also manufacturers devices, which are the result of significant innovation and are also protected by patents. These devices allow for more accurate and convenient delivery of insulin, allowing patients to dose themselves more easily and with less pain. They also allow patients who may struggle with fine motor skills to self-dose, thereby obviating the need for medical assistance and permitting patients—particularly elderly patients—to maintain their independence.

Patents on Novo Nordisk's innovative devices do not impede the ability of generic competitors to produce the underlying medication. A generic competitor may produce the unpatented substance and market it in their own delivery device, or for use with a traditional vial and syringe.

4. During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.

    a. What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?

Answer: The disadvantage of a system in which administrative fees are paid as a percentage of list price is that there is increased pressure to keep list prices high because various actors in the supply chain benefit from the higher prices. This is an example of misaligned incentives in the current system.

    b. Does your company support moving to a system where administrative fees are based on a flat fee instead?

Answer: Novo Nordisk supports moving to a flat fee system, provided that the fees are based on the fair market value of the service rendered. Novo Nordisk agrees with the position taken in the proposed Rebate Rule that such fees cannot be determined based on additional business that is provided to the PBM or health plan by manufacturers.

The Honorable Jeff Duncan (R-SC)

1. One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba® and Fiasp® and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

    Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

    So, which is it? Is there innovation in the insulin market or not?

Answer: The suggestion that insulin has not changed in 100 years is incorrect. In fact, there has been significant innovation over the last several decades with continued research and development in the insulin space occurring even in these most recent years.

During the mid-20th century, advances in insulin purification and stability allowed many patients to dose insulin more safely and accurately. In the 1980s, advances in the use of recombinant DNA

technology meant that patients requiring insulin would no longer have to depend on bovine or porcine sources in order to control their glucose levels. Human insulin revolutionized the treatment of diabetes because it could be produced in a purer form, and it reduced the occurrence of allergic reactions.

The development of analog insulins in 2000 represented another significant change in diabetes therapies. Novo Nordisk's analog insulin, sold under the name NovoLog®, is a modified form of human insulin in which the amino acid structure of the insulin molecule has been altered at specific sites to change the onset and duration. For patients, this provides better control of mealtime blood glucose levels by more closely matching the body's natural insulin action. In doing so, the medication allows for a more flexible lifestyle, as injections can be taken immediately before, or even just after, meals. This flexibility offers a meaningful improvement in quality of life for patients as well as improvements in their glucose levels immediately following a meal.

In just the last five years, Novo Nordisk has introduced other new products that materially improve patients' lives. In 2015, Novo Nordisk introduced Tresiba®, a long-acting basal insulin, offering once daily dosing at any time of day for both type 1 and type 2 diabetes patients.[2] This medication's unique mechanism of action allows for improved blood sugar control with a lower risk for nighttime hypoglycemia as compared to other basal insulins. In addition to its standard concentration, Tresiba® is available in a more concentrated formula for those patients who require higher doses of insulin, allowing them to take a single dose per day with a pen device. Even more recently, in 2017, Novo Nordisk introduced Fiasp®, a new short-acting insulin that offers quicker onset when compared to other current analog insulins. These two recent advances, Tresiba® and Fiasp®, have allowed people who are insulin-dependent to safely and effectively control their diabetes around mealtimes, when blood sugar rises quickly after eating, as well as overnight and in-between meals. For patients, better nighttime control may mean the difference between getting a good night's sleep and waking for a productive day ahead, and experiencing the very frightening and often times dangerous sleep interruptions caused by fluctuations in glucose levels through the night.

Today, Novo Nordisk is the largest private funder of diabetes research and development in the world. Novo Nordisk has also formed research collaborations to further innovation in diabetes, including one with the Massachusetts Institute of Technology to develop a capsule device that contains compressed insulin, which is injected into the patient after the capsule reaches the stomach. This capsule could potentially replace insulin injections through pens or syringes, making it easier for patients to receive their medication. Novo Nordisk is also conducting research into stem cell therapies to treat diabetes in collaboration with the University of California, San Francisco, as well as other chronic diseases.

These developments in diabetes care and treatment demonstrate Novo Nordisk's commitment to improving patients' lives through new medications and delivery systems. Novo Nordisk will continue to innovate to address the needs of patients and to meet the goal of defeating diabetes.

---

[2] At the hearing, Chair DeGette suggested in a closing statement that Tresiba® is not an insulin, but is a product that is used to improve insulin absorption in patients with type 2 diabetes. *See* Tr. at 140. It is important to clarify that this is incorrect – Tresiba® is an insulin medicine and is FDA approved for patients with both type 1 and type 2 diabetes.

The assertion that there is no competition in the insulin market is also incorrect. As a single company, Novo Nordisk pays approximately 10% of all rebates across the entire pharmaceutical industry, much of that within the insulin space. This is a result of the fierce competition between the insulin manufacturers, in the current system, to secure and maintain formulary access. In 2018 alone, Novo Nordisk invested approximately $18 billion in rebates, discounts, and other fees. The company makes this investment to ensure that patients who rely on Novo Nordisk's medicines can continue to access them at reasonable co-pays.

2. One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."

   Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

   So, which is it? Are there patents preventing innovation and competition or not?

Answer: As outlined above, there is significant competition in the insulin market, as evidenced by the degree to which rebates to secure formulary access grow each year.

With respect to generic alternatives, Novo Nordisk cannot speak to the reasons why a generic competitor has not brought a product to market. This could be because insulin products, as large peptide biologics, are more difficult to produce than some other prescription medicines for a variety of reasons. Nonetheless, Novo Nordisk supports competition in the insulin market. Several of Novo Nordisk's medicines are no longer covered by patents and, if a generic competitor attempted to produce a generic alternative to those products, Novo Nordisk would not prevent them from doing so (assuming the product met applicable FDA requirements).

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"

April 10, 2019

Ms. Kathleen Tregoning, Executive Vice President for External Affairs, Sanofi

The Honorable Joseph P. Kennedy III (D-MA)

1. **At the Oversight Subcommittee hearing on April 2, 2019, the witnesses spoke about the ineffectiveness of patient assistance programs and testified the programs are untimely, unworkable, and a barrier to accessing insulin. Whether the programs' criteria are too difficult to find or the application processes require already sick people to jump through hoops, there is wide consensus the programs are a cruel substitute for lower list prices.**

   Regarding patient assistance programs specifically for insulin at your company, please provide a clearer picture of how they operate by answering the following questions.

Sanofi has adopted a variety of approaches to work within the current system to improve access and affordability of insulin for patients. We have developed some of the most forward-leaning programs to help patients afford Sanofi's insulin products. We have three primary patient support programs that are designed to improve patient access to, and affordability of, Sanofi insulins.[1] In addition, Sanofi has various other patient support programs that provide patient access and assistance for our non-insulin products. We have developed these programs to address affordability challenges patients face due to the different circumstances they face, including insurance status, formulary design, and the increased prevalence of high deductible health plans. Each program is tailored to a specific population and designed to help address a different problem. Despite the many challenges and perverse incentives that exist in our health care system, Sanofi's commitment to patient affordability means that, today, approximately 75 percent of all patients taking Sanofi insulin pay less than $50 per month.

[1] Additionally, Sanofi offers the eVoucherRX Program to patients who manage their diabetes with Apidra/Apidra SoloSTAR, Lantus/Lantus SoloSTAR, Toujeo SoloSTAR/Toujeo Max Solostar, or Soliqua 100/33. The purpose of the eVoucherRX Program is to provide commercially insured patients with financial support through pharmacies participating in the program. The program is a co-pay assistance program applied automatically at the pharmacy counter without any enrollment process. The program reduces these patients' out-of-pocket costs to $0 with a maximum benefit of $1500 per year. The third-party vendor that administers the program screens claim submissions to mitigate the risk that the program could be used by federal health care program beneficiaries, consistent with OIG guidance.

Federal beneficiaries, including beneficiaries enrolled in Medicare and Medicaid, do not have access to some of our patient assistance programs. We support changing the law to allow co-pay assistance to be provided to federal program beneficiaries.

Our patient support programs for insulins and other products are described below.

- **Sanofi Co-pay Assistance Programs:** Sanofi has co-pay assistance programs for insulins and for other Sanofi products. Sanofi co-pay assistance programs aim to lower out-of-pocket costs for commercially insured patients regardless of income level.

  Patients are able to register and download electronic co-pay cards from a Sanofi website, or may contact our call center at (855) 984-6302 to request an actual co-pay card. Patients also may receive actual co-pay cards from their healthcare providers. Consistent with prior OIG guidance regarding the application of the federal Anti-Kickback Statute to coupon programs for federal beneficiaries,[2] Sanofi does not make its co-pay card programs available to patients covered by federal healthcare programs. In addition, and also consistent with OIG recommendations, Sanofi co-pay cards must be activated prior to use through an online activation process or by calling a call center number specified on the card. Patients who apply for Sanofi co-pay assistance may be approved that same day.

- **Insulins Val*you* Savings Program:** In early 2018, Sanofi launched the Insulins Val*you* Savings Program to provide financial relief to uninsured and cash paying patients. The program enabled eligible patients to access Sanofi insulins for $99 per 10 mL vial or $149 for a pack of SoloSTAR pens, which was approximately a 60% discount below the list price; this could result in savings of up to $3,000 per year.[3]

  In April, Sanofi announced an expansion of the **Val*you*** Savings program. Effective June 8, we will transition the program to a monthly 'Netflix'-like subscription model so that uninsured patients exposed to high out-of-pocket costs at the pharmacy counter will be able to access any combination of Sanofi insulin (with the exception of Soliqua) for a fixed price of $99/month for up to 10 vials or packs of SoloSTAR pens. Under the

[2] *See* https://www.oig.hhs.gov/compliance/alerts/bulletins/index.asp (May 2014).

[3] Patients with type 1 diabetes require insulin replacement with both background (basal) and mealtime (bolus) insulin. An average adult with type 1 diabetes who weighs 70 kg (155 pounds) should be taking anywhere from 0.5-1 u/kg/ day - depending upon activity levels, and meal choices. If a higher daily dose of 1 u/kg/day is used, the patient would need a total of 70 units/day of insulin, of which ~ half should be mealtime bolus insulin and half should be background basal insulin. That would mean the patient could possibly manage her disease with one vial of long acting and one vial of short acting or a pen pack for basal and bolus each month. For the average patient with type 1 diabetes, under the Val*you* program, the patient would meet the monthly insulin requirement with two payments of $99.

For patients with type 2 diabetes, many require background (basal) insulin only. Our internal data show that the average daily dose is roughly 45 units per day which results in a monthly requirement of 1350 units of basal insulin per month. The Lantus SoloSTAR pack contains 1500 units of insulin (5 pens x 300 units per pen) and the Toujeo SoloSTAR pack contains 1350 units of insulin (3 pens x 450 units per pen). For the average patient with type 2 diabetes, under the Val*you* program, the patient would meet the monthly insulin requirement with one payment of $149. Patients on lower doses of Lantus per month could opt for the 10ml vial, which is $99 per vial.

Val*you* Savings Program, prices are guaranteed for 12 consecutive monthly fills. The program is available through all U.S. pharmacies and there are **no income** requirements.

Patients are able to register and download an electronic savings card from a Sanofi website (https://www.admelog.com/insulins-valyou-savings-program/), or may contact Sanofi's call center at (855) 984-6302 to request the savings card. Patients also may receive savings cards from their healthcare providers. Consistent with the analysis contained in an OIG advisory opinion on programs that allow patients to access drugs outside of their insurance at a cash price,[4] Sanofi does not make the Val*you* Savings Program available to federal healthcare program beneficiaries. In addition, consistent with OIG recommendations, patients must activate the savings cards prior to use through an online process or by calling a call center number specified on the card. Patients who meet eligibility criteria are immediately approved for the Insulins Val*you* Savings Program and may be used the same day.

- **Sanofi Patient Connection (SPC):** The purpose of Sanofi Patient Connection (http://www.sanofipatientconnection.com/) is to administer Sanofi's patient assistance program, which provides financially needy patients who meet eligibility criteria with free medicine. The Sanofi Patient Connection application is available online[5] or by calling Sanofi Patient Connection and Patients who apply for Sanofi Patient Connection are approved, on average, within two to five business days.

- **Additional Sanofi Patient Assistance Programs:** In addition to the SPC, Sanofi provides other medicines within its portfolio free of charge to eligible patients through other patient assistance programs. The purpose of all Sanofi free drug patient assistance programs is to provide financially needy patients who meet the eligibility criteria with free medications.

In addition to the programs outlined above, Sanofi continues to work with policy-makers on initiatives that would remove the existing barriers to patient access and affordability, including removing the restrictions on providing co-pay assistance to Medicare Part D beneficiaries.

a. Where can patients find information on eligibility and criteria for the programs?

Sanofi makes information about its co-pay assistance programs, Insulins Val*you* Savings Program, and SPC — including eligibility criteria — readily accessible to, and easily understandable for, patients. Sanofi publishes information about its patient support programs in a variety of forums, including on the Internet, through social media, through direct outreach to physicians, pharmacies and advocacy organizations (including those focused on diabetes awareness and education), in direct-to-consumer advertising, and over the phone to patients who contact the Sanofi patient support call centers.

---

[4] See OIG Advisory Opinion No. 14-05.
[5] *See* http://www.sanofipatientconnection.com/media/pdf/SPC_Application.pdf.

With respect to information on the Internet, patients can access information about Sanofi's patient support programs, including eligibility criteria for those programs, through: (1) program-specific Sanofi websites,[6] (2) the Teaming Up For Diabetes website (http://www.teamingupfordiabetes.com), the Sanofi US website, which provides a link to each program-specific website, and (3) on Medication Assistance Tool (https://mat.org/), a publicly available website maintained by the Pharmaceutical Research and Manufacturers of America (PhRMA), which provides a dedicated search engine to help patients search for financial assistance resources.

b. What are the eligibility criteria for the programs?

Outlined below are the eligibility criteria for each of the three Sanofi patient support program described above.

I. Sanofi Co-pay Assistance Programs for Insulin Products

Commercially insured patients, regardless of income level, are eligible to participate in Sanofi's co-pay assistance programs. To help Sanofi determine a patient's eligibility, the patient must answer the following questions:

- Are you a current resident of the United States, Puerto Rico, Guam, or the US Virgin Islands?
- Are you a patient or caregiver over 18 years old?
- Do you have private commercial health insurance?
- Do you currently receive Medicaid?
- Are you currently serving in the US military?
- Do you qualify for Medicare?

Based on the answers to these questions, Sanofi's vendor determines eligibility.

The Sanofi co-pay cards may not be used for prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or other federal or state programs, including any state pharmaceutical reimbursement program. This restriction is in place to comply with OIG guidance relating to the Anti-Kickback Statute — namely that pharmaceutical manufacturers may not offer co-pay assistance to federal program beneficiaries.

[6] For eligibility and criteria information relating to Sanofi's Rx Savings Program for Lantus, patients can visit https://www.lantus.com/sign-up/savings-and-support. For eligibility and criteria information relating to Sanofi's Rx Savings Program for Toujeo, patients can visit https://www.toujeo.com/toujeo-savings-card-coupon-and-support. For eligibility and criteria information relating to Sanofi's Apidra $0 Co-Pay Program, patients can visit https://www.apidra.com/apidra/saving.aspx. For eligibility and criteria information relating to Sanofi's Soliqua 100/33 Savings Card, a patient can visit https://www.soliqua100-33.com/savings-andsupport. For eligibility and criteria information relating to the Sanofi Val*you* Savings Program, patients can visit https://www.admelog.com/insulins-valyou-savings-program/. For eligibility and criteria information relating to Sanofi's provision of free medicines through Sanofi Patient Connection, patients can visit Sanofi Patient Connection, http://www.sanofipatientconnection.com/patient-assistance-connection.

Sanofi supports policy reforms that would remove these restrictions, which would help to make insulins and other products more accessible and affordable to patients in federal programs.

II. Sanofi Insulins Val*you* Savings Program

Uninsured and cash paying patients, regardless of income level, are eligible to participate in the Insulins Val*you* Savings Program. Similar to the Sanofi co-pay assistance programs, to help determine a patient's eligibility for the Sanofi Insulins Val*you* Savings Program, the patient must answer the following questions:

- Are you a current resident of the United States, Puerto Rico, Guam, or the US Virgin Islands?
- Are you a patient or caregiver over 18 years old?
- Do you have private commercial health insurance?
- Do you currently receive Medicaid?
- Are you currently serving in the US military?
- Do you qualify for Medicare?

Based on the answers to these questions, Sanofi's vendor determines eligibility.

Consistent with the OIG guidance explained above, as well as an advisory opinion from OIG concerning direct-to-patient cash price programs,[7] the Insulins Val*you* Savings Program is not available to federal program beneficiaries, such as Medicare patients. Sanofi supports policy reforms that would remove these restrictions, so that we could extend the Val*you* Savings Program to Medicare and other federally insured patients.

III. Sanofi Patient Connection

To be eligible for our patient assistance program through Sanofi Patient Connection, a patient must meet the following criteria:

- The patient must be a U.S. citizen or resident and be under the care of a licensed healthcare provider authorized to prescribe, dispense and administer medicine in the U.S.;
- The patient must also have:
    - No insurance coverage or access to the prescribed product or treatment via their insurance; or
    - Medicare Part D coverage and 1) not have coverage for a generic equivalent product and 2) have spent at least 5% of their annual household income on prescription medications covered through their Part D plan in the current year; and

[7] See OIG Advisory Opinion No. 14-05.

- In each instance, an annual household income of ≤250% of the current Federal Poverty Level (for example, in 2019, $64,375 for a family of 4).

Patients potentially eligible for Medicaid are required to provide documentation of a Medicaid denial before they may be eligible for patient assistance through Sanofi Patient Connection.

c. What information and documents must patients submit in order to qualify for the programs?

The product and program-specific websites referenced in footnote 6 above outline the documents and information that patients must submit to qualify for a Sanofi patient support program.[8] A more general description follows for ease of reference.

I. Sanofi Co-pay Assistance Programs for Insulin Products and Insulins Val***you*** Savings Program

To qualify for Sanofi's insulin co-pay assistance programs and Insulins Val***you*** Savings Program, a patient must provide his or her name, email address, and date of birth on the enrollment form. The patient also must certify that he or she meets all eligibility criteria. If the patient meets the criteria, the patient may access the program.

II. Sanofi Patient Connection

To qualify for free medicine through Sanofi Patient Connection, a patient and/or the patient's physician must complete an application, which can be submitted online, by fax, or through U.S. mail. The application requires, in part: the patient's HIPAA authorization for the release of the patient's identification and insurance information to Sanofi and their agents and representatives for benefit verification; information relating to the patient's prescription, including dosage and the diagnosis code; the state license number and signature of the prescriber; the patient's household income verification and authorization to run a soft credit inquiry/background check; and the patient's signature. The patient must also provide his or her own identifying information, including name, address, date of birth, social security number, and health insurance information, and identifying information for the prescriber.

[8] *See infra* Footnote 6.

d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

The chart below outlines the estimated[9] number of patients that applied for, were approved, and were denied for Sanofi's insulin-related patient support programs during the 2018 calendar year:

Program	Applications Received	Applications Approved[10]	Applications Denied
Insulin-Related Co-Pay Assistance Programs and Insulins Val*you* Savings Program	382,000	250,841	56,000
Sanofi Patient Connection for Insulin Products	84,164	61,095	23,069

e. What are the ten most common reasons your company denies a patient's application?

As a business practice, Sanofi tracks the top three reasons for denials of patient support program applications for insulin products. Those three reasons for 2018 are provided below for each of the three programs.

I. Sanofi Co-pay Assistance Programs for Insulin Products

The top three reasons for denial of a patient's application for an insulin co-pay assistance program are:

1) the patient has health care coverage for the insulin product under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs;
2) the patient is not a resident of the US; and
3) the patient does have commercial insurance and has been prescribed Admelog (in which case the patient is invited to apply for the Insulins Val***you*** Savings Program).

These three reasons represent 100% of the total application denials for Sanofi's Insulin Co-pay Assistance Programs.

[9] Sanofi does not track or maintain data regarding the total number of applications received and denied for insulin co-pay assistance programs and the Insulins Val***you*** Savings Program. The information provided regarding the total number of applications received and denied are estimates.
[10] The number of applications approved for Insulin-Related Co-Pay Assistance Programs and the Insulins Val*you* Savings Program reflects total unique patients approved for enrollment, rather than number of applications approved.

II. Insulins Val*you* Savings Program

The top three reasons for denial of a patient's application for the Insulins Val*you* Savings program are:

1) the patient has health care coverage for the insulin product under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs;
2) the patient is not a resident of the US; and
3) the patient has commercial insurance and utilizing one of our co-pay programs would allow the patient to access their insulin at a lower out-of-pocket cost.

These three reasons represent 100% of the total application denials for the Insulins Val*you* Savings Program.

III. Sanofi Patient Connection

The top three reasons for denial of a patient's application for SPC are:

1) the patient has insurance coverage for the product;
2) financial eligibility for the program has not been met; and
3) an off-label diagnosis code was provided.

The first two reasons mentioned above represent 94% of the total application denials. If a patient is denied, the patient is offered the opportunity to apply for the Insulins Val*you* Savings Program.

f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

The reapplication process for Sanofi's insulin-related patient support programs varies by program and is designed to comply with OIG guidance.

I. Sanofi Co-pay Assistance Programs for Insulin Products and Insulins Val*you* Savings Program

With respect to the insulin-related co-pay assistance programs and the Insulins Val*you* Savings Program, patients must reapply for approval after the patient has used the co-pay card 12 times. Sanofi requires patients to reapply for approval under a co-pay assistance program or the Insulins Val*you* Savings Program to help ensure that all enrolled patients continue to meet the eligibility criteria, including eligibility criteria relating to compliance with the Anti-Kickback Statute.

II. Sanofi Patient Connection

Patients eligible for Medicare Part D must reapply for the free drug through Sanofi Patient Connection at the end of every calendar year, which aligns with OIG guidance that patient

assistance must be available for the Medicare Part D plan year.[11] All other patients must reapply for approval for free drug through Sanofi Patient Connection every 12 months. Sanofi requires that patients reapply for approval every 12 months to ensure that patients' insurance status has not changed from the prior year and that they continue to meet eligibility requirements.

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for insulin in 2018?

In 2018, Sanofi spent approximately $414.87 million on advertising for insulin products, which includes direct-to-consumer advertising, direct-to-physician advertising, and promotion of co-pay assistance programs for insulin and the Insulins Val***you*** Savings Program through the Internet, social media, direct outreach to physicians, pharmacies and advocacy organizations (including those focused on diabetes awareness and education), and over the phone to patients who contact the Sanofi patient support call centers.

2. Regarding patient assistance programs at your company for all types of medication, please provide a clearer picture of how they operate by answering the following questions.

a. Where can patients find information on eligibility and criteria for the programs?

As with its patient support programs for insulin products, Sanofi publishes information about its patient support programs for all products in a variety of forums, including on the Internet, through social media, through direct outreach to physicians, pharmacies, and advocacy organizations, in direct-to-consumer advertising, and over the phone to patients who contact the Sanofi patient support call centers at (855) 984-6302.

b. What are the eligibility criteria for the programs?

I. Sanofi Co-Pay Assistance Programs

In addition to the co-pay assistance programs for insulin products described above, Sanofi has developed and maintains co-pay assistance programs for Aubagio, Lemtrada, Dupixent, Kevzara, Libtayo, Alprolix, Eloctate, Aldurazyme, Cerdelga, Cerezyme, Fabrazyme, Lumizyme, and Thyrogen, and Praluent. The eligibility criteria and other terms for each of the programs are outlined on the websites that describe each program.[12] Generally, there are two predominant

[11] 70 Fed. Reg. 70623, 70627 (Nov. 22, 2005).

[12] Eligibility criteria for the Aubagio $0 Co-Pay Program can be found at https://www.aubagiohcp.com/support-resources?s_mcid=ps-AGH-google-Branded-Information-Co-Pay. Eligibility criteria for the Lemtrada Co-Pay Program can be found at https://www.lemtradahcp.com/patient-support. Eligibility criteria for the Dupixent MyWay Co-Pay Card Program can be found at https://www.dupixenthcp.com/atopicdermatitis/access-support/dupixent-myway. Eligibility Criteria for the Kevzara Connect Copay Card can be found at https://www.kevzarahcp.com/kevzara-connect. Eligibility criteria for the Libtayo Surround Commercial Co-Pay Program can be found at https://www.libtayohcp.com/accessinglibtayo/patientaccessandreimbursementsupport. Eligibility criteria for the Alprolix Co-Pay Program can be found at https://www.alprolix.com/resources/financial-

eligibility criteria that are consistent across all Sanofi co-pay assistance programs: 1) commercially insured patients can participate in Sanofi's co-pay assistance programs regardless of income level; and 2) consistent with OIG guidance relating to the Anti-Kickback Statute, Sanofi co-pay assistance may not be used in connection with prescriptions that are covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs, including any state pharmaceutical program.

II. Sanofi Free Drug Patient Assistance Programs

The predominant eligibility criteria for SPC described above in response to Question 1(b) generally apply to all of Sanofi's free drug patient assistance programs, with minor differences in eligibility criteria among the various programs.

c. What information and documents must patients submit in order to qualify for the programs?

I. Sanofi Co-Pay Assistance Programs

The information and enrollment forms a patient must submit to qualify for Sanofi's co-pay assistance programs for its other products are similar to the information and enrollment forms described in Question 1(c) above for insulin-related co-pay assistance programs.

II. Sanofi Free Drug Patient Assistance Programs

The information requirements and enrollment process outlined in response to Question 1(c) for SPC (including for insulin products) is similar to and generally consistent with the information requirements and enrollment process applicable to the other Sanofi free drug patient assistance programs.

---

assistance.aspx. Eligibility criteria for the Eloctate Co-Pay Assistance Program can be found at https://www.eloctate.com/resources/downloads.aspx?gclid=CjwKCAjw27jnBRBuEiwAdjQXDCWEfWNfC78ioeULgVejHZLwutiy9X7t4VrYvQSugdVZrI6UDx2iMxoCkBQQAvD_BwE&gclsrc=aw.ds. Eligibility criteria for the Aldurazyme Co-Pay Assistance Program can be found at https://www.aldurazyme.com/patients/patient-services/sanofi-genzyme-co-pay-assistance-program.aspx. Eligibility criteria for the Cerdelga Co-Pay Assistance Program can be found at http://cerdelga.com/co-pay.html. Eligibility criteria for the Cerezyme Co-Pay Assistance Program can be found at https://www.cerezyme.com/patients/patient_services/cerezyme_co-pay_assistance_program.aspx. Eligibility criteria for the Fabrazyme Co-Pay Assistance Program can be found at https://www.fabrazyme.com/patients/Patient-Services/co-pay-assistance-program.aspx. Eligibility criteria for the Lumizyme Co-Pay Assistance Program can be found at https://www.lumizyme.com/patients/patient_services/co-pay_assistance_program_prequalifier.aspx. Eligibility criteria for the Thyrogen Co-Pay Assistance Program can be found at https://www.thyrogen.com/patients/Financial-Assistance/Financial-Assistance-Programs.aspx.

d. What number of patients apply for the programs each year, what number are approved, and what number are denied?

Across its patient support programs in 2018, Sanofi approved a large number of applications that resulted in thousands of patients having access to Sanofi products at more affordable prices. Sanofi received 106,477 applications for free drug product provided through SPC. Of those applications, Sanofi approved 67,216 applications and denied 26,652 applications (12,609 applications were cancelled by the patient or the patient's provider prior to approval or denial). Sanofi is committed to helping patients access its products.

e. What are the ten most common reasons your company denies a patient's application?

Please see the response to Question 1(e) above for information responsive to this question with respect to products provided through Sanofi Patient Connection. Sanofi Patient Connection includes insulins and certain other Sanofi product, but does not include certain other Sanofi products that are available through other patient assistance programs.

f. Once a patient qualifies for a program, how often must the patient reapply or recertify? How long does the approval last?

Please see the response to Question 1(f) above for information responsive to this question with respect to products provided through Sanofi Patient Connection. Sanofi Patient Connection includes insulins and certain other Sanofi product, but does not include certain other Sanofi products that are available through other patient assistance programs.

g. How much did your company spend on public awareness campaigns to promote the patient assistance program in 2018? How much did your company spend on advertising for medication in 2018?

In 2018, Sanofi spent approximately $4.5 billion on advertising and marketing for all of its products.[13] Such spending is inclusive of public awareness campaigns to promote Sanofi patient support programs.

3. Are there any medications not on your company's patient assistance program? Please provide a list of the drugs that are available for patient assistance and those that are not a part of patient assistance programs.

Through the Val*you* Savings Program, Sanofi helps to lower out-of-pocket costs for patients who manage their diabetes with the following products:

- Lantus
- Lantus SoloSTAR
- Admelog

[13] "Advertising and marketing" includes global spending on promotion and marketing management.

- Admelog SoloSTAR
- Apidra
- Apidra SoloSTAR
- Toujeo
- Toujeo SoloSTAR

Through Sanofi co-pay assistance programs, Sanofi helps to lower the out-of-pocket costs for patients who are prescribed the following products:

- Aldurazyme
- Alprolix
- Apidra
- Apidra SoloSTAR
- Aubagio
- Cablivi
- Caprelsa
- Cerdelga
- Cerezyme
- Dupixent
- Eloctate
- Fabrazyme
- Kevzara
- Lantus
- Lantus SoloSTAR
- Lemtrada
- Libtayo
- Lumizyme
- Multaq
- Praluent
- Soliqua 100/33
- Thyrogen
- Toujeo
- Toujeo SoloSTAR
- Toujeo Max SoloSTAR

Sanofi provides free medicine through patient assistance programs for the following products:

- Adacel
- Admelog
- Adlyxin
- Aldurazyme
- Alprolix
- Apidra
- Aubagio

- Cablivi
- Caprelsa
- Cerdelga
- Cerezyme
- Dupixent
- Elitek
- Eloctate
- Fabrazyme
- Imogam
- Imovax
- Jevtana
- Kevzara
- Lantus
- Lemtrada
- Libtayo
- Lovenox
- Lumizyme
- Menactra
- Mozobil
- Multaq
- Pentacel
- Praluent
- Priftin
- Soliqua 100/33
- Tenivac
- Thymoglobulin
- Thyrogen
- Toujeo
- Zaltrap[14]

4. **Does your company make medication available to patients for free or reduced prices, or does it use a private foundation or other third parties to operate patient assistance programs? When your company makes contributions of medication to private foundations, such as Sanofi's Patient Connection, Sanofi's Foundation for North America, Novo Nordisk's NovoCare, Eli Lilly's Lilly Cares, or other third parties, does your company correspondingly reduce its tax liability? Please provide the amount by which your company reduced its tax liability for 2018 as a result of making contributions to patient assistance programs.**

Sanofi's "Sanofi Cares North America" and "Genzyme Charitable Foundation, Inc" are 501(c)(3) organizations through which Sanofi makes its medications available free of charge to financially eligible uninsured and under-insured patients. Sanofi Cares North America provides

[14] Sanofi does not provide patient support for the following products: Ambien, Arava, Avalide, Avapro, Clolar, Eloxatin, Ferrlecit, Hectorol, Seprafilm, Synvisc, and Taxotere.

Sanofi products free of charge to eligible financially needy uninsured and underinsured patients through Sanofi Patient Connection. Sanofi Cares North America also donates product to five non-governmental organization partners—Americares, DirectRelief, Heart to Heart International, MAP International, and Project Hope—and to approximately one hundred summer camps with 501(c)(3) status for children with diabetes.

Under the US Internal Revenue Code, a corporation can claim a deduction for charitable contributions to qualifying organizations. The deduction is limited to 10% of the corporation's taxable income. The product donations described above qualify for that deduction and therefore reduce Sanofi's federal taxable income, subject to the limitations in the tax code. Sanofi also makes cash donations that qualify as tax deductible charitable contributions. As there is no ordering rule to distinguish between cash and product donations, it is not possible to determine exactly how much of the 2018 charitable deduction is attributable to product donations as compared to cash donations. Consistent with IRS requirements, Sanofi determines the amount of the charitable tax deduction for donations to foundations by calculating the lower of: (i) two times the cost of the drug (where cost is measured based on an adjusted WAC that subtracts certain discounts and fees); or (ii) cost plus half the product margin. This calculation is performed on a product-by-product basis.

Because Sanofi's 2018 tax return is not due until October 2019, Sanofi's 2018 deductible product donation amounts have not yet been finalized. At this point, and subject to change prior to filing, Sanofi estimates that product donations will result in a 2018 tax deduction of between $23 and $32 million.

The Honorable Nanette Díaz Barragán (D-CA)

1. **Sanofi has filed 74 patent applications on Lantus, and more than 90 percent of these were filed after the drug was already approved and on the market. I'm concerned that these patents are not related to innovative improvements to the drug, but are part of Sanofi's strategy to further delay competition and retain control of this market.**

   Please explain the innovative nature of these patents filed after the approval of Lantus, and why they merit additional exclusivity to the detriment of diabetes patients?

There are currently twenty-one patents listed in the FDA Orange Book for Lantus and Lantus SoloSTAR. Each patent granted on a Sanofi product, including the patents for Lantus and Lantus SoloSTAR, represents the US Patent and Trademark Office's (PTO) determination that the particular product innovation is worthy of patent protection. The PTO grants a patent only after conducting a lengthy examination process that tests whether the new invention meets all of the legal requirements for patentability, including that the invention is new, not obvious, and useful. Although many of the patents listed in the Orange Book were granted after FDA initially approved Lantus in 2000, FDA approval of a medicine does not foreclose future innovation with respect to that product. To the contrary, the PTO's patent process encourages ongoing innovation that further helps patients long after products are FDA-approved. Additionally, we note that patents granted after FDA approval do not limit competition in general, and have not limited competition in the diabetes market in particular. With respect to insulin, for example,

Lantus faces competition from a follow-on biologic insulin glargine that launched shortly after the loss of patent exclusivity for the Lantus compound, despite the twenty-one patents currently listed.

By way of background, the patents granted for Lantus reflect that Sanofi's initial discovery of insulin glargine and subsequent development of an improved insulin glargine formulation and a more convenient, easy-to-use injection pen to deliver the insulin glargine have enhanced the lives of millions of patients living with diabetes in the United States and worldwide. The earliest insulin preparations were limited by their short duration of action, requiring patients to inject themselves multiple times a day and to wake up at night for injections in order to control blood glucose levels. Each such injection of insulin caused a sharp spike in the patient's insulin levels, which could cause symptoms of low blood sugar ranging from shakiness and confusion to, in the extreme, coma, or death. Injections also had to be timed before every meal, disrupting patient's lives, sleep times, and ability to eat with friends and family. As such, the consistent goals of insulin therapy have included reducing the frequency of insulin administration and flattening the post-administration peak of insulin in the bloodstream. Prior attempts to achieve these goals included cumbersome mechanical pumps that had to be worn on the body for constant infusion, and NPH insulin, which had an intermediate duration of action but still caused a pronounced peak in insulin levels.

The initial discovery and development of insulin glargine were therefore significant. Sanofi scientists succeeded in fundamentally altering the human insulin molecule at the amino acid level, changing its pharmacological characteristics to give patients a steady release of insulin with just a single daily administration. Unlike anything that came before it, glargine forms tiny solid crystals upon injection that dissipate over time to provide a flatter, stable, long-lasting effect that mimics the flat profile of insulin release from a healthy pancreas and reduces the risks caused by low blood sugar. The FDA approved insulin glargine under the tradename Lantus in 2000. But there was more to do to enhance the lives of patients with diabetes.

Lantus initially received FDA approval for, and launched, a vial; patients were required to inject the product with a syringe. Since that time, Sanofi has developed, received FDA approval for, and launched, several improved injection devices for administering glargine. Sanofi also reformulated the original Lantus vial formulation to solve the unexpected and unknown problem of potential cloudiness in prior Lantus vials and to make it more stable. The PTO awarded Sanofi two patents on this new formulation, both of which are listed in the Orange Book. Sanofi began selling its reformulated Lantus vial product in the U.S. in 2006, after the initial approval of Lantus.

Sanofi's latest pen delivery system, SoloSTAR, similarly has been a key improvement in easing the daily burden of insulin administration for patients. Sanofi partnered with premier design firms to develop this pre-filled, disposable injection pen for self-administration, which in turn has improved the lifestyle and medication compliance of diabetes patients. The SoloSTAR contains numerous features specifically designed to address the needs of people with diabetes, who often have health complications such as impaired vision and reduced dexterity. The pen's

features include a clutch that can reversibly lock the complex device components in rotation to allow patients to "dial up" a dose for injection; dose dial stops that prevent patients from setting an excessive dose; a rotating dial that can easily correct an over-dialed dose; and a specially designed injection button that is easy for people with diabetes to depress and receive a highly accurate delivery of the set dose. All of the pen's complex mechanical features and parts were seamlessly incorporated into the SoloSTAR's design, while still providing a robust and reliable feel suitable for daily use by patients with a chronic condition. Sanofi launched the Lantus SoloSTAR in 2007. It has subsequently won awards for its novel design. The patents currently listed in the Orange Book for Lantus SoloSTAR relate to the SoloSTAR pen injector dosage form.

The PTO granted Sanofi patents for each of these innovations, reflecting that each met the PTO's rigorous standards for patentability. Those patents protected Sanofi's innovations; they have not served to inhibit competition.

The Honorable Brett Guthrie (R-KY)

1. **There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of the medicine. Has Sanofi received a letter from any PBMs or insurers requesting that it provide the PBM or insurer with notice before Sanofi lowers the list price of insulin or any other medicine? If so, please list the entities that have sent such a letter to Sanofi and describe the requirements set forth in the letter.**

On December 14, 2018, Sanofi received a draft amendment to its Medicare Part D rebate agreement with OptumRx, Inc. (Optum). In the communication from Optum, Optum reported that a similar amendment would be forthcoming for the Sanofi-Optum commercial rebate agreement. The draft amendment requested that Sanofi provide advance written notice to Optum by March 1 of each calendar year if the following were to occur in that calendar year: 1) reduction of the WAC of any existing NDC; or 2) introduction or authorization of a lower priced authorized generic or a lower priced brand version of an existing NDC. Under the terms of the amendment, if Sanofi were to fail to notify Optum of a price reduction or launch of a lower list price alternative with the required advance notice, Optum would earn an "Effective Rebate Amount per Unit," calculated as a dollar amount, per unit, based on the original WAC, for a set period of time. Sanofi has not signed the proposed amendment.

   a. **Does Sanofi have any contractual obligations to provide a supply chain partner with notice before lowering the list price of insulin or any other medicine? If so, please list the entities and describe the contractual provisions.**

With respect to insulins and most other Sanofi products, Sanofi is not party to any contractual requirements to provide supply chain partners, including health plans, PBMs, and wholesalers, with notice before lowering list price. Sanofi is currently party to contractual relationships with

specialty distributors for certain rare disease products that require advance notification of price changes.

b. Has Sanofi provided any of its supply chain partners with notice of a list price decrease? If so, please describe these interactions.

No, Sanofi has not provided any of its supply chain partners with notice of a list price decrease.

c. What happens to Sanofi's rebate obligations with PBMs if Sanofi lowers the list price of insulin or any other medicine?

Because PBM rebates are currently set as a percentage of a product's list price, absent agreement to the contrary with the PBM, a lower list price would result in lower aggregate rebates per unit to the PBM. As noted above, one PBM has asked for advance written notice of such list price reductions. Other PBMs are currently evaluating and proposing various options to address the issue of lower list prices.

d. Has the letter sent by OptumRx or any other similar requests by supply chain partners impacted Sanofi's decisions regarding whether to lower the list price of insulin or any other medicine? If so, please describe.

Sanofi makes pricing changes based on its own independent assessment of the value proposition of the product, the competitive environment, patient access considerations, and investment in further product development or needs to reinvest in R&D more generally. Nevertheless, certain decisions by PBMs and wholesalers may affect a patient's ability to access Sanofi medicines. Because patient access considerations play a role in Sanofi's pricing decisions, actions by PBMs and wholesalers could have a future effect on those decisions.

2. In Sanofi's testimony, Sanofi notes that the average net price of Sanofi's most prescribed insulin, Lantus, has declined by over 30 percent since 2012 while the average out-of-pocket burden for patients with commercial insurance and Medicare has increased by approximately 60 percent over that same period. Which factor described in Sanofi's testimony (*e.g.*, list price, increase in number of high deductible health plans, changes in insurance design, changes to drug formularies, etc.) has had the greatest impact on the out-of-pocket burden for patients using insulin?

The formulary design for health plans and PBMs is determined independently by the health plan or its PBM. Sanofi does not have visibility into that decision-making process and therefore believes that this question is best addressed to the health plans, or PBMs that represent or negotiate on behalf of health plans. However, we can confirm that Sanofi offers significant rebates on certain of our products in a highly competitive marketplace, including for Lantus. These negotiations have resulted in net prices that are well below the product's list price. While we do not have insight into PBM relationships with their clients, or their clients' relationships with pharmacies and patients, we do know that Lantus' average net price since 2012 has declined by more than 30% while the average out-of-pocket burden for commercially insured and Medicare patients has increased by approximately 60% over the same time period.

3. According to a November 2018 I-MAK report on Lantus, 74 patent applications have been filed on Lantus and 95 percent of the patent applications on Lantus were filed after the drug was first approved and on the market in 2000.[15] Is this correct, and if so, why did Sanofi file these patent applications after the drug was first approved and on the market?

Sanofi does not know the basis for the statement in the I-MAK report and is therefore unable to confirm the information in it. That said, there are currently twenty-one patents listed in the FDA Orange Book for Lantus or Lantus SoloSTAR. The patents currently listed in the Orange Book for Lantus SoloSTAR relate to the SoloSTAR pen injector dosage form. Those patents, granted by the PTO, protect Sanofi's innovations. Sanofi files patent applications when it believes that there has been meaningful innovation worthy of patent protection, but it is the PTO that ultimately decides when it is appropriate to grant a patent, based on its assessment of patentability. Innovation does not cease simply because a product has been approved by FDA. As described above, FDA's approval of Lantus did not halt innovation on Lantus or curtail competition. Sanofi filed new patent applications after Lantus's initial approval to protect new innovations with regard to the Lantus formulation as well as with the SoloSTAR pen device.

a. How many of the patents relating to Lantus are on the insulin drug substance and how many are on the delivery device?

Of the twenty-one patents listed in the FDA Orange Book for Lantus or Lantus SoloSTAR, nineteen relate to the Lantus SoloSTAR injectable pen product and two relate to the Lantus vial product. The insulin glargine compound patents previously listed in the Orange Book for Lantus and SoloSTAR expired in 2009 and late 2014 and thus are no longer listed in the Orange Book. We note that, in addition to the patents, the FDA grants regulatory exclusivity to new molecular entities that meet statutory standards. Those exclusivities for Lantus did not expire until February 2015.

b. How many potentially competing products for Lantus has Sanofi challenged because of the existing patents on Lantus?

Sanofi has initiated five patent infringement lawsuits against competitors to protect its innovations relating to Lantus.

In two lawsuits against Eli Lilly (one relating to the company's application to market and sell a vial product and another relating to its application for a pen product), Sanofi asserted infringement of certain formulation and device patents that were listed in the FDA Orange Book for Lantus or Lantus SoloSTAR. Eli Lilly and Sanofi entered into a settlement agreement to resolve one of the lawsuits in September 2015. Under the settlement, Eli Lilly was permitted to market Basaglar, a follow-on biologic to Lantus SoloSTAR, in December 2016, more than seven years before the last expiration date of the patents asserted in the Eli Lilly lawsuit. Basaglar is

[15] I-MAK, Overpatented, Overpriced: Lantus (Nov. 1, 2018), *available at* https://www.i-mak.org/lantus/.

currently on the market and competing against Lantus. The court dismissed the other lawsuit against Eli Lilly after the company decided against commercializing the product at issue.

In a September 2016 lawsuit against Merck following Merck's application for a follow-on biologic for Lantus and Lantus SoloSTAR, Sanofi asserted infringement of several drug and device patents listed in the FDA Orange Book for Lantus and Lantus SoloSTAR. Sanofi also filed a separate lawsuit against Merck in August 2017 alleging infringement of two other Orange Book-listed patents. Those lawsuits were both dismissed voluntarily at Merck's request, as Merck unilaterally decided not to commercialize follow-on versions of Lantus or Lantus SoloSTAR.

A lawsuit against Mylan and its development partner Biocon is ongoing, and involves claims that Mylan and Biocon have infringed certain formulation and device patents that are listed in the FDA Orange Book for Lantus or Lantus SoloSTAR.

c. What impact, if any, did these patent applications have on the launch of Basaglar?

Patent applications do not affect competition. Thus, Sanofi's patent applications have not impeded the launch of Basaglar, which occurred in 2016 -- more than seven years before the last expiration date of the patents asserted in the Eli Lilly lawsuit and not long after the expiration of the Lantus compound patent. Basaglar is currently on the market and competing against Lantus.

4. Eli Lilly launched a follow-on insulin product—Basaglar—in 2016 to compete with Lantus. What impact, if any, has the launch of Basaglar had on the list price and net price of Lantus?

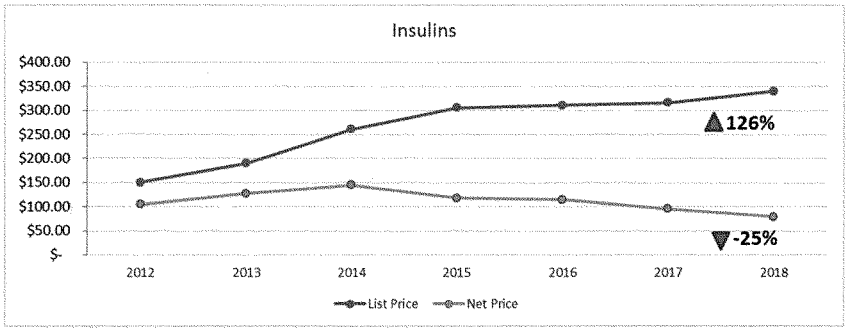
The competition between Lantus and Basaglar has led to Sanofi substantially lowering the Lantus net price, as compared to prior years. Sanofi hopes that those price reductions will benefit patients but, as explained in our testimony and in the below chart, that does not appear to have been the case to date. As with all other Sanofi pricing decisions, any increase in the list price for Lantus since the launch of Basaglar has been consistent with Sanofi's progressive pricing policy, which includes a commitment to keep annual list price increases at or below the projected U.S. National Health Expenditure growth rate.

5. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. For example, in Sanofi's testimony, Sanofi said that, between 2012 and 2018, the average aggregate net price across all Sanofi insulin products has declined by 25 percent while the list price has increased by 126 percent. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why

manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price. Please explain.

As shown in the below chart, between 2012 and 2018, the average aggregate net price across all Sanofi insulin products has declined by 25 percent while the list price across all Sanofi insulin products has increased by 126 percent.

Sanofi Insulins List vs. Net Price Changes Between 2012-2018



In May 2017, Sanofi announced its progressive and industry-leading pricing principles to help stakeholders understand our pricing decisions and to advance a more informed discussion of issues related to the pricing of medicines.[16] These principles include a pledge to keep annual list price increases at or below the projected U.S. National Health Expenditure (NHE) growth rate, an estimate of medical spending calculated by the Centers for Medicare and Medicaid Services (CMS) and often used as a measure of healthcare inflation. These principles apply to all of our prescription medicines if a price increase results in more than a $15 annual increase in the price of the medication. In addition, we committed to making both our average aggregate list and net price changes across our portfolio transparent to help illustrate how revenue accrues to Sanofi versus other parts of the pharmaceutical supply chain. In 2018, all of our price increases were consistent with our policy, as are all pricing actions we have taken in 2019.

With respect to PBMs interests, as HHS and HHS OIG have observed in their recent proposed Medicare Part D rebate rule, rebate payments and other forms of payment to PBMs are often based on a percentage of list price. Whether this causes PBMs to favor higher list price products over lower cost products is a question best directed to them, but it is clear that payments based on a percentage of list price result in a higher margin for the higher list price product than for the lower list price product. To illustrate this point, consider Sanofi's experience with Admelog, a biosimilar of insulin lispro. When it launched in 2017, Admelog was the lowest list price

[16] *See* https://www.sanofi.us/-/media/Project/One-Sanofi-Web/Websites/North-America/Sanofi-US/Home/corporateresponsibility/Prescription_Medicine_Pricing_2019.pdf.

mealtime insulin product, yet it was not, and still is not, covered by any Medicare Part D or commercial plans. At the committee hearing, PBM witnesses testified that this was due to another product having a lower net price and a higher list price.[17] As we have experienced, within the current system, declining prices for payers or new treatments priced at responsibly lower list prices are no guarantee that those actions will translate to affordability or access for patients.

6. **During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.**

    a. **What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?**

The payment of administrative fees that are a percentage of product list prices is a standard industry practice. The Anti-Kickback Statute safe harbor for GPO administrative fees protects percentage of list price-based administrative fees up to 3% of list price, and further protects percentage of list price-based fees above 3% if the fee amount is disclosed to the members of the GPO. In 2003, the OIG extended this safe harbor to PBM administrative fees.[18] Nevertheless, because percentage of list price payments could potentially create incentives for manufacturers to maintain high list prices, Sanofi supports reform of the current system to ensure that administrative fees are fixed and reflect fair market value for bona fide services performed for Sanofi.[19]

    b. **Does your company support moving to a system where administrative fees are based on a flat fee instead?**

Yes, Sanofi supports a shift toward flat fees throughout the supply chain. Specifically, Sanofi supports the recent HHS OIG Proposed Rulemaking regarding the creation of a new safe harbor for PBM fees, and Sanofi has submitted comments on those proposals.

The Honorable Jeff Duncan (R-SC)

1. **One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate**

[17] Priced Out of a Lifesaving Drug: Getting Answers on the Rising Cost of Insulin: Hearing Before the Subcomm. on Oversight and Investigations, 116 Cong. 51 (2019) (Statement of Amy Bricker, Senior Vice President, Supply Chain, Express Scripts).
[18] Notice, OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731, 23736 (May 5, 2003).
[19] *Id.*

and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

So, which is it? Is there innovation in the insulin market or not?

There is substantial innovation in the diabetes marketplace, including for insulin products. Diabetes continues to be a critical area of focus of Sanofi's research and development efforts. Since Sanofi's discovery and development of Lantus, Sanofi has continued to invent new formulations to meet individualized patient needs. For example, Toujeo, approved by the FDA in 2015, more closely mimics endogenous basal insulin secretion and provides an improved therapeutic effect at a higher concentration of glargine than Lantus; Toujeo exhibits a different and longer-acting profile. In 2017, Sanofi launched Soliqua 100/33, a fixed-ratio combination of Lantus and a non-insulin glucagon-like peptide receptor agonist (GLP-1 RA) that starts working after eating a meal. GLP-1s have been shown to reduce post-mealtime glucose peaks, which have been linked to cardiovascular disease in patients with diabetes; however, their use has been limited by gastrointestinal side effects. Soliqua 100/33 has demonstrated reduction in average and overall glucose levels while also reducing the gastrointestinal side effects related to GLP-1s.

There has also been significant innovation related to insulin delivery mechanisms. As noted above, the launch of Lantus SoloSTAR has enhanced the lifestyles and medication compliance rates of millions of diabetes patients throughout the US and around the world. Sanofi has also developed Toujeo SoloSTAR, a pre-filled disposable injection pen that includes innovative design features and attributes, ranging from the length of time it can be held without overheating the contents to other ergonomic features designed to make the device easier to use.

Sanofi's scientists are working every day on ways to transform the future of diabetes care by addressing the underlying disease. Sanofi has initiated multi-pronged research efforts aimed at preventing progression of the disease, reducing insulin-dependence, and restoring insulin-producing cells though stem cell technologies. Sanofi researchers are also exploring the molecular mechanisms by which obesity leads to diabetes, and they are working to design molecules that aim to restore healthy metabolism and thereby stop diabetes in its tracks. Sanofi is committed to continued investment so that we can bring better and more convenient breakthrough treatments to diabetes patients.

2. **One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."**

Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

So, which is it? Are there patents preventing innovation and competition or not?

Patents are not preventing innovation and competition. To the contrary, there is robust competition among diabetes drug manufacturers. This competition only continues to intensify with the introduction of additional generic and biosimilar medicines. As with any technology, this a reflection of the number of problems that had to be solved with novel and innovative solutions to bring the technology to the market. Sanofi's patents reflect novel inventions, as evidenced by PTO's grant of those patents. US patents are granted only after a comprehensive examination process by the PTO that tests whether the invention meets all the legal requirements of patentability including that the invention be new, not obvious, and useful.

Sanofi invests billions of dollars in the pursuit of new treatments for patients and our patents serve to protect our innovative discoveries. From 2012 through 2018, Sanofi's total research and development (R&D) investment in diabetes was approximately $4.5 billion. In 2018 alone, Sanofi's total research and development investment in diabetes was approximately $800 million. Sanofi plans to maintain this level of research and development investment through 2021. From a life sciences perspective, the patent system serves to attract the risk-taking, entrepreneurial spirit, and the capital needed to engage the brightest minds in science to solve some of the world's greatest health challenges—in short, the patent system encourages innovation.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"
April 10, 2019

Mr. Thomas Moriarty, Executive Vice President,
Chief Policy and External Affairs Officer, and General Counsel
CVS Health

The Honorable Joseph P. Kennedy III (D-MA)

1. Last year, CVS Caremark sent a letter regarding the 340B program to various pharmacies in Massachusetts stating that CVS Caremark would be reducing reimbursement rates. Please provide a list of all pharmacies to which CVS Caremark sent this letter.

Our intent was to bring reimbursement at pharmacies owned by 340B covered entities in line with the rest of our network. In all, the pharmacies that received that notification represented less than 2.5 percent of our total pharmacy network and was based on their own self-identification in their reporting to us.

Certain pharmacies that participate in CVS Caremark's pharmacy network are also participants in the federal government's 340B Drug Pricing Program, which is a program that requires pharmaceutical manufactures to provide significant discounts on prescription drugs to providers who serve low-income and vulnerable patient populations. As such, pharmacies that are owned by a 340B covered entity and serve 340B-eligible patients are able to acquire their products at very deep discounts through the program. Participation in this program creates unique financial implications for payors (including governmental and non-governmental payors). Most importantly, due to these large discounts manufacturers must provide to these pharmacies, the manufacturers will typically not pay rebates on claims for drugs purchased under the 340B program. Because payors do not receive rebates for these claims, they represent a much higher net cost than traditionally purchased drugs.

2. It is my understanding CVS Caremark has since rescinded its proposal to reduce reimbursement rates to pharmacies owned by safety net providers. What caused CVS Caremark to change course? Will CVS Caremark commit to refrain from similar anticompetitive tactics undermining the 340B program in the future?

After careful review, CVS Caremark decided not to implement commercial reimbursement rate changes for 340B covered entity-owned pharmacies that were scheduled to become effective on April 1, 2019 (with an original effective of February 1, 2019). CVS Caremark made this decision after speaking to many of the pharmacies and trade associations who would be impacted by this change, and took into consideration the feedback they provided.

3. How would the reduction in reimbursement rates affect medication adherence for diabetic patients if CVS Caremark put it in place? How would the reduction in reimbursement rates affect access to insulin?

The proposed change would have only applied to pharmacy reimbursement and would have had limited effect on patient cost sharing. In limited instances where cost share may have been affected, we believe it may have lowered patient out-of-pocket costs.

The Honorable Brett Guthrie (R-KY)

1. In December 2018, CVS Health announced that it was introducing a new approach to pricing of pharmacy benefit management services, referred to the Guaranteed Net Cost Model. Will the Guaranteed Net Cost Model apply to all insulin products?

Yes, the Guaranteed Net Cost model applies to all prescription drugs. The Guaranteed Net Cost model guarantees the client's average spend per prescription, after rebates and discounts, across each distribution channel – retail, mail order and specialty pharmacy. The model focuses on a simple concept – net cost per claim. Under the new model, CVS Caremark will pass through 100 percent of rebates to plan sponsors and take accountability for the impact of drug price inflation and shifts in drug mix. With the Guaranteed Net Cost model, clients continue to have the option to implement point-of-sale rebates to reduce cost-sharing for plan members.

a. What percentage of CVS Caremark's clients have chosen to adopt the new model? What is CVS Caremark doing, if anything, to incentivize clients to adopt this model?

Although a limited number of clients have chosen to adopt the new model since it was announced six months ago, we have provided approximately 70 pricing quotes to current and prospective clients thus far who are considering moving to Guaranteed Net Cost.

b. According to press releases, CVS Health will pass through 100 percent of rebates in the Guaranteed Net Cost Model. Why under the traditional rebate model does CVS Health only pass through 98 percent of the rebates? How will CVS Health be compensated under the Guaranteed Net Cost model? Will the amount CVS Health receives be a fixed fee or will it vary depending on different factors?

As a whole, we are currently only retaining two percent of rebates, while the rest are passed along to our clients. In Part D, we effectively pass along 100 percent of the rebates to the Part D plans, which use them, in general, to lower premiums. Two main items determine the share of rebates we retain. First, we may guarantee a certain level of rebates to a client. If we exceed the guarantee level, we may keep all or some of those rebates above the guarantee. Second, a client may choose to compensate us for our services by allowing us to retain some or all rebates.
In the Guaranteed Net Cost model, CVS Caremark will be compensated by the difference between the client's performance versus our cost of the products and dispensing. If the client elects to pay CVS Health an upfront administrative fee in lieu of making a differential between

client price and pharmacy reimbursement, that is another option of how CVS Caremark would be compensated.

c. One article notes that a CVS spokesperson said that "the company does not expect CVS Health's profitability to increase or decrease as a result of the shift to 100% pass-through rebates."[1] Is this correct? If so, please explain why a shift to 100 percent pass-through of rebates will not impact CVS Health's profitability.

The majority of our clients today receive 100% pass-through of rebates (as previously stated our average pass-through rate across our book of business is 98%), so we do not expect a noticeable profitability change as clients move to the Guaranteed Net Cost Model.

d. Under the Guaranteed Net Cost Model, will CVS Health share information about the price of the medicine paid by CVS Health to obtain a medicine such as insulin with its clients?

All clients receive disclosure of rebates and fees received from manufacturers and all clients have audit rights covering our contracts with manufacturers and the amount of rebates or fees collected from manufacturers. We do not, however, typically provide product specific rebate levels outside of an audit.

e. What impact, if any, will the Guaranteed Net Cost Model have on the out-of-pocket costs for a patient at the pharmacy counter—especially those patients that are in the deductible phase of a high deductible health plan or that have coinsurance for their insulin?

The Guaranteed Net Cost model is a model offered to health plan sponsors in how to structure their overall prescription drug benefit costs. It does not necessarily have any impact on patient out-of-pocket costs at the pharmacy counter, which are determined by how the plan sponsor decides to set up their plan's benefit design. We offer our clients the option of doing point-of-sale rebates to lower drug costs at the pharmacy counter and if the client is using a high deductible health plan with an HSA, the option of using a preventive drug list to provide coverage for preventive medications, like insulin, prior to satisfaction of the deductible.

2. We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many Pharmacy Benefit Managers (PBMs), including CVS Health, that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue

---

[1] Evan Sweeney, *CVS Caremark shifts PBM model to 100% pass-through pricing and focus on net cost*, FIERCE HEALTHCARE (Dec. 5, 2018), *available at* https://www.fiercehealthcare.com/payer/cvs-caremark-launches-guaranteed-pbm-model-100-pass-through-pricing.

to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price.

To help us better understand the role of rebates, there is a hypothetical question below.

> There are two therapeutically equivalent insulin products, product A and product B. Product A has a list price of $100 and CVS Health is offered a rebate of 50 percent, thereby making the final price to CVS Health's client $50. Product B has a list price of $50, and CVS Health is not offered any rebates for the product.

a. Is there any reason CVS Health would prefer Product A, the product with the higher list price and rebate, over Product B? If so, please describe.

Our goal is to provide our clients with the lowest net cost drugs for their health plans. In this example, we would certainly consider both products carefully, review the clinical evidence, and provide the best option for our clients and members.

b. Which drug would be more profitable for CVS Health to include on the formulary?

We cannot say which product would be more "profitable" for CVSH to include on a formulary because individual clients choose to compensate CVSH for its services differently. As an example, for a client that receives 100% of rebates, CVSH would retain no rebate difference based on individual sales of those products.

c. How does CVS Health determine the "net price" of the medicine?

The net price of a product is the list price net of any rebates offered by the manufacturer to CVS Caremark's clients.

d. How would CVS Health decide which product to include on formulary or would CVS Health include both products on its formulary?

Our goal is to provide our clients with the lowest net cost drugs. In the instance you describe here we would certainly consider both products closely, review the clinical evidence, and provide the best option for our clients and their members.

e. My understanding is that pharmacy benefit managers (PBMs) have generally provided their clients with guaranteed levels of rebates, and in some instances, if the PBM exceeds the guarantee level, they may keep all or some of those rebates.

   i. During the last 5 years, how many times has CVS Health exceeded the level of rebates that it guaranteed to its clients? How much did CVS Health retain as a result?

We pass along 98% of the rebates we collect to our clients, who can use them to lower the premiums they charge their beneficiaries, including the limited number of contracts that allow us to retain rebates collected above a guarantee. We also encourage our clients with high deductible health plans to use point-of-sale rebates – and now cover approximately 10 million lives under point-of-sale rebates. It is an infrequent occurrence for us for us to collect rebates above such guaranteed levels for retention.

ii. What happens if CVS Health does not achieve this guaranteed level of rebates?

When rebates do not equal the guaranteed level, CVS Health provides the client with the guaranteed level of rebates.

3. What factors does CVS Health consider when deciding whether to include an authorized generic on its formulary?

   a. In CVS Health's experience, how many manufacturers making an authorized generic refuse to provide a rebate that would make the net price of the authorized generic less than the brand drug?

Typically manufacturers of an authorized generic have not provided rebates. However, more recently we are seeing manufacturers use this pathway to introduce alternate lower WAC brand drugs. In some instances, those brand manufacturers have offered rebates, but not at a sufficient level to result in the new product having the same or lower net cost than the original brand. This seems to be a strategy by the manufacturer to increase the net cost of the drug.

   b. If CVS Health does get a lower net price on the authorized generic and put it on formulary, will CVS Health keep the branded product on formulary as well? Why?

Whether we keep the brand product on the formulary would be made on a case-by-case basis. However, we would strive to give preferential treatment to the lowest net cost product, just as we do in any other instance.

   c. Has CVS Health ever gotten a lower net price on an authorized generic and put it on its formulary and kept the branded product on formulary as well? If so, why?

This may occur depending upon the formulary the client wants to use.

4. There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer decides to lower the list price of a medicine. Has CVS Health sent a similar letter to pharmaceutical manufacturers and/or does CVS Health require that manufacturers provide the company with advance notice of a list price decrease? If yes:

a. Please describe the terms of this requirement and when CVS Health established this requirement.

CVSH has not sent a similar letter to manufacturers.

b. If a pharmaceutical manufacturer does not provide CVS Health with sufficient notice that the manufacturer will decrease the list price of a medicine, what will the manufacturer's rebate liability be for the product in each market (*e.g.*, commercial, Medicare Part D, etc.)?

CVS does not require from manufacturers any notice of changes in list prices before they occur.

c. Have any manufacturers reduced the list price of insulin without giving CVS Health sufficient notice and triggered this provision?

No, as CVS does not require from manufacturers any notice of changes in list prices before they occur.

5. During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.

a. What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?

Percentage-based fees may provide an accurate reflection of fair market value. For example, the volume and value of dispensing data that is provided to manufacturers are directly impacted by, and thus the fair market value of the data is directly impacted by, the dispensing activity, whether number of units or frequency of dispensing. As another example, the volume and value of PBM administrative services provided to manufacturers are directly impacted by, and dependent on, the number of plans, the number of beneficiaries, and the number units of product dispensed, validated, and reported. As a result, these fees are typically based on the number of units of product dispensed and reported to the manufacturer and based on a fixed percentage of the product's list price. We pass along approximately 98% of our rebates to our clients, and effectively 100% of rebates in Part D. These amounts also include fees we have received from manufacturers.

b. Does your company support moving to a system where administrative fees are based on a flat fee instead?

We do not support moving to a flat fee.

6. During the hearing, pharmaceutical manufacturers testified that one reason pharmaceutical companies have increased their list prices is because the companies had to provide larger rebates to have their product included on formularies and maintain formulary access and access to patients. If manufacturers lowered the list price of their medicines and therefore

provided lower rebates to PBMs, would your company continue to offer the same formulary access that you are offering to pharmaceutical manufacturers at higher list prices? In your opinion, if insulin products had lower list prices and lower rebates as a result, would the use of exclusive formularies increase or decrease?

We will prefer the product with the lowest net cost on our formulary for our clients regardless of the list price of a drug.

The Honorable Michael C. Burgess (R-TX)

1. One thing that has constantly come up in our conversations about drug pricing is that high deductible plans have become increasingly common. When did high-deductible health plans start to become more common?

High-deductible plans have been growing in popularity for the last fifteen years. According to one Kaiser Family Foundation survey, enrollment among covered employees in high-deductible plans grew from 4% in 2005 to approximately 29% in 2018.[2]

2. As enrollment in high deductible health plans has grown, patients have been increasingly exposed to higher out-of-pocket costs for medicines. We've heard that some PBMs have recommended that their clients include insulin on preventive drug lists, which would result in there being first-dollar coverage of insulin for beneficiaries in high deductible health plans.

    a. What kinds of drugs are commonly included on preventive drug lists?

In accordance with IRS guidance, preventive drug lists generally include drugs intended to prevent a disease that has not yet manifested itself or prevent the reoccurrence of a disease from which a person has recovered. These can include cholesterol-lowering drugs, smoking deterrents, anti-asthmatics, blood pressure medications, and insulins and other anti-diabetic drugs. We include all covered insulins on our preventive list.

3. One chart from Express Scripts' 2018 Drug Trend Report shows that the out-of-pocket cost for patients in a high-deductible plan per 30 day adjusted Rx in 2018 was $40.69 when insulin was on a preventive drug list, compared to $105.16 when insulin was not on a preventive drug list. Given preventive medications can help people avoid many illnesses and conditions, and the aforementioned chart shows that having a drug, such as insulin, on a preventive drug list can save the patient money – do each of you have data that shows the savings to the patient as well as the overall health care system as a result of having a medication, such as insulin, on a preventive drug list?

We provide for our own employees and also recommend that our clients adopt a $0 copay for preventive drugs. When our clients combine a $0 copay preventive drug list with point of sale

---

[2] *2018 Employer Health Benefits* Survey at https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-8-high-deductible-health-plans-with-savings-option/.

rebates they can drive member OOP to zero dollars and still save money through medical savings, gaps in care closure, productivity gains, and better adherence and improved outcomes. Clients can save up to $3 million per 100,000 lives as a result of using a preventive drug list with $0 copays and POS rebates, despite a slight increase in pharmacy costs due to greater adherence. Patients on such plan have no out-of-pocket costs for insulin.

a. CVS told the Committee that you encourage clients who use health savings accounts (HSAs) to cover preventive drugs with a $0 copay and prior to satisfaction of the deductible. Additionally, since CVS Health provides its employees with an HSA plan, CVS said it covers certain preventive drugs and supplies with a $0 copay and prior to satisfaction of the deductible. Does CVS provide insulin to its employees with an HSA plan with a $0 copay and prior to satisfaction of the deductible? Why or why not?

Yes, CVS Health provides insulin for its employees with an HSA plan with a $0 copay prior to satisfaction of the deductible. This allows the plan to reduce patient out-of-pocket costs and improve adherence.

i. We've heard that some plans have the option of taking insulin out of the deductible entirely for enrollees in a high deductible health plan. Do you offer this to your clients and, if so, do you recommend that your clients include insulin on their preventive drug lists for high deductible health plans?

Yes, we recommend this option to our clients.

ii. How long have you recommended that your clients include insulin on their preventive drug list?

We have included insulin on our template HDHP/HSA preventive drug list and recommended that clients do the same for over a decade.

iii. Do you know how many of your clients use preventative drug lists, and have insulin on their preventive list? What percentage of your clients is that?

Of the HDHP clients that have adopted our template HDHP/HSA preventive drug list (in whole or in part), 95% include insulin.

iv. How many covered lives does that translate to?

Seven million HDHP lives have implemented our standard template HDHP/HSA preventive drug list.

4. What are some of the reasons why a client wouldn't use a preventive list and include insulin on that list?

We provide our plans with a wide range of benefit plan design options. Including a preventive drug list, $0 copays, and point-of-sale rebates may increase a plan's pharmacy spending and increase premiums. We give our clients the option to balance a variety of options so they can manage both premiums and member out-of-pocket.

The Honorable Jeff Duncan (R-SC)

1. One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.

   Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

   So, which is it? Is there innovation in the insulin market or not?

It is true that manufacturers have introduced a number novel insulin products onto the market in the past years. While many of these products can help limited populations, we have also found that a variety of legacy products are just as efficacious for many patients. As an example, most Type 2 diabetes patients who require insulin can remain stable on older human insulins, rather than newer analog products. We design our clinical programs to strive to get patient the most efficacious, cost-effective treatment.

2. One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."

   Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

   So, which is it? Are there patents preventing innovation and competition or not?

The regulatory status of insulins is certainly complex. FDA has recently finalized a rule redesignating insulin as a biologic rather than a traditional small molecule drug as it has been

historically. The existence of patents on newer products also increases the cost of development for generic manufacturers who must go through expensive patent litigation to bring a product to market. The longer these patents keep competitors off the market, the longer the brand has to increase prices. Commissioner Gottlieb himself recognized the challenges in bringing substitutable insulin to the market, and expressed hope that the new regulatory regime will lead to competition in the future.[3]

3. As follow-up to that, we have specifically heard concerns about patent "evergreening," which is when brand-name companies patent a slight modification of an older drug. Some say that evergreening does not significantly improve the therapeutic nature of the drug, but rather it provides the company that made the drug an economic advantage by avoiding more competition entering the market.

   In your opinion, do these patent "evergreening" concerns apply to the insulin products themselves or does it more so have to do with the newer delivery devices?

CVSH believes that patent evergreening is a problem generally in the pharmaceutical industry. For that reason we have recently endorsed a bill introduced by Senators Cornyn and Blumenthal, the Affordable Prescriptions for Patients Act, which would give FTC the authority to review pharmaceutical patenting practices.

a. If a company wants to create a generic alternative or biosimilar version of an insulin pen product, what are the existing regulatory barriers that make it difficult for them to create the generic alternative if there are only patents remaining on the delivery device?

We cannot speak to the drug development or commercialization process, as CVSH does not develop or commercialize prescription drugs. However, recent regulatory uncertainty around the status of insulin products may have discouraged development of follow-on products. We are grateful for FDA for finalizing guidance that will clarify this for biosimilar developers going forward. Additionally, follow-on developers face costly litigation from brand products looking to delay competition.

b. If the delivery device is the only part of the product that is patented, why aren't we at least seeing generic versions of insulin vials?

We cannot comment on the decision making process employed by generic pharmaceutical manufacturers

[3] Statement from FDA Commissioner Scott Gottlieb, M.D., on the agency's continued efforts to bring competition to the insulin market to lower prices and expand access available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-agencys-continued-efforts-bring-competition-insulin

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"

April 10, 2019

Ms. Amy Bricker, Senior Vice President, Supply Chain, Express Scripts

The Honorable Michael C. Burgess (R-TX)

1. **One thing that has constantly come up in our conversations about drug pricing is that high deductible plans have become increasingly common. When did high-deductible health plans start to become more common?**

   Consumer directed health plans (CDHPs) have become increasingly common since Congress created health savings accounts (HSAs) in 2003, as part of the Medicare Prescription Drug, Improvement, and Modernization Act.

   It is estimated that more than 9 out of 10 employers are offering a CDHP to their employees this year. Also known as high-deductible health plans, CDHPs can be designed in a variety of forms. Typically, a CDHP offers a high-deductible health plan with a spending account for out-of-pocket costs, such as a health savings account (HSA) or health reimbursement arrangement (HRA). Most employers still offer a CDHP as a choice alongside a traditional PPO or HMO.

   Plan sponsors are turning to CDHPs as a way to lower premiums and incentivize consumers with the belief that patients will take a more proactive approach to purchasing health care and make the most informed choices possible as they bear more out-of-pocket expenses.

2. **As enrollment in high deductible health plans has grown, patients have been increasingly exposed to higher out-of-pocket costs for medicines. We've heard that some PBMs have recommended that their clients include insulin on preventive drug lists, which would result in there being first-dollar coverage of insulin for beneficiaries in high deductible health plans.**

   a. **What kinds of drugs are commonly included on preventive drug lists?**

   One of the key ways CDHP members receive support is though a Preventive Medications program. This helps improve member adherence to medications, reducing the risk of worsening conditions and lowering overall healthcare costs.

   Our standard set of preventive medication lists may include the following:

   - Asthma/COPD medications

Internal Information

- Blood pressure lowering medications
- Blood thinners
- Cavity prevention agents
- Certain vitamins and fluoride supplements
- Cholesterol lowering medications
- Colonoscopy preparation agents
- Diabetic medication and supplies
- Migraine prevention
- Miscellaneous antivirals
- Osteoporosis prevention agents
- Respiratory syncytial virus prevention agents
- Smoking cessation agents
- Vaccines
- Weight loss agents

3. **One chart from Express Scripts' 2018 Drug Trend Report shows that the out-of-pocket cost for patients in a high-deductible plan per 30 day adjusted Rx in 2018 was $40.69 when insulin was on a preventive drug list, compared to $105.16 when insulin was not on a preventive drug list. Given preventive medications can help people avoid many illnesses and conditions, and the aforementioned chart shows that having a drug, such as insulin, on a preventive drug list can save the patient money – do each of you have data that shows the savings to the patient as well as the overall health care system as a result of having a medication, such as insulin, on a preventive drug list?**

   Express Scripts takes a holistic approach to supporting CDHP members. We work to ensure that members who have greater financial responsibility for managing their care are able to do so effectively in terms of making better decisions that deliver healthier outcomes. Express Scripts' 2018 Drug Trend Report shows that out-of-pocket costs for patients with diabetes in high-deductible plans were cut in half when insulin is included on the preventive drug list.

   a. **I have a similar question for you. During a briefing with Committee staff, Express Scripts said that your company makes preventive drug lists with first dollar coverage available to your clients but that preventive drug lists are not widely used.**

      i. **Do you recommend that your clients include insulin on their preventive drug lists?**

   As noted above, diabetic medication and supplies, including insulin, are part of our standard set of preventive medication lists.

      ii. **How long have you recommended that your clients include insulin on their preventive drug list?**

Diabetic medication and supplies, including insulin, have been part of our standard set of preventive medication lists for more than a dozen years.

iii. Do you know how many of your clients use preventative drug lists, and have insulin on their preventive list? What percentage of your clients is that?

An analysis in Express Scripts' 2018 Drug Trend Report showed that 64% of high-deductible plans used a preventive drug that included first-dollar coverage of insulin.

iv. How many covered lives does that translate to?

Approximately 3 million.

4. What are some of the reasons why a client wouldn't use a preventive list and include insulin on that list?

Plan sponsors, based on their own unique situation, determine the scope of their coverage, applicability of coverage criteria, and cost sharing that is most appropriate for their members. They make these decisions based on the needs of their covered individuals, including factors that may affect the cost of coverage, such as preventive lists.

The Honorable Brett Guthrie (R-KY)

1. What factors does Express Scripts consider when deciding whether to include an authorized generic on its formulary?

Recently, we introduced a novel formulary option to provide employers and health plans an opportunity to leverage changing dynamics to help lower their members' out-of-pocket costs. The Express Scripts' National Preferred Flex Formulary, which became available January 1, 2019, provides a way for plans to cover lower list price products, such as new authorized alternatives that drug makers are bringing to the market. Specifically:

- When a manufacturer launches a lower-cost authorized alternative to a branded medication currently on the market, Express Scripts will evaluate the product for placement on the National Preferred Flex Formulary.
- If appropriate, the authorized alternative product will be added to the Flex formulary with preferred or possibly non-preferred status. The innovator brand-name product, and potentially other products in the therapy class, then will be excluded from coverage.
- Members enrolled in the Flex formulary who have a high-deductible or co-insurance plan design can have access to the lower-priced authorized alternative medication.

Branded innovator products will remain preferred or non-preferred on other formularies, including Express Scripts' standard National Preferred Formulary, while the authorized alternative product may be excluded.

a. **In Express Script's testimony, Express Scripts said that the company is in discussions with Eli Lilly about the authorized generic version of Humalog, and if the net cost is lower, Express Scripts will add the authorized generic to the company's Flex Formulary. In Express Script's experience, how many manufacturers making an authorized generic refuse to provide a rebate that would make the net price of the authorized generic less than the brand drug?**

On March 4, 2019, Eli Lilly announced the introduction of a lower list price authorized alternative for its highly prescribed short-acting insulin, Humalog. The authorized alternative version will be added to the National Preferred Flex Formulary with an effective date of July 1, 2019, and the brand will be excluded. In our experience to date, we have not seen manufacturers of authorized alternatives offer a rebate that would result in a net cost lower than that of the brand.

b. **If Express Scripts does get a lower net price on the authorized generic and put it on the Flex Formulary, will Express Scripts keep the branded product on the company's formulary as well? Why?**

As noted above, the brand will be excluded from the National Preferred Flex Formulary effective July 1, 2019. The brand product will remain on the other Express Scripts formularies. In our experience to date, we have not seen manufacturers of authorized alternatives offer a rebate that would result in a net cost lower than that of the brand.

c. **Has Express Scripts ever gotten a lower net price on an authorized generic and put it on formulary and kept the branded product on formulary as well?**

In our experience to date, we have not seen manufacturers of authorized alternatives offer a rebate that would result in a net cost lower than that of the brand.

2. **We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many Pharmacy Benefit Managers (PBMs), including Express Scripts, that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price.**

To help us better understand the role of rebates, there is a hypothetical question below.

There are two therapeutically equivalent insulin products, product A and product B. Product A has a list price of $100 and Express Scripts is offered a rebate of 50 percent, thereby making the final price to Express Script's client $50. Product B has a list price of $50, and Express Scripts is not offered any rebates for the product.

a. **Is there any reason Express Scripts would prefer Product A, the product with the higher list price and rebate, over Product B? If so, please describe.**

We are not aware of this hypothetical scenario happening within classes of therapeutically equivalent insulin products. However, the process Express Scripts uses to develop formularies has been constructed to ensure that clinical considerations are paramount and fully taken into account *before* cost considerations. Formulary management is a highly effective strategy that pharmacy plan sponsors can implement to maintain a safe, affordable and meaningful benefit for patients. Our formulary development approach for the products you describe would follow this rigorous process, which is described in more detail below. For reasons outlined in the responses below, Express Scripts would likely include both products A and B on the formulary. The goal of the Express Scripts National Preferred Formulary is to provide broad access to products that will meet the clinical and financial needs of our clients and their members. Ultimately, plan sponsors choose the formulary design based on the unique needs of their members and make the decision to include or exclude products.

b. **Which drug would be more profitable for Express Scripts to include on the formulary?**

Financial impact to Express Scripts is expressly excluded and prohibited from consideration in the formulary development process.

c. **How does Express Scripts determine the "net price" of the medicine?**

While "net price" may be defined various ways, the net price plan sponsors or insurers pay for a drug is generally a function of the list price less any applicable discounts.

d. **How would Express Scripts decide which product to include on formulary or would Express Scripts include both products on its formulary?**

Express Scripts develops formularies through a four-step process involving the work of distinct committees: the Therapeutic Assessment Committee, National Pharmacy & Therapeutics Committee, Value Assessment Committee, and an annual formulary review by the National Pharmacy & Therapeutics Committee.

The Therapeutic Assessment Committee (TAC) is an internal clinical review body, consisting of clinical pharmacists and physicians who are employed by Express Scripts. From a formulary development perspective, the committee is tasked to review specific medications following approval by the Food and Drug Administration. Before discussing

a new drug at TAC, Express Scripts' clinical team conducts a search of the medical literature, evaluates published data from clinical trials, and develops comprehensive drug evaluation summary documents. The drug evaluation documents include, at a minimum: a summary of the pharmacology, safety, efficacy, dosage, mode of administration, and the relative place in therapy of the medication under review compared to other pharmacologic alternatives. Following a review of the drug evaluation summary document, TAC ultimately provides a formulary placement recommendation that is shared with the Express Scripts' National Pharmacy and Therapeutics (P&T) Committee. TAC formulary recommendations are merely a suggestion and cannot be formally implemented without the approval of the P&T Committee.

Express Scripts' P&T Committee is a group of independent, actively practicing physicians and pharmacists who are not employed by Express Scripts. The P&T Committee is tasked to review medications from a purely clinical perspective. The Committee does not have access to, nor does it consider, any information regarding Express Scripts' rebates/negotiated discounts, or the net cost of the drug after application of all discounts. The Committee does not use price, in any way, to make formulary placement decisions.

The P&T Committee can establish one of the following three formulary placement designations: *include*, *exclude*, or *optional* from a formulary. Drugs with a designation of **include** are recommended for placement on all formularies. Drugs may be given an include designation for one or more of the following clinical reasons: unique indication for use addressing a clinically significant unmet treatment need; efficacy superior to that of existing therapy alternatives; a safety profile superior to that of existing therapy alternatives; a unique place in therapy; and/or drugs which treat medical conditions that necessitate individualized therapy and for which there are multiple treatment options. Drugs with an **exclude** designation are not recommended for formulary inclusion. Drugs may be given an exclude designation for one or more of the following clinical reasons: efficacy inferior to that of existing therapy alternatives; a safety profile inferior to that of existing therapy alternatives; and/or insufficient data to evaluate the drug. Medications recalled from the market for safety reasons take an automatic exclude status, and are formally reviewed at the next P&T Committee meeting. Drugs may also be designated as **optional** on a formulary. Drugs may be given an optional designation based on the conclusion that they are clinically similar to other currently available drug alternatives.

Optional medications are forwarded to the Value Assessment Committee (VAC) for further analysis, which considers the value of drugs by evaluating the net cost, market share, and drug utilization trends of clinically similar medications. VAC consists of Express Scripts employees from various areas. No member of VAC can serve in any capacity on TAC (and vice-versa). VAC reviews drugs designated as optional by the P&T Committee, and develops a formulary placement recommendation.

Finally, on an annual basis, the National P&T Committee will review the final formulary recommendations, by drug class, for the upcoming plan year. The Committee utilizes this opportunity to ensure adherence to previously established formulary placement recommendations, and to recommend any additional changes to ensure that the formulary is clinically appropriate. The Committee also ensures that all Express Scripts national

formularies cover a broad distribution of therapeutic classes and categories, and that the formularies neither discourage enrollment by any group of enrollees nor discriminate against certain patient populations.

e. **Has Express Scripts ever been offered two therapeutically equivalent insulin products at the same price? Is there a threshold Express Scripts uses if the prices are substantially similar when deciding whether to include both products on the formulary?**

As noted above, the process Express Scripts uses to develop formularies has been constructed to ensure that clinical considerations are paramount and fully taken into account before cost considerations. Many insulins are considered easily interchangeable from a clinical perspective. We then evaluate the lowest net cost of the drug. Express Scripts is not aware of two therapeutically equivalent insulin products having the same list price. Additionally, we generally do not see multiple insulin manufacturers offering the same rebate discount. As noted in the hypothetical scenario above, if the net cost for two products are the same, both may be included on formulary.

f. **My understanding is that pharmacy benefit managers (PBMs) have generally provided their clients with guaranteed levels of rebates, and in some instances, if the PBM exceeds the guarantee level, they may keep all or some of those rebates.**

i. **During the last 5 years, how many times has Express Scripts exceeded the level of rebates that it guaranteed to its clients? How much did Express Scripts retain as a result?**

Our clients, which are sophisticated entities and are often represented by benefit consultants and advisors, negotiate the overall pricing arrangement they believe best suits their pharmacy benefit needs. Terms vary across clients and contracts. Express Scripts' contractual terms with its clients are confidential and based on those confidentiality obligations, Express Scripts cannot disclose the individual financial performance of any specific contract.

Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates.

ii. **What happens if Express Scripts does not achieve this guaranteed level of rebates?**

It would depend on the individual contract.

3. **There have been press reports about a letter that one Pharmacy Benefit Manager (PBM), OptumRx, sent to pharmaceutical manufacturers requesting that pharmaceutical manufacturers provide the PBM with notice if the manufacturer**

decides to lower the list price of a medicine. Has Express Scripts sent a similar letter to pharmaceutical manufacturers and/or does Express Scripts require that manufacturers provide the company with advance notice of a list price decrease? If yes:

No. Express Scripts welcomes manufacturers lowering their list prices so that patients can have greater access to medications. Nothing in our agreements prohibits any manufacturer from decreasing the list price of a drug.

a. **Please describe the terms of this requirement and when Express Scripts established this requirement.**

N/A

b. **If a pharmaceutical manufacturer does not provide Express Scripts with sufficient notice that the manufacturer will decrease the list price of a medicine, what will the manufacturer's rebate liability be for the product in each market (*e.g.*, commercial, Medicare Part D, etc.)?**

N/A

c. **Have any manufacturers reduced the list price of insulin without giving Express Scripts sufficient notice and triggered this provision?**

N/A

4. **During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.**

   a. **What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?**

Percentage-based fees are used throughout the pharmaceutical supply chain. However, the use of such fees has no impact on list prices set by manufacturers.

   b. **Does your company support moving to a system where administrative fees are based on a flat fee instead?**

As noted above, the use of percentage-based fees has no impact on list prices. We welcome the opportunity to work with policymakers on initiatives that could increase competition and lead to lower list prices, providing greater access and affordability for plans and patients.

5. **During the hearing, pharmaceutical manufacturers testified that one reason pharmaceutical companies have increased their list prices is because the companies**

had to provide larger rebates to have their product included on formularies and maintain formulary access and access to patients. If manufacturers lowered the list price of their medicines and therefore provided lower rebates to PBMs, would your company continue to offer the same formulary access that you are offering to pharmaceutical manufacturers at higher list prices? In your opinion, if insulin products had lower list prices and lower rebates as a result, would the use of exclusive formularies increase or decrease?

As an initial matter, we note that rebates do not cause increases in list prices. Moreover, our formulary development approach for all medications prioritizes clinical considerations first and foremost before evaluating net cost to clients. Express Scripts has maintained a clear, unwavering position that achieving the lowest net cost for a clinically appropriate prescription medication is our mission for our clients and their members, whether that is through a negotiated rebate or reduction in list price.

Since 2014, Express Scripts has continued to evaluate the financial opportunities that clinically-appropriate exclusions represent for our clients, and our approach to driving savings would not change if manufacturers lowered their list prices. As noted above, our focus is on net cost, whether through a negotiated rebate or reduction in list price. We also offer an option for plans not implementing exclusions to utilize step therapies requiring the trial of a clinically appropriate preferred product before the patient can try a non-preferred drug. A medical exception process is always available for the prescribing physician to pursue if a patient's unique health situation requires a non-preferred product to be the only option. Like formularies, step therapies and other elements of benefit design are ultimately determined by our clients.

The Honorable Jeff Duncan (R-SC)

1. **One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.**

   Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

   So, which is it? Is there innovation in the insulin market or not?

Over the last several years, the list prices for insulin products have steadily increased. We have seen rates of growth in list prices of widely-used insulins increase more than 50 percent—and in some cases even higher—over the last five years. While there is limited innovation in the insulin market, Express Scripts is concerned that price increases are often the result of arbitrary increases and market manipulation rather than recovering the cost of insulin innovation.

2. **One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."**

   Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

   So, which is it? Are there patents preventing innovation and competition or not?

   Yes, there are. Express Scripts is concerned about practices such as so-called "pay-for-delay" arrangements, which delay the availability of lower-cost generics and biosimilars. We applaud the Committee's recent unanimous passage of legislation that would block these anti-competitive agreements, removing barriers to competition and expanding the availability of lower-cost generics and biosimilars. According to a Federal Trade Commission (FTC) study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.

   We also support preserving the ability of the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office to invalidate patents that do not represent true innovation. Legislative and regulatory efforts to weaken this process will extend patent monopolies for pharmaceutical and biological products, resulting in higher prices for patients.

   In our 2018 Public Policy Analysis, Express Scripts identified an increasing number of patent settlements between biologic and biosimilar manufacturers as a trend that lawmakers need to resolve. Brand and generic drugmakers have been required since 2003 to file patent settlement agreements with the FTC, which evaluates the information and decides whether to take any legal action challenging the settlement. That requirement previously did not extend to biosimilar settlements, potentially delaying the market introduction of these lower cost biological treatments.

3. **As follow-up to that, we have specifically heard concerns about patent "evergreening," which is when brand-name companies patent a slight modification of an older drug. Some say that evergreening does not significantly improve the therapeutic nature of the drug, but rather it provides the company that made the drug an economic advantage by avoiding more competition entering the market.**

In your opinion, do these patent "evergreening" concerns apply to the insulin products themselves or does it more so have to do with the newer delivery devices?

Express Scripts remains concerned about competition-limiting practices such as patent "evergreening," whereby drug manufacturers can extend a brand drug's patent or exclusivity by the development of new formulations. These concerns apply to both insulin and insulin delivery devices, but are more widespread on the delivery devices.

a. **If a company wants to create a generic alternative or biosimilar version of an insulin pen product, what are the existing regulatory barriers that make it difficult for them to create the generic alternative if there are only patents remaining on the delivery device?**

Although patents are long-expired for some insulin brands, no biosimilar/follow-on versions were approved until recently due to the complexity of insulin production and, until recently, a lack of FDA guidelines for manufacturers. Basaglar (insulin glargine), the first follow-on insulin approved in the U.S., launched in December 2016. In fact, FDA tentatively approved Basaglar in August 2014, but due to litigation and the terms of a confidential settlement, the product was not launched in the United States until December 2016.

Although approved, FDA has not deemed the follow-on version A-rated (or interchangeable) with brand Lantus. For a drug/delivery device combination to receive interchangeability status with the brand (A-rated), it must have the same look and feel as the innovator (brand) product. This is where the device patents can delay in interchangeable competition (e.g. generics to EpiPen). Express Scripts looks forward to working with the Committee to identify policy solutions to address these barriers and speed generic and biosimilar entry.

b. **If the delivery device is the only part of the product that is patented, why aren't we at least seeing generic versions of insulin vials?**

Insulin is a complicated compound created in bacteria using recombinant DNA technology. The FDA will be transitioning from New Drug Applications (NDA's) -- or small molecule drugs -- to Biologic License Applications (BLA's) -- biologic drugs-- in March of 2020 for insulin products. After this date, manufacturers will have to receive FDA approval for a biosimilar to an insulin moving forward.

The number of patents for drug delivery devices has increased significantly in recent years, which has resulted in extending the patent and exclusivity period for certain brand drugs that otherwise could have lower cost generic versions. Express Scripts looks forward to working with the Committee to identify policy solutions to address these barriers and speed generic and biosimilar entry.

Committee on Energy and Commerce
Subcommittee on Oversight and Investigations

Hearing on
"Priced Out of Lifesaving Drugs: Getting Answers on the Rising Cost of Insulin"

April 10, 2019

Dr. Sumit Dutta, Senior Vice President and Chief Medical Officer, OptumRx

The Honorable Michael C. Burgess (R-TX)

1. **One thing that has constantly come up in our conversations about drug pricing is that high deductible plans have become increasingly common. When did high-deductible health plans start to become more common?**

RESPONSE: The Kaiser Family Foundation has studied the market share of various types of employer health plans over the years. It reports that in 2006, 4% of covered workers were in High-Deductible Health Plans (HDHPs). That number rose to 13% by 2010; 24% by 2015, and 29% in 2018.[1]

2. **As enrollment in high deductible health plans has grown, patients have been increasingly exposed to higher out-of-pocket costs for medicines. We've heard that some PBMs have recommended that their clients include insulin on preventive drug lists, which would result in there being first-dollar coverage of insulin for beneficiaries in high deductible health plans.**

    a. **What kinds of drugs are commonly included on preventive drug lists?**

RESPONSE: As a general matter, HDHP preventive drug lists are developed based on a clinical evaluation of whether a drug is able to prevent a disease or condition, as opposed to treating an existing illness or condition. These lists are intended to comply with the HDHP safe harbor outlined in § 223(c)(2)(C) of the Internal Revenue Code. That section states, in relevant part:

> [a] plan shall not fail to be treated as a high deductible health plan by reason of failing to have a deductible for preventive care (within the meaning of section 1871 of the Social Security Act, except as otherwise provided by the Secretary).

A HDHP may, therefore, provide preventive care benefits, including certain prescription drug benefits, without a deductible or with a deductible below the minimum annual deductible. There is, however, no requirement that a plan *must* provide those benefits. Different plans might reach different conclusions about the preventive nature of a drug, and therefore make different determinations about whether a particular drug should be included on the preventive drug list so as not to affect the plan's tax status.

---

[1] *See* Kaiser Family Foundation, *2018 Employer Health Benefits Survey*, October 3, 2018, (https://www.kff.org/report-section/2018-employer-health-benefits-survey-section-5-market-shares-of-health-plans/)

Nevertheless, HDHP preventive drug lists commonly include medications such as those that prevent blood clots and reduce the risk of a stroke; prevent heart disease and reduce high blood pressure; and prevent osteoporosis. As noted below, OptumRx includes insulins (and non-insulin products used to treat diabetes) on its template preventive drug list for members on HDHPs.

3. **One chart from Express Scripts' 2018 Drug Trend Report shows that the out-of-pocket cost for patients in a high-deductible plan per 30 day adjusted Rx in 2018 was $40.69 when insulin was on a preventive drug list, compared to $105.16 when insulin was not on a preventive drug list. Given preventive medications can help people avoid many illnesses and conditions, and the aforementioned chart shows that having a drug, such as insulin, on a preventive drug list can save the patient money – do each of you have data that shows the savings to the patient as well as the overall health care system as a result of having a medication, such as insulin, on a preventive drug list?**

RESPONSE: In large part because OptumRx has insulin on its HDHP preventive drug list, and encourages its customers to do the same, we have helped our customers keep Out-of-Pocket (OOP) costs low for insulin products. Indeed, 76% of our customers' enrollees who need insulin pay nothing at the pharmacy counter, or pay only a fixed co-pay. Due to policy terms, including the fact that insulin is on OptumRx's HDHP preventive drug list, the average OOP costs for a 30-day supply of insulin are approximately $41 per month for our commercial plan and Medicare enrollees, which is less than 8% of the average list price for major insulin products.

a. **I have a similar question for you. During a briefing with Committee staff, Express Scripts said that your company makes preventive drug lists with first dollar coverage available to your clients but that preventive drug lists are not widely used.**

i. **Do you recommend that your clients include insulin on their preventive drug lists?**

RESPONSE: Yes.

ii. **How long have you recommended that your clients include insulin on their preventive drug list?**

RESPONSE: OptumRx has recommended that our customers include insulins on their HDHP preventive drug list – either by adopting OptumRx's list as their own, or including it on a list they develop – since the list was established in 2011.

iii. **Do you know how many of your clients use preventative drug lists, and have insulin on their preventive list? What percentage of your clients is that?**

RESPONSE: As suggested above, preventive drug lists benefit members in HDHPs, who constitute only a portion of the members OptumRx serves. Currently, 459 customers have implemented OptumRx's template HDHP preventive drug list, which includes insulin. In addition, OptumRx has other customers, including UnitedHealthcare, that have developed their own HDHP preventive drug lists that include insulin.

iv. **How many covered lives does that translate to?**

RESPONSE: Approximately 2.8 million lives are covered by the OptumRx template HDHP preventive drug list or UHC's preventive drug lists that include insulin.

4. **What are some of the reasons why a client wouldn't use a preventive list and include insulin on that list?**

RESPONSE: The decision to add a drug to a preventive drug list is a complex, multi-faceted decision that balances clinical effectiveness, cost, and application of relevant rules and regulations. OptumRx has determined that insulin products are appropriate for inclusion on its template HDHP preventive drug list, which an individual customer can adopt as is. Individual customers can also ask us to implement a customized preventive drug list of their own choosing. We cannot speak to individual customers' reasons for using a preventive drug list, or including or not including a particular drug on that preventive drug list.

The Honorable Brett Guthrie (R-KY)

1. **The press has reported on letters that OptumRx sent to pharmaceutical manufacturers requesting that manufacturers provide the Pharmacy Benefit Manager (PBM) with notice if the manufacturer decided to lower the list price of the medicine. During a briefing with Committee staff, OptumRx explained that they requested advance notice of price changes because of the long timeline for the Part D bid process and because the company wants to ensure greater transparency and predictability for plan sponsors.**

    a. **If a pharmaceutical manufacturer does not provide OptumRx with sufficient notice that the manufacturer will decrease the list price of a medicine, what will the manufacturer's rebate liability be for the product in each market (*e.g.*, commercial, Medicare Part D, etc.)?**

RESPONSE: Our customers who are Part D plan sponsors consider contracted-for discounts when setting their premiums. Those premiums must be submitted with their bids to the Centers for Medicare and Medicaid Services (CMS) six months before each plan year starts. CMS holds plan sponsors to those premiums for the duration of their contracts. We believe it is important for plans to be able to calculate premiums with confidence. For this reason, OptumRx proposed a Part D contract amendment requesting either advance notice from a drug manufacturer of list price decreases in the middle of a plan year or, in the absence of advance notice, a commitment by the manufacturer to honor its contracted-for discounts for the entire plan year.

If a manufacturer agreed to the terms of the proposed amendment, and then failed to provide the requested notice, it would be expected to maintain its contracted-for discounts for the duration of the plan year for which the discounts were negotiated to provide premium continuity and stability in the Part D market.

    b. **Have any manufacturers reduced the list price of insulin without giving OptumRx sufficient notice and triggered this provision?**

RESPONSE: We are not aware of a single insulin manufacturer lowering the list price of brand insulin. In fact, as we noted in written testimony we submitted to the Committee, multiple independent studies have shown that the list price of insulin has skyrocketed in recent years. The Health Care Cost Institute (HCCI), for example, found that manufacturers doubled the price

of insulin between 2012 and 2016.[2] The Journal of the American Medical Association (JAMA) published research that found insulin prices went up 197% between 2003 and 2013.[3] Some manufacturers have introduced so-called "authorized generics" at a list price lower than that of the corresponding brand product; we address that circumstance below.

2. What factors does OptumRx consider when deciding whether to include an authorized generic on the company's formulary?

a. In OptumRx's experience, how many manufacturers making an authorized generic refuse to provide a rebate that would make the net price of the authorized generic less than the brand drug?

RESPONSE: OptumRx promotes the use of clinically effective, lowest net-cost prescription drugs. This work starts with an independent, clinically based formulary design process. OptumRx's Pharmacy & Therapeutics (P&T) Committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an evidence-based way. A drug's cost plays no role in the P&T Committee's clinical review. Cost only becomes relevant after the P&T Committee has identified drugs in a particular therapeutic class that are clinically equivalent.

If there is more than one drug in a particular class, OptumRx negotiates preferred formulary status among clinically equivalent alternatives, including so-called "authorized generics," based in part on the lowest net price. Whether a manufacturer could achieve the lowest net price by discounting their list price on a particular drug depends, therefore, on the circumstances, and in particular on the pricing of competitor drugs.

It is important to understand that "authorized generics" are not true generics. The marketing and production of "authorized generics" is exclusively controlled and directed by the brand drug manufacturers. They do nothing to promote competition. In fact, drug manufacturers generally make more money per "authorized generic" script. In our experience, these so-called "authorized generics" can result in net prices higher than the brand drugs they replace. In fact, we have found that drug manufacturers often seek to introduce so-called "authorized generics" at a list price that is lower than the original brand's list price, but higher than the net price that has been negotiated for the original brand. OptumRx proactively pursues discounts off the so-called "authorized generic" list price to achieve lower net prices, but is not always able to achieve such discounts for all of its plans.

Finally, OptumRx develops template formularies that its customers can adopt as their own. Those formularies reflect the independent clinical judgment of OptumRx's P&T Committee. Customers can also choose to develop their own drug formularies, and indeed many of our customers (generally large employers and health plans) have their own P&T Committees to make those judgments.

---

[2] Binek & Johnson, *Spending on Individuals with Type 1 Diabetes and the Role of Rapidly Increasing Insulin Prices*, Health Care Cost Institute, January 21, 2019 (available at https://healthcostinstitute.org/research/publications/entry/spending-on-individuals-with-type-1-diabetes-and-the-role-of-rapidly-increasing-insulin-prices).

[3] Hua, Carvalho, Tew, Huang, Herman, and Clarke, Research Letter: *Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013*, Journal of the American Medical Association, Volume 315, Number 13 (April 5, 2016) (available at https://jamanetwork.com/journals/jama/fullarticle/2510902).

b. **If OptumRx does get a lower net price on the authorized generic and put it on formulary, will OptumRx keep the branded product on formulary as well? Why?**

RESPONSE: OptumRx supports strategies that lower the overall net cost to our customers for a therapeutic category. Achieving that goal requires analysis. OptumRx performs customer-specific analysis and consults with customers to help drive to the lowest costs for them and their employees. Ultimately, the decision about which drugs to include on a formulary is one made by the customer. Depending on the circumstances, it may be advantageous for our customers to cover the "authorized generic," the original brand, or both.

c. **Has Optum Rx ever gotten a lower net price on an authorized generic and put it on the company's formulary and kept the branded product on formulary as well? If so, why?**

RESPONSE: As noted above, OptumRx seeks to negotiate even lower net pricing on so-called "authorized generics". As a result, there have been occasions where both products are covered on a customer's formulary.

3. **We have heard that for many insulin products, the net price the manufacturer receives for the insulin products has been decreasing. Manufacturers have said that they oftentimes increase list prices to provide greater rebates and obtain formulary placement for their product. On the other hand, we have heard from many PBMs, including OptumRx, that PBMs typically prefer the product with the lowest net price when there are competing products available—such as generic medicines or therapeutically equivalent alternatives. It therefore is not clear why manufacturers continue to increase the list price of insulin and provide greater rebates for these products rather than simply reducing the list price.**

To help us better understand the role of rebates, there is a hypothetical question below.

There are two therapeutically equivalent insulin products, product A and product B. Product A has a list price of $100 and OptumRx is offered a rebate of 50 percent, thereby making the final price to OptumRx's client $50. Product B has a list price of $50, and OptumRx is not offered any rebates for the product.

a. **Is there any reason OptumRx would prefer Product A, the product with the higher list price and rebate, over Product B? If so, please describe.**

RESPONSE: Net price is one consideration among several factors OptumRx considers in making formulary recommendations. Other factors include improving adherence, product availability, market share, potential disruption to patients, and negotiated price protection guarantees. While it is not possible for OptumRx to answer this hypothetical question with certainty without additional factual context, it is likely OptumRx would recommend coverage of Product B to its customers under the circumstances described above.

b. **Which drug would be more profitable for OptumRx to include on the formulary?**

RESPONSE: If we recommended covering Product B, we would seek to negotiate adjustments to our customer contracts as needed to ensure our customers and their members get the benefit of lower prices. As a practical matter, our customers expect us to drive costs lower and to the extent we make decisions and recommendations at odds with those interests, we would have difficulty retaining those customers.

c. How does OptumRx determine the "net price" of the medicine?

RESPONSE: Net price is the manufacturer list price of a drug minus the discount associated with that drug.

d. How would OptumRx decide which product to include on formulary or would OptumRx include both products on its formulary?

RESPONSE: See answer to 3(a), above.

e. Has OptumRx ever been offered two therapeutically equivalent insulin products at the same price? Is there a threshold OptumRx uses if the prices are substantially similar when deciding whether to include both products on the formulary?

RESPONSE: If two therapeutically equivalent insulins are offered at substantially the same list price (as are Humulog and Novolog, for example), we negotiate with manufacturers to drive to the lowest net cost for the customer. That may result in exclusivity of one brand or parity for both, depending on the price concessions offered by each manufacturer, their application to various formulary options, and other factors including those referenced in 3(a), above.

f. My understanding is that pharmacy benefit managers (PBMs) have generally provided their clients with guaranteed levels of rebates, and in some instances, if the PBM exceeds the guarantee level, they may keep all or some of those rebates.

i. During the last 5 years, how many times has OptumRx exceeded the level of rebates that it guaranteed to its clients? How much did OptumRx retain as a result?

RESPONSE: OptumRx has exceeded the level of rebates guaranteed to its customers in some instances, and has fallen short of those guarantees in others. In either instance, OptumRx honors its commitments to its customers, which vary depending on the terms of those customer agreements. Overall, OptumRx passes on to its customers approximately 98% of the discounts it negotiates with manufacturers.

ii. What happens if OptumRx does not achieve this guaranteed level of rebates?

RESPONSE: How discount guarantees are negotiated varies from customer-to-customer, but it is predicated in substantial part on an analysis of trends in the marketplace and predictions about where the market for insulin pricing – and who the potential new entrants, if any, to the market – will be 2-5 years in the future, when contracts being negotiated today will be in effect. Our predictions are imperfect, however, because manufacturers continue to have unfettered

control over the setting and raising of list prices, and because they alone decide whether, when, and by how much to raise prices.

As we noted above, we are not aware of any list price reductions for brand insulins. Some manufacturers have introduced so-called "authorized generics" at a list price lower than that of the corresponding brand product. In those cases, OptumRx proactively pursues discounts off the so-called "authorized generic" list price to achieve lower net prices, but is not always able to achieve such discounts for all of its plans. In addition, with insulin, unlike some other therapeutic categories, there have been fewer new market entrants to lower costs, and as a result we have been unable to factor future increased competitive dynamics into our forecasting. OptumRx must balance this market uncertainty in an intensely competitive marketplace for pharmacy benefit management services. In some instances, market forces shift in ways that were not predicted, and manufacturer discounts are less than were anticipated during negotiations with the plan customer. As in all its dealings with customers, OptumRx honors its agreements and ensures that our customers receive the benefit promised, whether or not the market acts as OptumRx predicted.

4. **During the hearing, the witnesses were asked about administrative fees paid by manufacturers to PBMs and how these administrative fees are oftentimes a percentage of the wholesale acquisition cost (WAC)—or list price—of a medicine.**

    a. **What are the advantages and disadvantages of having administrative fees that are a percentage of the WAC, or list price, of a medicine?**

RESPONSE: OptumRx does not collect an administrative fee from manufacturers for Medicare or Medicaid plans, or with respect to drugs for which manufacturers provide no discount. The drugs in this latter category – the majority of which are generics – constitute approximately 90% of all prescriptions processed by OptumRx.

OptumRx supports moving to a fair market value fee not based on list price. For that small minority of drugs for which OptumRx currently charges manufacturers a fee to administer the discount program, consistent with market practice and current regulations, OptumRx has based those fees on a percentage of list price.

    b. **Does your company support moving to a system where administrative fees are based on a flat fee instead?**

RESPONSE: Yes. OptumRx supports moving to a system where all payments by pharmaceutical manufacturers for services provided by third parties are set in advance, fixed, and based on fair market value.

5. **During the hearing, pharmaceutical manufacturers testified that one reason pharmaceutical companies have increased their list prices is because the companies had to provide larger rebates to have their product included on formularies and maintain formulary access and access to patients. If manufacturers lowered the list price of their medicines and therefore provided lower rebates to PBMs, would your company continue to offer the same formulary access that you are offering to pharmaceutical manufacturers at higher list prices? In your opinion, if insulin products had lower list prices and lower rebates as a result, would the use of exclusive formularies increase or decrease?**

RESPONSE: OptumRx promotes the use of clinically effective, lowest net-cost prescription drugs. This work starts with an independent, clinically based formulary design process. OptumRx's P&T Committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an evidence-based way. A drug's cost plays no role in the P&T Committee's clinical review. Cost only becomes relevant after the P&T Committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered.

If there is more than one drug in a particular class, OptumRx negotiates preferred formulary status among clinically equivalent alternatives based in part on the lowest net price. Whether a manufacturer could achieve the lowest net price by discounting its list price on a particular drug depends, therefore, on the circumstances, and in particular on the pricing of competitor drugs. Whether a customer chooses to prefer or exclude certain products from its formulary would likewise depend on multiple factors, including the negotiated net price of the various clinically equivalent products and the customer's prescription drug benefit philosophy.

While we would welcome the lowering of list prices of insulin, history tells us that manufacturers will not lower list prices without true generic competition. That is why we support Congress taking action to:

- Eliminate "pay-for-delay" agreements that delay the market entry of lower cost alternatives;
- Eliminate manipulation and abuses of the Risk Evaluation and Management Strategies (REMS) program to block timely entry of generics;
- Prevent "evergreening" of patents in which drug manufacturers make minor changes to their product, or to the delivery technology for their product, which extends the patent exclusivity period, preventing lower-cost alternatives from reaching patients;
- Reduce the exclusivity period for brand and specialty drugs; and
- Continue Food and Drug Administration (FDA) reforms to promote greater uptake of biosimilars, which is even more important with FDA's recent guidance to treat insulin as a biosimilar beginning in 2020.

The Honorable Jeff Duncan (R-SC)

1. **One thing that we heard from patients and doctors last week is that insulin hasn't changed much, so they don't understand why the price keeps going up. In testimony from the hearing, however, the manufacturers described their significant research and development efforts to improve the treatment options available for patients with diabetes. For example, Eli Lilly described some of the improvements with modern insulin. Similarly, Novo Nordisk noted that in just the last few years they have developed new drugs like Tresiba and Fiasp and have also created new, more accurate and convenient delivery systems. Further, Sanofi noted that their innovations in diabetes, and specifically for insulin, have been significant and diabetes continues to be an area of focus for their research and development efforts.**

Yet, testimony from one of the Pharmacy Benefit Managers (PBMs) implied almost the complete opposite stating that there is a lack of innovation and therefore a lack of competition. OptumRx's testimony stated that "[i]nsulin has been used to treat diabetes for nearly 100 years, and "manufacturers have not introduced any significant new innovations, yet they continue to drive list prices higher and extend their patents."

So, which is it? Is there innovation in the insulin market or not?

RESPONSE: Insulin has been used to treat diabetes for nearly 100 years, and manufacturers have not introduced any significant new innovations to the drug itself to improve clinical efficacy in decades. To the extent there have been advancements, they have been primarily in the area of delivery devices, which are heavily patented and create significant hurdles to the introduction of generic alternatives.

2. **One thing that we've heard may be a barrier to innovation and competition are patents. Eli Lilly's testimony noted that "[n]one of the active ingredients in Lilly's insulin products are covered by an active patent. There are few generic insulins on the market because insulin is complicated and expensive to produce and safely distribute as a refrigerated product."**

   Yet, OptumRx's testimony states that "[f]or years, insulin manufacturers have used loopholes in the patent system to stifle competition. One manufacturer has filed 74 patents on one of its brands to prevent competition. Others have engaged in multi-year patent disputes to delay the introduction of lower-cost products."

   So, which is it? Are there patents preventing innovation and competition or not?

RESPONSE: Insulin manufacturers are exploiting the patent system to stifle competition. As an example, I-MAK's Report *Overpatented, Overpriced Special Edition: Lantus* notes that "the wall of patents" one insulin manufacturer built around its insulin product "continues to keep competitors' biosimilar products to treat diabetes out of the market in the U.S."[4]

3. **As follow-up to that, we have specifically heard concerns about patent "evergreening," which is when brand-name companies patent a slight modification of an older drug. Some say that evergreening does not significantly improve the therapeutic nature of the drug, but rather it provides the company that made the drug an economic advantage by avoiding more competition entering the market.**

   In your opinion, do these patent "evergreening" concerns apply to the insulin products themselves or does it more so have to do with the newer delivery devices?

RESPONSE: While we believe patent "evergreening" applies to both products and delivery devices, it appears to be easier for drug manufacturers to continue to maintain their exclusivity through slight modifications in their delivery devices.

   a. **If a company wants to create a generic alternative or biosimilar version of an insulin pen product, what are the existing regulatory barriers that make it**

[4] I-MAK Report, October 30, 2018, *Overpatented, Overpriced Special Edition: Lantus (insulin glargine)*, available at https://www.i-mak.org/lantus/.

difficult for them to create the generic alternative if there are only patents remaining on the delivery device?

RESPONSE: As mentioned above, we believe this problem applies to both products and delivery devices. For drug/device combination products, like many insulins, FDA requires not only bioequivalence of the drug; it also requires essentially equivalent use of the device. When a delivery device is on patent, it is difficult for a generic manufacturer to provide sufficient data to show the FDA that a user's experience with the generic device is sufficiently similar to the brand.

Drug device combination products are becoming increasingly common. And the term of many device patents last years beyond the primary patents on the drug itself. The brand-name insulin companies have built a significant patent portfolio surrounding the devices that accompany many of the insulin products. For example, according to Novo Nordisk's website, patents covering Novo Nordisk's NovoPen®, do not expire until 2032.[5] There has also been extensive coverage of the patent portfolio Sanofi has built around its Lantus product. According to the FDA Orange Book, Sanofi has 26 active patents across 4 insulin products, only 5 of which are for insulin medications. One study of insulin pens published in 2015, found that the number of patents listed with the FDA on insulin combination products more than doubled between 2004 and 2014.[6]

As companies begin to seek approval for biosimilar versions of insulin, it is possible that patent "evergreening" or other life-cycle extension strategies will become a concern for the product, as well. These can include "product hopping" strategies whereby the brand makes minor changes in the product and switches doctors and patients to the new product before the generic comes to market, thereby eliminating the existing market for the current version of the drug without obtaining additional patent exclusivity.

b. **If the delivery device is the only part of the product that is patented, why aren't we at least seeing generic versions of insulin vials?**

RESPONSE: We address some of these issues in our response to Question 3(a), above. Broadly speaking, we believe there are several reasons why there is a lack of true generic competition in the insulin market, including abuse of the patent system by drug manufacturers and a complex and burdensome regulatory approval process (which is not helped in the short term due to the upcoming reclassification of insulin as a biologic product as that could delay the approval of generic insulins existing in the pipeline).

[5] https://www.novonordisk-us.com/products/product-patents.html.
[6] Luo, J. & Kesselheim, *A.S. Lancet Diabetes Endocrinol.* 3, 835–837 (2015).