Thank you Chairwoman DeGette, Ranking Member Guthrie, and Members of the Oversight and Investigations Subcommittee. My name is Christel Marchand Aprigliano and I am speaking today as the CEO of the Diabetes Patient Advocacy Coalition and as a person with Type 1 diabetes on how the lack of affordable access to insulin analogs impacts over 8 million American families. Like many others here today, I have been personally impacted by the rising list prices of insulin analogs.

I. Diabetes Patient Advocacy Coalition

The Diabetes Patient Advocacy Coalition is a nonpartisan nonprofit organization of people with diabetes, caregivers, patient advocates, health professionals, disease organizations and companies working collaboratively to promote and support public policy initiatives to improve the health of people with diabetes. DPAC seeks to ensure the safety and quality of medications, devices, and services; and access to care for all 30.3 million Americans with diabetes.

It is my hope that my testimony today will provide insight on how individuals like me are attempting to access a life-essential drug that many cannot afford due to high list prices and what can be done to ensure a future in which no one rations their dosage or dies from lack of affordability.

II. Insulin (Analog versus Human)

It's important to preface that I specifically use the term insulin analogs to describe the drug that is currently prescribed by most medical professionals in the United States today. Before 1996, insulin analogs did not exist.

When I was diagnosed in 1983, the drug given to me was a mixture of purified beef and pork insulin, and then recombinant DNA - or human insulin that was created in the mid 80s. This insulin is the equivalent to the insulin produced in the human pancreas, but please note that like any treatment for diabetes, it is not perfect. Human insulin requires meticulous regimentation and is well known for an increase in severe low blood glucose episodes. It is available for purchase for under $30 per vial without a prescription in all 50 states except for Indiana and many individuals still use human insulin to treat their diabetes.

Insulin analogs were introduced into the U.S. market in 1996. Analogs are designed to be better than human insulin. Rapid acting insulins begin to work significantly faster than its closest human insulin counterpart, known as Regular. The basal insulins (also known as long-acting insulins) allow people with diabetes to have more flexibility in their daily lives. The dosage combination of rapid and basal insulin analogs is designed to mimic how a normal pancreas would release insulin throughout the day.

When we are discussing the high list price of insulin, we are discussing insulin analogs. We consider human insulin to be an important safety net if an individual is in an emergency situation or has been prescribed this regimen by a medical professional; everyone should know that human insulin is available. However, we are only discussing the high list price of insulin analogs and its impact on people with diabetes.

I would be remiss not to note that while there are no generics for insulin analogs; there are follow-on drugs that were approved pursuant to Section 505(b)(2) of the Food, Drug, and Cosmetic Act (“FD&C Act”). Unlike true generics, we have not seen significant overall list price decreases with their introduction into the market. Even the recent addition of a 50% list price discounted rapid acting insulin, there has been no respite for those of us shackled by the current insulin supply chain.

III. Insurance Benefit Design and the Cost-Sharing Shift Contribution to This Issue

To discuss the increasing list price of insulin analogs and its impact on families, we must review the shift in insurance benefit design, how list prices have rapidly increased and why it is being addressed now. As traditional commercial insurance plans with low to no deductibles and a standard copayment for prescription drugs has been thrown out by many employers in favor of plans that include high deductibles and coinsurance based on list price rather than a copayment, more people with diabetes are being subjected to list price than ever before. Nobody should ever pay list price.

In December of 2011, I paid a $40 copay for my insulin prescription at the pharmacy counter under a traditional health insurance plan. In January of 2012, that same prescription cost $1,269. We were under a new insurance plan offered through my husband’s employer, which placed the burden of full list price on me until we reached a $13,500 deductible. Up to that moment, I had no idea what the list price of insulin was; I had erroneously assumed that the $21 list price I had paid in 1996 had remained relatively stable, rising slowly alongside the annual inflation rate. We met that $13,500 deductible, with much of it going to pay for insulin.

Many people with diabetes find themselves in the same horrific situation standing at the pharmacy counter at the beginning of a plan year. List prices are set by manufacturers and include the obfuscated rebate designed to entice Pharmacy Benefit Managers (PBMs) to give preferred status to a drug on the formulary. During the deductible phase of any insurance plan or for those who do not have insurance, plan subscribers do not benefit from the rebate at the pharmacy counter.

The people with diabetes who can least afford this drug are paying the most. Some are paying with their lives. Even the financial help offered through copay cards and patient assistance programs designed to help are not enough to make access affordable, as I’ll explain.

IV. How Patients Are Currently Accessing Insulin Analogs

1. Copay Cards

For those with diabetes on commercial insurance, copay cards can help defray the high list price of insulin. Patients do not use copay cards just to get the highest-cost drug available. Treatment decisions are never made based on what will cost the most money; they're made by a medical professional based on what will work best for the person's individual health needs. Copay cards first appeared in 2005, and have increased in use over the last decade. According to a 2018 study out of the University of Southern California, in 2009 there were fewer than 100 brand name drugs with coupon programs, and by 2015 there were more than 700.[1]

People with diabetes expect to be able to use copay cards because of how commonplace they are, and many people budget their healthcare expenses for the year based on the availability of copay cards. Furthermore, people with diabetes may not be able to switch medicines in order to get a cheaper price. Among all brands with copay coupons, a majority (51%) are for drugs with no generic substitute. This means patients do not have any cheaper options to choose from. For 12% of brands that have copay coupons, there's no close therapeutic substitute of any kind.[2] The problem is not that patients are choosing expensive drugs - it's that they don't have any other choice.

Copay accumulator programs are restricting the ways patients can use copay coupons. In the past, copay cards could help people with diabetes pay for their medications early in the year, when people had not yet met their deductibles. But now, patients are finding out that they still have full deductibles to pay after their copay coupon has expired or reached its maximum contribution. This is because of copay accumulator programs. Copay accumulator programs are tactics used by pharmacy benefit managers that prevent copay coupon contributions from counting towards peoples' deductibles. Pharmacy benefit managers are instituting these programs with no warning and no notification, so people are showing up to the pharmacy and getting surprised with huge deductible obligations that they thought were already paid off.

Some states have already taken action - Virginia became the first state to protect patients' right to use copay cards last week. But other states (Massachusetts and California) are banning the use of certain copay cards, which is a huge step backward in access to prescription drugs prescribed by medical professionals. Copay cards serve an important purpose for the patient community - to access prescribed drugs affordably .

2. Manufacturer Patient Assistance Programs

Patient assistance programs exist to help people who have financial difficulty affording their prescription medications and/or other supplies. Nonprofit foundations which receive

---

[1] http://healthpolicy.usc.edu/documents/2018.02_Prescription%20Copay%20Coupons%20White%20Paper_Final.pdf
[2] http://healthpolicy.usc.edu/documents/2018.02_Prescription%20Copay%20Coupons%20White%20Paper_Final.pdf

large donations from insulin manufacturers offer patient assistance programs to provide financial assistance to people who are low-income or are facing a short-term financial crisis. Though patient assistance programs have admirable goals, in a recent survey, we identified several areas where they could be improved. First, let me briefly outline what patient assistance programs are available to people with diabetes who use insulin.

All three insulin manufacturers - Eli Lilly, Novo Nordisk, and Sanofi - have options ranging from insulin given at no cost to the patients, shipped to healthcare professionals' offices, to low-payment options at the point of sale (i.e. the pharmacy counter). The patient assistance programs have varying requirements. The household income requirements are the easiest to compare: Lilly allows people with incomes under 400% of the federal poverty level into their patient assistance program, Novo Nordisk allows in people with incomes under 300% of the federal poverty level, and Sanofi allows in people with incomes under 250% of the federal poverty level. But even with these parameters, the patient assistance programs can fail. I can personally attest to this.

In 2013, the unexpected happened. My husband was laid off without warning. Instead of focusing on the next step in his employment search, we panicked at how we were going to get insulin. We had no income. A COBRA payment was several times more expensive than what he would have received through unemployment benefits.

I immediately applied for a patient assistance program to access insulin until my husband was employed again; I was shocked to learn that not only did I not qualify, but that any decision would take four to six weeks to process my application. I didn't qualify because the documentation required did not allow for a letter stating we had no income coming in after his severance. They would only accept a pay stub or a previous year's tax return. We were in crisis. The system was not and is not set up to help people in crisis.

I was able to obtain insulin from my medical professional's office and I was lucky to be able to have that as a safety net. This happens to families daily; through no fault of our own unexpected financial difficulties rise with no immediate help to access a life-saving drug. This is unacceptable.

A. Patient Assistance Programs in Detail

The Lilly Cares Foundation offers two patient assistance programs for Eli Lilly and Company's insulins: Humalog, Humalog, and Basaglar. BlinkHealth offers a forty percent discount for patients who either do not have prescription insurance coverage or have high copays/deductibles. The Lilly Cares Foundation Patient Assistance Program is for patients with no prescription insurance coverage and offers qualifying patients medications at no cost. Lilly also offers the Lilly Diabetes Solutions Center, which connects patients to a Lilly representative who can help them find solutions to their insulin needs.

The Novo Nordisk Foundation has two patient assistance programs for patients who use Levemir, Novolog, Novolog Mix 70/30, and Novolin. The first is a collaboration with CVS Health called ReducedRx. ReducedRx is for patients who are uninsured or have high copays or high deductibles, offering Novolin human insulin for $25 at CVS pharmacies. The second program is called the Novo Nordisk Patient Assistance Program. This program provides free insulin to qualified patients who are uninsured.

Sanofi manufacturers the insulins Apidra, Lantus, Soliqua, and Toujeo. The Sanofi Foundation for North America has one patient assistance program, the Sanofi Patient Connection Program, that provides these products to patients at no cost. The Patient Connection Program is only for qualified patients who have no insurance coverage for their prescribed medication.

B. Patient Assistance Programs Examined

Along with several partner organizations, DPAC recently distributed a survey to learn more about how patients were using patient assistance programs. We wanted to answer basic questions about patient assistance programs.

- How are patients learning about patient assistance programs?
- How is the application process affecting patients?
- Who is ultimately able to access patient assistance programs?

The answers to these questions have allowed us to draw several conclusions about the application process and operation that we will discuss below. Four conclusions merit action:

First, applicants had a fifty percent chance of being helped by the patient assistance program. Those who did not receive help were turned away because they did not qualify for the PAP (as opposed to finding assistance elsewhere or giving up on the application process).

Second, most patients are not learning about patient assistance programs at the pharmacy counter, where they're facing high list prices of insulin head-on. About forty three percent of patients discovered a patient assistance program via the internet. Another thirty nine percent were informed by their healthcare provider. In contrast, a tiny seven percent of patients were informed of a patient assistance program at their pharmacy. Pharmacists must be empowered to proactively give patients information when they need it most.

Third, patients had generally good experiences with the application process, except when they were asked to provide additional documentation, such as proof of income or residency. About forty two percent of patients thought that qualifications to apply were difficult to find and understand.

Fourth, some patients did not receive their medications in a timely manner even with patient assistance program assistance. About forty four percent of surveyed patients reported that they did not receive their medications in a timely manner. Often, patients turn to patient assistance programs when they are facing an urgent need for their medication. Many patients do not realize they will have an issue affording their medication until they are faced with the cost of the drug at the pharmacy counter. At this point, patients likely do not have a large amount of the needed medication on hand. When a patient is under pressure needs a drug very soon, they need to know that they can access a patient assistance program and get a quick turnaround in order to access their medication in time.

3. Medicare Part D and Patient Assistance

We cannot discuss access issues responsibly without noting that **Medicare Part D beneficiaries are ineligible for help from most patient assistance programs and copay cards.** According to CMS, “PAPs can provide assistance to Part D enrollees and interface with Part D plans by operating "outside the Part D benefit" to ensure separateness of Part D benefits and PAP assistance. The PAP's assistance on behalf of the PAP enrollee does not count towards a Part D beneficiary's true-out-of-pocket cost (TrOOP). The calculation of TrOOP is important for determining whether an individual has reached the threshold for catastrophic coverage under the Part D benefit.”[3] Sanofi is the only manufacturer that bans Medicare beneficiaries from using their patient assistance program. Functionally, because of CMS’s rules, patients who have Part D coverage cannot access patient assistance programs.

For the 2.3 million Medicare beneficiaries who use insulin, this is the ultimate betrayal. They are directly impacted by the high list prices at the beginning of the plan year and again during their donut hole phase. Without financial relief, many ration their analog dosage or attempt to use human insulin.

4. Additional Avenues of Access to Insulin: GoFundMe, Grey Market, Importation

There are additional avenues and desperate extremes that many individuals in our community may go through in order to stay alive with diabetes. You’ll find thousands of active GoFundMe requests specifically raising money for insulin. We have individuals who are selling or giving extra insulin to other members of the community through grey market transactions. We have individuals who travel to Canada, Mexico, or other countries that have list prices significantly lower than the United States.

All of these avenues are a response to our current broken healthcare system and the ever increasing high list prices of insulin analogs. None of these are permanent solutions to high list prices and all come with risks.

---

[3] https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html

V. Steps Toward Solutions

Our community is crying out for relief from the inflated list prices caused by the perverse rebating system. All players in the supply chain play a role in helping ensure that all people with diabetes can affordably access insulin and must commit to being part of the solution. We believe that reforms in patient assistance programs and Medicare Part D will help provide some relief to portions of our community, but that list prices must be radically decreased for all to solve this issue.

1. Patient Assistance Program Reforms

DPAC is taking our findings from the patient assistance program survey and making recommendations to patient assistance program administrators. Our survey showed that patients are attempting to access these programs, but are facing significant barriers to doing so. Over five thousand people viewed the survey, but only 322 of them could answer “yes” to the screening question “have you ever received help from a patient assistance program?” Our solutions address the lack of education surrounding patient assistance programs and address barriers to applying to - and receiving help from - patient assistance programs. We believe that with these recommendations put in place, more patients will be able to access patient assistance programs and therefore affordably access their prescribed insulin.

As noted above, only about half of all people who apply to patient assistance programs are receiving help. Overwhelmingly, those who do not receive help are turned away because they do not qualify for the program. In order to reduce barriers to entering a patient assistance program, we recommend administrators consider the following changes.

Administrators should:

- Raise income caps to include patients whose household income is lower than 500% of the federal poverty level (FPL). In 2019, for a family of four, 500% of FPL is only $64,375 ($5,364.58 per month).
- Publish a flowchart-style graphic that explains who qualifies for which programs. For example, a patient who has a high deductible health insurance plan may have only one patient assistance program option but a patient who does not have any insurance may have multiple options. The chart would illustrate the options for different patient situations.
- Publish a comprehensive list of applicant qualifications and requirements in English and Spanish, including what paperwork is needed, what is needed from a healthcare professional, any costs associated with the application or membership, expected timeframe for a decision, expected timeframe for receiving needed medication, and where patients can turn if they encounter a barrier while applying (a helpline telephone number or email address).
- Provide a separate application available for situations in which a patient does not have a healthcare provider readily available.

- Provide a section for written explanation in the application process so that patients with unusual circumstances can explain their situation (for example, families that include multiple insulin-dependent patients, patients who lose their insurance coverage, etc.).

Patients are not learning about patient assistance programs at the pharmacy, where they are faced with the high cost of their insulin at the cash register. We recommend that patient assistance program administrators develop educational programs that pharmacists can use to learn patients' options. Administrators should distribute these educational programs to pharmacy workers' professional associations so that it reaches the largest number of pharmacy professionals possible. Such organizations could include, but are not limited to, the American Pharmacists Association, the National Community Pharmacists Association, the American Association of Colleges of Pharmacy, the American Society of Consultant Pharmacists, the American Society of Health-System Pharmacists, and/or the American College of Clinical Pharmacy.

Healthcare professionals need to have comprehensive information about patient assistance programs so they can be more empowered to discuss options with their patients. We recommend that patient assistance program administrators develop printed materials that healthcare providers can distribute to patients. Because diabetes is such a prevalent disease (one out of every four U.S. healthcare dollars is spent on diabetes) and because medications used to treat diabetes can be out of financial reach for many patients, we recommend that administrators collaborate together to create one handout or pamphlet that encompasses all patient assistance programs available to patients who have diabetes. The handout or pamphlet should not be drug-specific; it should include information from every patient assistance program. The handout or pamphlet should have the following information included: a comprehensive list of applicant qualifications and requirements, including which medications are covered by the patient assistance program, what paperwork is needed to apply, what is needed from a healthcare professional, any costs associated with the application or membership, and where patients can turn if they encounter a barrier while applying (a helpline telephone number or email address).

Unfortunately, often patients who reach out to patient assistance programs are experiencing an urgent crisis and need insulin quickly. Patient assistance program administrators should institute a 30 day crisis grace period during which patients receive access to their needed medications while they gather all the paperwork needed to apply to the program. This grace period should be offered once every 365 days. During this grace period, we encourage administrators to follow up with the patient to assess their progress towards getting their paperwork together so that the patient is not again facing a crisis at the end of the 30 day grace period. The process of applying to the patient assistance program should include a way for patients to indicate that they intend to use the 30 day grace period in order to get their medications quickly. Additionally, the definition of 'crisis' should include situations in which a patient is facing the possibility of rationing or going without a medication that keeps them healthy in the short- or long-term.

These solutions are some initial steps that will make patient assistance programs more accessible to patients who need them.

2. Rebate Reforms

Patient assistance programs are a vital resource for patients who have trouble affording their insulin, but we need systemic change as well. **DPAC is supportive of efforts to reform the rebating system in our drug supply chain.** Specifically, we are supportive of the administration's proposed rule that would create two safe harbors - the first protection being discounts that would be passed on to consumers at the point of sale for Medicare Part D beneficiaries. This would be in place of rebates. The second safe harbor protection would be the creation of a "fixed fee" arrangement for PBMs, rather than a percentage of the list price of a drug.

This second safe harbor protection is what DPAC is most excited about, as it destroys the perverse system of increasing list prices in order to increase the rebate amount given to PBMs.

Many cost-sharing amounts are tied to the list price of prescription pharmaceuticals, but insurers are charged far less than list price for the drugs. This results in patients with greater health needs subsidizing insurers and so-called "healthier" patients. This proposal would begin to put an end to this practice by forcing insurers to bear more of the list cost for drugs. This may result in slightly higher premiums as insurers seek to offset their increased cost burden- an estimated $3-$6 per person per month for Medicare Part D beneficiaries. But the prescription drug savings for patients will be offset that cost and provide savings on top of it.

When insurance works as it is meant to work, patients win. We call on Congress to make HHS's proposed rule apply to private market insurance plans and Affordable Care Act marketplace insurance plans as well so that all patients can benefit from rebate reform.

VI. Psychological Cost

It would be irresponsible to discuss access to insulin without noting that we are ignoring a huge part of the issue. We need to discuss the untenable financial situation with logic and reason, but we cannot continue to ignore the psychological ramifications of living with insulin-dependent diabetes in a world where affordable access to insulin is not always attainable. The instability caused by not knowing how to access affordable insulin - not a "nice to have" drug, but a "cannot live without it" drug - is nothing short of emotional torture.

For individuals who worry about their family members with diabetes, for patients who go to extremes to access insulin to stay alive, and for those medical professionals who feel helpless when faced with accessibility issues by their patients - we all bear the brunt of decisions made not by us, but by a system that is broken. We must begin to repair it immediately, by any means necessary and it will take help from Congress to do so.

VII. Conclusion

Thank you for allowing me to speak on this important subject. I hope that with action from all actors in the insulin supply chain - the government, insulin manufacturers, insurance plans, pharmacy benefit managers, and people with diabetes - we can find a solution to this problem.