ENDOCRINE SOCIETY
Hormone Science to Health

Endocrine Society
Statement for the Record
Subcommittee on Health of the Committee on Energy and Commerce
Negotiating a Better Deal: Legislation to Lower the Cost of Prescription Drugs
May 4, 2021

The Endocrine Society would like to thank Chairwoman Anna Eshoo (CA-18) and the members of the House Energy & Commerce Health Subcommittee for conducting this important hearing on legislation to lower the price of prescription drugs and reduce Americans' out-of-pocket drug costs. The Society believes that Congress must act immediately to improve the affordability of and access to prescription drugs to improve the health of all Americans, including those living with diabetes and other chronic conditions. We also want to highlight the high price of insulin as an urgent issue that requires immediate attention. We applaud the efforts of Energy and Commerce Committee Chairman Frank Pallone Jr. (D-NJ), Ways and Means Committee Chairman Richard E. Neal (D-MA), and Education and Labor Committee Chairman Robert C. "Bobby" Scott (D-VA) to reintroduce H.R. 3, the Elijah E. Cummings Lower Drug Costs Now Act. The re-introduction of this legislation is an important step forward in addressing this ongoing problem.

The Endocrine Society is the world's oldest and largest organization of scientists devoted to hormone research and physicians who care for people with hormone-related conditions like diabetes. While we hear from our members about many different clinical and research issues, the rising out-of-pocket cost of insulin is the one causing the greatest concern for their patients.

More than 34 million Americans have diabetes, and another 88 million are at risk for developing the disease. Insulin is a life-saving medication for many people living with diabetes. Over 7 million people in the United States use insulin to control their blood sugar and avoid life-changing complications, including dialysis, amputation, and heart disease. People living with type 1 diabetes need insulin to survive. This year marks the 100th anniversary of the discovery of insulin. Despite this important milestone, insulin is unaffordable for many who rely on it. Over the past 15 years, the price of insulin has nearly tripled making it difficult for people with diabetes to manage their chronic disease. The lack of transparency in the drug supply chain has made it challenging to identify and address the causes of these soaring prices. Low-income individuals, those on high deductible health plans, Medicare beneficiaries using Part B to cover insulin delivered via pump, Medicare beneficiaries in the Part D donut hole, and those who turn 26 and must transition from their parents' insurance increasingly face difficult decisions about how to afford the insulin they require and avoid unnecessary complications and hospitalizations. It is unacceptable that we still hear stories of patients foregoing or rationing their prescribed insulin because of cost resulting in serious health effects and, in many cases, death.

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In January, the Society published a position statement on insulin access and affordability, which recommends policymakers include government negotiation as part of an overall strategy to reduce insulin prices. A copy of our position statement is attached. We are pleased to see that H.R. 3 would allow the Secretary of Health and Human Services (HHS) to negotiate for better prescription drug prices, including the prices of many commonly prescribed insulins. In addition to price negotiations, our position statement also offers other recommended policy changes to increase access to affordable insulin. The Society recommends limiting future price increases to the rate of inflation, increasing transparency across the supply chain, reducing out-of-pocket costs by lowering or removing cost-sharing, the elimination of rebates or passing rebate savings along to the consumer, and expediting the approval of biosimilar insulins to create competition in the marketplace. We are glad to see that H.R. 3 addresses some of our other recommendations including a provision to cap out-of-pocket spending on prescription drugs at $2,000 a year for Medicare beneficiaries.

We commend the subcommittee for its efforts to shed light on this important and truly a life and death issue. We urge you to work in a bipartisan manner to pass legislation to make insulin and other costly prescription drugs more affordable as soon as possible because our patients cannot wait longer. The Endocrine Society would like to be a resource to you and provide you with information, patient and physician examples, and share our recommendations. Please do not hesitate to contact our Director of Advocacy and Policy Robert Goldsmith at rgoldsmith@endocrine.org for more details.

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Position Statement

Position Statement

Addressing Insulin Access and Affordability: An Endocrine Society Position Statement

The Endocrine Society

Abbreviations: ASP, average sales price; DME, durable medical equipment; PAP, patient assistance program; PBM, pharmacy benefit manager.

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Abstract

Rising costs have made access to affordable insulin far more difficult for people with diabetes, especially low-income individuals, those on high deductible health plans, beneficiaries using Medicare Part B to cover insulin delivered via pump, Medicare beneficiaries in the Part D donut hole, and those who turn 26 and must transition from their parents' insurance, to manage their diabetes and avoid unnecessary complications and hospitalizations. For many patients with diabetes, insulin is a life-saving medication. Policymakers should immediately address drivers of rising insulin prices and implement solutions that would reduce high out-of-pocket expenditures for patients. The Endocrine Society recommends policy options to expand access to lower cost insulin in this paper.

Freeform/Key Words: diabetes, insulin, drug prices, policy, diabetes medications, type 1 diabetes, type 2 diabetes

Summary of Society's Position and Recommendations on Addressing Insulin Access and Affordability

Rising costs have made access to affordable insulin far more difficult for people with diabetes, especially low-income individuals, those on high deductible health plans, beneficiaries using Medicare Part B to cover insulin delivered via pump, Medicare beneficiaries in the Part D donut hole, and those who turn 26 and must transition from their parents' insurance, to manage their diabetes and avoid unnecessary complications and hospitalizations. For many patients with diabetes, insulin is a life-saving medication. Policymakers should immediately address drivers of rising insulin prices and implement solutions that would reduce high out-of-pocket expenditures for patients. The Endocrine Society believes the following policy changes could help expand access to lower cost insulin:

- create greater transparency across the supply chain to understand rising insulin costs
- limit future list price increases to the rate of inflation
- allow government negotiation of drug prices
- limit out-of-pocket costs through 1, or more, of the following policies without increasing premiums or deductibles:
  - limit cost-sharing to a copay of no more than $35
  - providing first-dollar coverage
  - capping costs at no more than $100 per month
- eliminate rebates, or pass savings from rebates along to consumers without increasing premiums or deductibles
- expedite the approval of insulin biosimilars to create competition in the marketplace
- include real-time benefit information in electronic medical records
- develop a payment model for Medicare Part B beneficiaries in addition to Part D that lowers their out-of-pocket copays.

The Society believes all stakeholders across the supply chain have a role to play in addressing the high price of insulin. In addition, to prevent against inadvertent impact on people with diabetes, new pricing methodologies and policy

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changes should be tested prior to implementation. Key recommendations for each stakeholder include the following.

Manufacturers

- Improve patient assistance programs (PAPs) to be less restrictive and more accessible.
- Eliminate copay savings cards in favor of providing actual cost savings to the system and price reductions to patients.

Pharmacy Benefit Managers

- Develop pricing arrangements with manufacturers that do not result in large annual increases in the manufacturers' list prices.

Physicians and hospital administrators

- Train healthcare providers to use lower-cost human insulins (NPH and regular), which should be available at no cost to patients.
- Provide access to real-time benefit information to help prescribe the lowest cost insulin when clinically appropriate.

Pharmacists

- Learn about and share information with patients about lower cost options offered by manufacturers.

Employers

- Limit cost to copay without increasing premiums or deductibles
- Seek plan options that benefit people with diabetes and provide education about these options in open enrollment.

Background

Insulin is a life-saving medication for people with diabetes. However, its cost has nearly tripled in the past 15 years making it difficult for many patients to afford this medication and effectively manage their disease (1). This has put patient safety in jeopardy as patients who cannot afford the high cost of insulin ration their insulin or forgo other medical care. Research indicates that a lack of transparency in the drug supply chain has made it challenging to identify the root cause of price increases. This position statement will identify barriers to accessing affordable insulin and potential policy solutions, with a focus on uninsured, underinsured, and people turning 26 who no longer can be covered by their parents' insurance.

More than 34 million Americans have diabetes, with another 88 million at risk for developing the disease (2). Having diabetes increases one's risk for serious health problems including heart attack, stroke, blindness, kidney failure, amputations, and death (3). Diabetes is also the most expensive chronic condition in the United States (4). Average medical expenses are 2.3 times higher for people with diabetes (5). In 2017, the cost of diagnosed diabetes was estimated to be $327 billion annually, with $237 billion in direct medical costs (6). It is estimated that insulin accounts for ~$48 billion (20%) of the direct costs associated with diabetes care (7). Because 1 in 4 people with diabetes are unaware they have the disease, costs to the healthcare system are even higher than estimated (8).

Given the complex nature of diabetes, it is essential that patients adhere to their medication regimens to reduce or avoid unnecessary complications and hospitalizations. For people with type 1 diabetes and people with type 2 diabetes who are dependent on insulin, taking the appropriate dose or doses of insulin each day is required to avoid complications, including death. However, adherence can be difficult as people with diabetes often have comorbidities that require them to take multiple, costly medications or they may be unable to make sustained lifestyle changes that could improve outcomes.

One study indicates that improved adherence among people with diabetes could prevent nearly 700 000 emergency department visits, 341 00 hospitalizations and save $4.7 billion annually (9). Recent increases in drug costs and changes to insurance design are some of the most common reasons for poor medication adherence, particularly for patients on insulin (10).

Rising insulin costs

The true cost of insulin can be difficult to pinpoint because of a lack of transparency in financial agreements between stakeholders in the supply chain, geographical differences in cost, and insurance coverage (11). Novolog, a commonly used insulin, has been available since 2001. While this product has been unchanged, its price increased by 353% over a 15-year period between 2001 and 2016 and it continues to rise (12). Humulin U500 has increased from $170 to more than $1400 since 1987 (13). From 2001 to 2019, the price of Humalog increased 1200% for a vial of insulin (14). In addition, changes in federal policy can affect the price of insulin. For example, Section 5004 of the 21st Century Cures Act inadvertently contributed to pump-delivered insulin's high cost by changing the reimbursement methodology for durable medical equipment (DME)–infused drugs, including pump-delivered insulin (15).

Currently, 7.4 million Americans use insulin to treat their diabetes (16). At minimum, these patients use 1 vial of insulin each month. However, some patients require multiple vials of insulin or use multiple types of insulin (which necessitates multiple vials) each month. According to a survey conducted by the American Diabetes Association, 27% of respondents stated that insulin costs have affected their past year purchase or use of insulin.

Thirty-four percent of families with children on insulin were impacted (17). Those affected by rising costs were more likely to experience adverse health effects than those for whom cost did not impact their purchase or use of insulin and were twice as likely to experience negative emotions like stress and anxiety. Many of these patients were also forced to forgo other needs such as transportation (32%), utilities (30%), housing (27%), doctor's visits (32%), or other medications (36%), and were more likely to ration their insulin (17).

Patient cost-sharing

Insurance plan design directly impacts out-of-pocket costs. As shown in Table 1, numerous factors impact how much a patient will be required to pay for their insulin, including plan type, medication used, the amount of their deductible, and where they are in the plan year. In addition to making it difficult for patients to anticipate how much they will be required to pay when they pick up their prescription at the pharmacy, it is also difficult, if not impossible, for the prescribing physician to take these factors into account when choosing which medication to prescribe. Electronic health records are starting to display real-time, patient-specific, benefit information that provides the physician with the exact amount that the patient will pay at the pharmacy and what lower cost alternatives are available. However, this information is not available to most prescribing physicians, and therefore unable to have a true transformative effect on prescribing. Actions by the federal government through rule making are attempting to speed adoption of the resource.

Patients who are uninsured pay the list price of insulin. These individuals may be eligible for a manufacturer-sponsored PAP. However, these programs are restrictive, difficult to navigate, and it is unclear how many patients are able to use them. As currently implemented, PAPs create challenges for the patient. For example, it takes time to complete the paperwork, often the insulin shipment is delayed, patients must return to the physician office and this is difficult for some with transportation limitations, and frequently patients run out of insulin for periods of time.

Patients on some forms of commercial plans may need to pay full price, depending on the plan design, for their insulin until they meet an annual deductible and then pay a fixed copay. They may also be required to pay coinsurance, a percentage of the cost based on the list price of insulin that does not include rebates or discounts negotiated by the Pharmacy Benefit Manager (PBM).

Table 1. Types of plans and cost-sharing requirements

Plan coverage	Cost-sharing requirement
Uninsured	Full list price minus support from manufacturer assistance program
Underinsured (high deductible plan)	Full list price until deductible is met; person turning 26 more likely to be underinsured
Medicare Part D (syringe injected insulin)	Dependent on Part D plan selected and varies based on deductible, co-pay, and where they are in the coverage year (donut hole, catastrophic, etc.)
Medicare Part B (insulin delivered via pump)	Cost is shared between Medicare and the beneficiary at an 80/20 split based on the average sales price once the beneficiary meets the annual deductible

For patients with high-deductible plans (plans with a deductible greater than $1350 for an individual or $2700 for a family), out-of-pocket insulin costs are significant. Individuals must pay for the full list price of insulin until they meet their annual deductible. In 2016, approximately 40% of Americans had a high deductible health plan with an average annual deductible of $4358 for individual health plans and $7983 for family plans (18). In the same year, 44% reported selecting plans with annual deductibles of $6000 or greater (18).

Medicare beneficiaries with Part D coverage without a supplemental plan must also pay full price for insulin until they meet their deductible, after which point they will pay coinsurance until meeting their plan's initial coverage limit for prescription drugs ($4020 in 2020) (19). At this point, they experience the Part D "donut hole," a coverage gap between the plan's initial coverage limit and when catastrophic coverage kicks in. The coverage gap for Medicare beneficiaries can result in these patients being unable to afford to pay for their insulin and other medications, which leads to variation in care—often with poor control of their diabetes—and can have a serious impact on their health.

Medicare beneficiaries with Part B coverage without supplemental plan pay 20% of the average sales price (ASP) as their copayment for pump-delivered insulin once their annual deductible is met. While Medicare beneficiaries are in the donut hole, they will pay 35% of the plan's cost for covered brand-name prescription drugs until reaching their annual out-of-pocket limit of $5000 in true out-of-pocket spending. Catastrophic coverage will then begin,

and the Medicare beneficiary will pay a small coinsurance or copayment for covered prescription drugs (20).

Young adults are particularly likely to feel the impact of high list prices. Once a person turns 26 years old, he/she is no longer allowed to be covered by their parents' health insurance and must obtain coverage of his/her own. In some cases, these young adults may be eligible for health insurance through their employer. With only 58% of the US population covered by their employer, this is not likely to be the case for the majority of the newly-26-year-old population (21). Many can only afford a high deductible plan to keep monthly premiums low, thereby paying the full list price for their insulin until their deductible is met. This period at the start of the year is difficult on cash flow and when young adults may be more likely to ration their insulin as a result.

There are many stakeholders across the drug supply chain who influence rising costs, including wholesalers, PBMs, pharmacies, health plans, and employers. While manufacturers establish list prices, each of these players impacts the out-of-pocket cost to a patient on insulin through a complex series of negotiations and rebates not transparent to the public. The lack of transparency makes it difficult, if not impossible, to understand how much each stakeholder gains when costs to the patient increase. Research indicates that while list prices have skyrocketed, the net price increase that manufacturers receive has risen at a far slower rate (3-36% net increases annually) (12). Increasing transparency is critical to understand this divergence and other contributors to rising insulin costs.

Considerations

Complexity of the supply chain

The complexity of the supply chain makes it difficult to pinpoint the drivers behind increasing insulin prices. Manufacturers set the list price for the medication and typically sell their medications to wholesalers or PBMs. The process to get the medication from the manufacturer to the patient is rather straightforward, but the flow of money and the methodology to establish the price that the patient ultimately pays is much more complex. The net price manufacturers receive is based on the list price minus any fees paid to the wholesaler, discounts paid to the pharmacy, and rebates paid to the PBMs or health plans. Financial agreements between the stakeholders are confidential. For example, manufacturers are not privy to a PBM's negotiations with health plans.

Despite significant financial incentives negotiated between the stakeholders in the supply chain, most of these savings are not shared with the consumer. As such, an individual's cost is largely based on the list price. As list prices increase at double-digit rates, people with high-deductible plans, coinsurance, or no insurance suffer the effects the most.

Net price

The process to establish the net price involves the exchange of rebates, discounts, and other payments to encourage the purchase of a drug. For example, a manufacturer may offer a distributor volume discounts to purchase its drug or provide financial incentives to a PBM for placement on the preferred tier of its drug formulary. Manufacturers cite these financial incentives as a major driver of high list prices; the more incentives provided to the players across the supply chain, the higher the list price must be for the manufacturer to realize any profit. In theory, the rebates offered to a PBM to place a drug on its preferred formulary tier should reduce costs for the patient. However, these rebates may be used by the employer or the health plan to reduce insurance premiums, not the cost of the drug at point-of-sale. Because of this lack of transparency, it is unclear the extent to which both premiums and drug prices are affected by rebates.

The influence of rebates on the cost of insulin is greater than it is for most other medications, as only a small percentage of total prescriptions filled are subject to rebates. Reducing or eliminating the use of rebates could play an important role in reducing the list price of insulin.

Average sales price

The Centers for Medicare and Medicaid Services uses the ASP, instead of the list price, to establish the payment rates for Part B physician administered drugs and DME-infused drugs, including pump-delivered insulin. Before 2017, the overall Medicare payments for DME-infused drugs exceeded ASP; however, the Medicare payments to pharmacies for pump-delivered insulin was lower than ASP, resulting in lower copays for patients. This is because prior to January 1, 2017, Medicare payments for pump-delivered insulin were based on the average wholesale price of insulin in 2003.

Because Medicare was paying less than ASP to pharmacies for pump-delivered insulin, some large suppliers stopped providing insulin to Medicare Part B beneficiaries, making it difficult for patients to fill their prescriptions. In contrast, Medicare's overpayment for other infused drugs created potential incentives for overutilization and improper billing. To address the payment discrepancies, it was recommended that Medicare Part B payments for DME-infused drugs, including pump-delivered insulin, be brought in line with other Part B drugs, which are based on 106% of current ASP. This recommendation was enacted

with Section 5004 of the 21st Century Cures Act. As a result, the price of insulin increased 251% overnight (between December 31, 2016, and January 1, 2017) without any notification to patients and providers.

Programs to lower out-of-pocket costs

To address high out-of-pocket costs, manufacturers offer PAPs to provide insulin at low or no cost to qualifying low-income patients. These requirements vary by company and patients must apply annually, which can be problematic as PAPs can be difficult to navigate. Manufacturers also offer copay cards, but these are typically used to incentivize the use of higher cost medications. Therefore, while an individual patient receives a reduction in out-of-pocket costs by using a discount card, these programs result in overall higher medication prices. Furthermore, the federal government finalized regulations in 2020 that would allow private insurers and employers to exclude copay cards from counting toward deductibles and out-of-pocket maximums, thereby likely raising expenses for many patients.

Manufacturers have also taken steps to lower the out-of-pocket cost of insulin, either through the introduction of lower cost versions of their drugs or by reducing the copay that patients must pay for their insulin. For example, Eli Lilly introduced insulin lispro, an authorized generic, at half the price of Humalog and recently announced the availability of 2 additional authorized generics for its other insulin products. Novo Nordisk also developed authorized generics of Novolog and Novolog Mix at 50% of the list price.

All 3 insulin manufacturers have programs that limit the copay that a patient must pay for their insulin products. Eli Lilly has implemented policy that no patient should pay more than $99 each month for its insulin, and additionally announced the Lilly Insulin Value Program, allowing anyone with commercial insurance and those without insurance to fill their monthly prescription of Lilly insulin for $35 during the COVID-19 public health epidemic. Novo Nordisk launched My$99Insulin, a program that allows patients to purchase up to 3 vials or 2 packs of FlexPen pens of any combination of insulins for $99 and will provide no-cost insulin to people who have lost health insurance coverage due to the COVID-19 public health epidemic. Sanofi expanded its ValYou Savings Program to provide up to 10 boxes of pens or 10-mL vials per month at $99. Additional education should be provided to patients, physicians, and pharmacists to ensure people with diabetes know about these programs and how to access them.

Cigna and CVS Health have also introduced programs to lower out-of-pocket costs for employer-based insurance. Cigna, along with its PBM Express Scripts, announced a 30-day supply of insulin for $25. CVS Health, which owns Aetna, plans to eliminate out-of-pocket costs for all prescription diabetes medications starting in 2021. Both companies have indicated that these programs will not increase costs to their insurance plans. These programs will only lower costs, however, if the employer decides to include this benefit in their plan design, and recent reports suggest that some of these programs are still underutilized (22).

The Federal Government has taken steps to ensure that Medicare beneficiaries are protected from the high cost of insulin. The Part D Senior Savings Model, announced in May 2020 and effective for the 2021 plan year, provides beneficiaries the opportunity to select Part D plans that cover insulin at $35 per prescription through the coverage gap. While it is unclear how much this new model will save seniors, it will provide them with more clarity in the cost of insulin prescriptions each month and throughout the year.

Human insulin

Competition in the marketplace for both brand name and generics typically drives down prices. This has not been the case with insulin. The price of modern insulins has continued to increase despite the availability of multiple insulins on the market. In a true free-market economy, this should promote greater competition and drive down costs. Human insulins (ie, NPH and regular insulins) have been available for decades, can be effective therapy for some patients with type 2 diabetes, and are available at a significantly lower cost. However, most healthcare providers are no longer trained on how to use these older products and many patients are reluctant to use them.

Biosimilar availability

A potential solution to reduce insulin costs is the availability of biosimilar insulins, which are essentially "generics" of existing insulins. Insulin prices have not been affected by competition in part because the biosimilar insulins that have entered the market to date are made by Eli Lilly (Basaglar) and Sanofi (Admelog), 2 of the 3 insulin manufacturers. For biosimilars to have an impact on the price of insulin, availability must extend beyond current manufacturers and new companies must be willing to undertake a costly development and strict review process. On March 23, 2020, licensing of biosimilars transitioned to allow existing insulins to serve as a reference product by an applicant seeking approval of a proposed biosimilar or interchangeable product. The Food and Drug Administration

must ensure that the approval process for biosimilar insulin products is efficient while still ensuring the safety and effectiveness of the new products.

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Additional Information

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