Insulin:

A lifesaving drug too often out of reach

Congressional Diabetes Caucus Co-Chairs

Representatives Diana DeGette and Tom Reed

Executive Summary

Introduction

Every day 7.5 million Americans rely on insulin to manage their blood sugar levels and prevent debilitating, even deadly complications. This lifesaving drug, however, has become increasingly unaffordable. Its average price has nearly doubled since 2012, putting an enormous financial burden on millions of patients.

For more than a year, Representatives Diana DeGette (D-CO) and Tom Reed (R-NY), the co-chairs of the Congressional Diabetes Caucus, have conducted a bipartisan inquiry to uncover the sources of this dramatic price increase. This culminating report provides an overview of the insulin supply chain, discusses the drivers behind rising insulin prices, and recommends policy solutions to lower costs.

Insulin Supply Chain Overview

The insulin supply chain is composed of two interrelated pathways, the delivery of insulin from manufacturers to patients and the flow of payments for insulin throughout the supply and delivery chain. These pathways are not direct. Instead, wholesalers, pharmacists, providers, insurers, and pharmacy benefit managers serve as intermediaries.

Findings

The insulin market is nuanced in comparison to the traditional prescription drug market. This is because the insulin market is impacted by several upward price pressures, while the counterbalancing downward market forces are often blunted, resulting in an unusually complex market. Many of the complicating reasons will be detailed further in this inquiry, including the myriad steps that insulin takes from manufacturer to patient, the perverse payment incentives and methodologies, the lack of transparency in pricing and outdated patent regulations, among other things. These market failures have allowed a handful of players along the insulin distribution pipeline from manufacturers to health insurers to capitalize on their strategic positions, driving up the price of insulin and minimizing competition.

Policy Recommendations

Congress should pursue a handful of legislative actions to increase price transparency, promote competition among insulin makers, and encourage the use of value-based contracts. Congress should also consider working on targeted patent reforms to prevent anti-competitive practices and streamline the drug approval process at the Food and Drug Administration for biosimilar insulins.

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Patient Stories

"My husband and I have used the only resource I have, which is credit cards, to cover the costs of insulin and diabetes supplies. I just started another part-time job to help pay off our $20K credit card debt, most of which is diabetes debt."

-Robin, California

"I was diagnosed at the age of 7 in 1993. At that age I had no idea about any of this but as I started growing up, I could see it was a concern to my parents. I remember discussions about the cost of my medication. I remember in particular my parents talking about how my job choices would be limited because I would have to work for a big company in order to get insurance."

-Talia

"...I looked into smuggling insulin across the border, my doctor misused insulin samples to make sure I survived, and I had friends illegally hand off surplus insulin to keep me alive. Insulin is life support. It is not optional, we will die without it. This is not anything we did to ourselves, genetics and unknown environmental factors just dealt us a bad hand. Paying more for a month of insulin than our rent costs is unsustainable."

-Rebecca, Pennsylvania

"My boyfriend is a type 1 diabetic. He didn't have health insurance for a long time. He could only afford one vial of insulin every couple of weeks. Pharmacists denied giving him the insulin when he didn't have the money but was still standing in the pharmacy with a sugar high of 500. This needs to end now, this is people's lives they are dealing with."

-Colorado Resident

"My 23-year-old son is a Type 1 Diabetic and needs insulin to survive. He was diagnosed at age 7. He can stay on our insurance until he is 26 however I worry that he won't be able to afford it once he's off our insurance. I worry and pray about this daily. Something must be done. Insulin doesn't make him better, it keeps him literally alive."

-New York Resident

History of Insulin

Prior to the discovery of insulin, children diagnosed with diabetes rarely survived longer than a year. Children who did survive often experienced devastating health issues, including blindness, limb loss, and kidney failure.

Before the discovery of insulin, children were often times treated with unsuccessful diet modifications which prolonged survival by delaying the disease's progression but did not treat the underlying causes of diabetes. Then, in 1921, Canadian scientists Frederick Banting, J.J.R. Macleod, Charles Best, and James Collip had a scientific breakthrough and were able to produce the first pure form of insulin intended to be used as a treatment for humans with diabetes.

The Canadian scientists successfully treated their first diabetic patient with insulin in 1922. The following year they were awarded patents in the United States for their insulin solution. Instead of bringing their breakthrough insulin product to the commercial market, Banting, Macleod, Best, and Collip sold their patents to the University of Toronto for one dollar. Following in the scientists' charitable footsteps, the University of Toronto then allowed manufacturers to produce insulin royalty-free.

Since then, manufacturers have continued to develop and refine insulin to better manage diabetes. The first intermediate-acting form of insulin known as Neutral Protamine Hagedorn, for example, was developed in 1950. Thirty years later, the first synthetic human insulin hit the market. More recently, the Food and Drug Administration (FDA) approved the first rapid acting form of inhaled insulin. Despite these developments over the past century, the base formulation of insulin has remained generally the same. Recent price increases, however, have made innovative formulations and base formulations unaffordable for many Americans.

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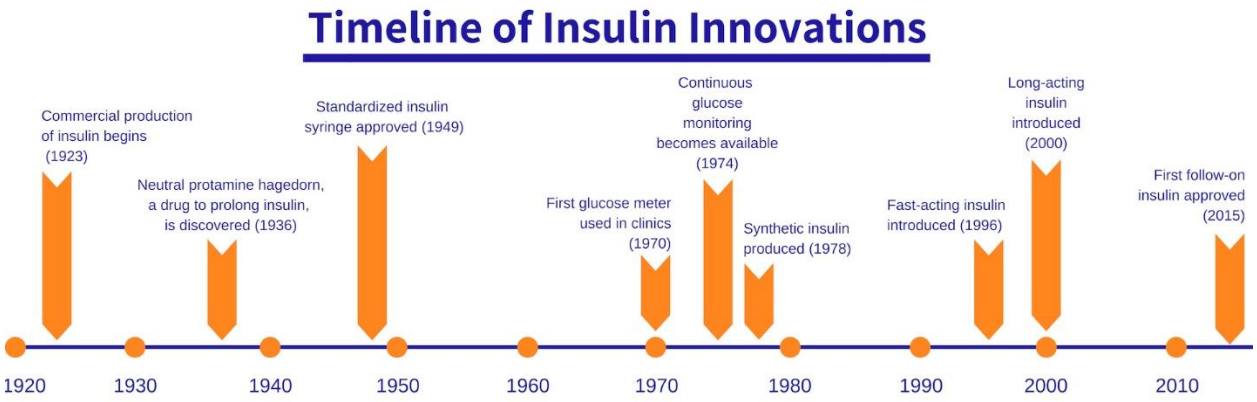

Introduction

Diabetes

Patients with diabetes suffer from this disease because their blood glucose, also referred to as blood sugar, is abnormally high. This is important because glucose is a main form of human energy obtained from food. To convert glucose from ingested food into usable energy, the human pancreas uses a hormone called insulin. If a patient's body doesn't make enough insulin, or doesn't use insulin correctly, then the glucose stays in the patient's blood stream and doesn't reach cells to be converted into energy. Having too much glucose in the blood stream can cause a number of health issues such as fatigue, blurred vision, increased thirst, and other more severe conditions.

Insulin

Insulin is critical to the management of diabetes as it helps patients control their blood sugar levels. Abnormal levels of glucose in the blood stream over time can cause serious damage to organs, including the eyes and kidneys. Of the combined 30 million Americans with type 1 and type 2 diabetes, about seven and half million use insulin.[1]

Insulin Inquiry

Many patients struggle to afford this lifesaving drug. The price of insulin has doubled since 2012, which follows a nearly 300 percent increase between 2002 and 2013.[2,3] Some patients have resorted to rationing and skipping doses, sometimes with tragic consequences. In 2017, for example, Alec Raeshawn Smith, a 26-year-old Minnesotan with diabetes who faced unaffordable insurance co-pays, tragically passed away after attempting to ration his insulin.

Based on stories like Alec's and millions of other patients like him, along with mounting documentation on the adverse health outcomes that improper management of diabetes causes, Representatives DeGette and Reed launched a bipartisan inquiry to identify the causes of rising insulin prices. Through their year-long probe, they met with patients, providers, insulin makers, wholesalers, pharmacies, pharmaceutical benefit managers (PBMs), and health insurers to develop a comprehensive overview of the insulin supply chain. They also conducted detailed investigations of value-based contracts, patient assistance programs, drug discount cards, and drug formularies.

Representatives DeGette and Reed found that the insulin market has an influx of upward price pressures without offsetting downward forces, producing a noncompetitive market.

This report will describe these findings by first providing an overview of the insulin supply chain. It will then analyze the factors contributing to insulin price increases and how they have created an imbalanced market. The report will conclude by recommending measures that Congress can take to stabilize the insulin market.

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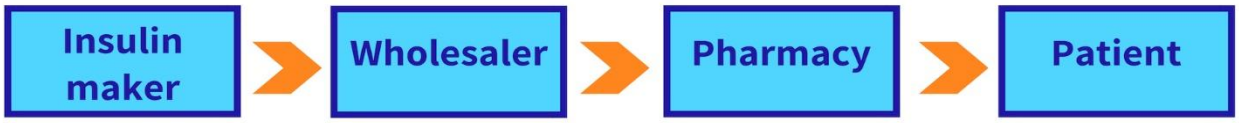
Insulin Supply Chain Overview

Introduction

Before insulin is purchased and used by diabetic patients, it must come to market through an enormously complex delivery system. This delivery system is most easily described by two interrelated pathways; the steps that the drug takes along the delivery system and the multifaceted purchase and payment system. The first pathway physically moves the insulin from manufacturers to pharmacies while the second processes insulin payments. In the delivery system pathway, manufacturers sell insulin to wholesalers, who then transport the drug to pharmacies. The second pathway begins when pharmacies sell the insulin to patients.

The patient point of purchase typically includes an out-of-pocket cost for the patient, which is pre-determined by the patient's insurance coverage for prescription drugs. After sale to the patient, the dispensing pharmacy sends a bill to a PBM, which passes a bill along to the patient's health insurer. After the PBM receives the insurer's payment, it then sends a portion of the payment to the dispensing pharmacy. The subsequent sections will provide an overview of these two pathways.



This figure shows the flow of insulin from manufacturers to patients.

Section I: Insulin Shipments and Delivery

Insulin's complex journey begins with manufacturers. These entities employ doctors and researchers to develop the insulin, scientists and engineers to manufacture the medication, and then marketing and business professionals to promote and sell the drug. The manufacturers set what is called the 'list price' of insulin, which is also known as the wholesale acquisition cost (WAC). Manufacturers set drug list prices based on operational expenses, including research and development costs and rebates.[4]

The list price set by manufacturers is used as the starting point for negotiations with wholesalers and PBMs. Rebates are discounts that are given by manufacturers to wholesalers for competitive shipping contracts. The manufacturers sell insulin to these wholesalers at a price lower than WAC due to rebates.[4]

Wholesalers are able to make a profit by selling insulin to pharmacies at a price greater than their acquisition cost. This business model is known as spread pricing and is also used by PBMs. Pharmacies then dispense insulin to patients, who are prescribed the drug by their

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health care providers. When this transaction occurs, it activates the second pathway in the drug supply chain.

This figure demonstrates the flow of insulin payments.

Section II: Insulin Payments

As previously mentioned, when insured patients purchase their insulin from a pharmacy, they usually pay a share of their insulin costs through out-of-pocket expenses. Patients either pay a co-payment (which is a fixed dollar amount) or a co-insurance payment (a fixed percentage amount of the total drug cost). After the patient pays their share of the insulin cost, the pharmacy collects the remainder from the patient's PBM. Health insurers typically contract with PBMs to administer the prescription drug benefit piece of the patient's insurance plan. This role allows PBMs to generate revenue through spread pricing.

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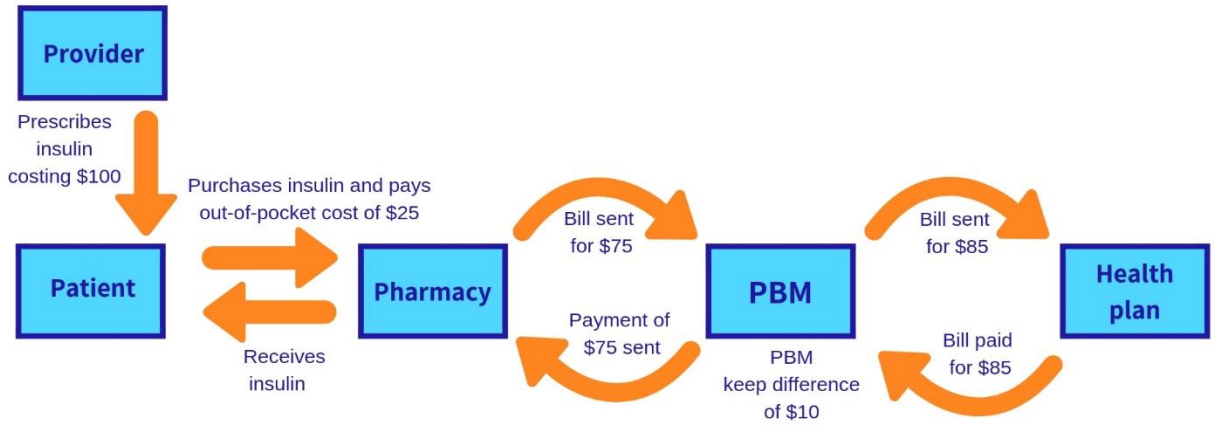
Spread Pricing

When a pharmacy sells insulin to a patient, it bills the patient's PBM for a share of the insulin cost. The PBM sends a bill to the patient's health insurer that includes both the base price of the insulin, plus a markup for services rendered. The mark-up accounts for administrative services such as claims processing, which the PBM provides to the health insurer. The markup amount is proprietary to each individual PBM contract, so we were unable to ascertain the impact on net insulin costs. The PBM sends a share of the health insurer's payment to the dispensing pharmacy. The figure below illustrates the use of spread pricing for a hypothetical insulin prescription costing $100. It also shows the amount paid by each entity.



This figure demonstrates the flow of payments for an insulin prescription costing $100. Through the use of spread pricing, the PBM makes a profit of $10.

Uninsured patients, however, pay insulin's full list price out-of-pocket. Paying for insulin out of pocket can amount to over $300 per vial. Since patients regularly use two or more vials a month, their monthly costs can quickly surpass $600, making this life-sustaining medication unaffordable for many patients.

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Analysis

Introduction

As discussed above, the structure of the insulin delivery and payment pathways create several incentives for entities along these pathways to artificially raise the price of insulin. Simultaneously, these incentives also insulate many of the pathway participants from market forces that normally provide a downward pressure on typical commodity prices. Combined, these two factors seem to be vital drivers of increasing insulin costs.

Upward Price Pressures

Insulin manufacturers offer rebates to wholesalers and PBMs to garner strategic advantages and increased market share over their competitors. Wholesalers frequently receive rebates for providing shipping contracts with exclusivity provisions. These exclusivity provisions require that wholesalers carry just one brand of insulin. PBMs, on the other hand, often negotiate rebates with manufacturers in exchange for preferential formulary placement of specific insulins.

Formularies—which are lists of covered drugs developed by PBMs on behalf of health insurers—influence patient access to prescription drugs such as insulin. While the use of formularies in practice should help reduce costs by directing patients to try cheaper insulins first, the use of rebates offsets this potential savings by raising overall insulin list prices. This usually results in increased costs at the pharmacy counter for patients. Further, patients react differently to different insulin formulas, therefore, sometimes trying a cheaper alternative first is ineffective. Additional details on the effects of formularies on insulin costs are detailed in the following section.

Formularies assign different drugs to different levels called tiers. Insulins placed on lower formulary tiers have lower out-of-pocket costs for patients, making them more affordable than higher-tiered insulins. Insulin manufacturers offer rebates to PBMs in exchange for things like lower-tier formulary placement of their insulins or offering exclusivity provisions, which limit patient choice to one brand of insulin. These agreements serve to drive increased patient consumption of lower-tiered insulin products because they are cheaper. Some PBMs with diabetes management programs will place insulin on the lowest formulary tier, significantly reducing costs for patients and helping them better manage their condition.

Typically, one brand of insulin is placed on a formulary's lower tier while competing brands are placed on higher tiers. If the lower-tier brand is not clinically appropriate for a patient, that patient must pay additional out-of-pocket costs to access the more appropriate, higher-tiered brand of insulin prescribed to them. Rebates can help serve as incentives for PBMs and/or insurers to place certain brand name insulins in specific formulary tiers, giving that manufacturer's insulin a competitive advantage over other brands placed in higher tiers. However, because of confidentiality agreements between PBMs and manufacturers, experts

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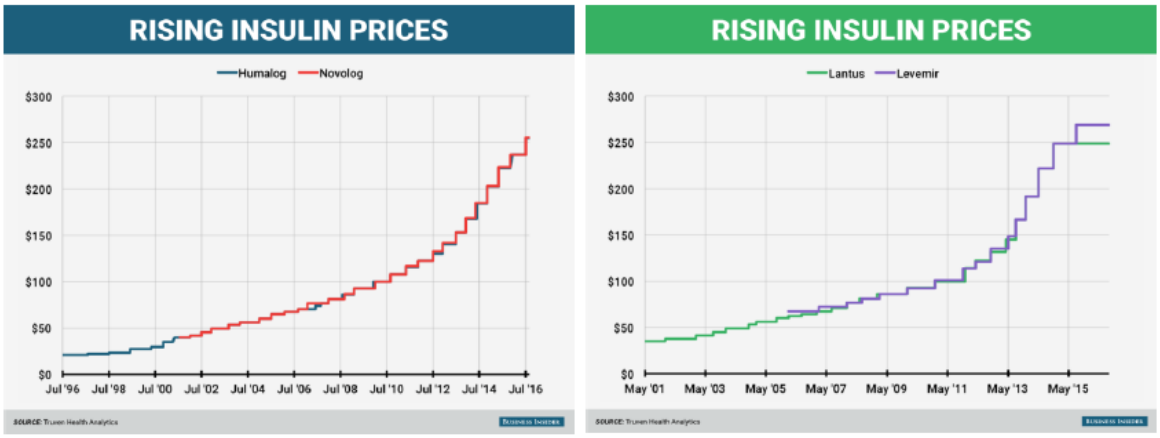
are uncertain of the exact amount garnered by rebates, however, data shows that they can amount to as much as 40 percent.

Wholesalers and PBMs will frequently attempt to negotiate larger rebates with insulin manufacturers, which can push manufacturers to raise their list prices. These list price increases affect transactions and price metrics further down the supply chain. Overall, the rebate system and price negotiations increase list prices, which raises costs for patients.

Limited Competition

From our 2017 summer meetings with stakeholders, we found that the list price of competing insulin formulations has appeared to rise in tandem, a market phenomenon some observers have called "shadow pricing."



Humalog (Eli Lilly) and Novolog (Novo Nordisk) are two short-acting insulins while Lantus (Sanofi) and Levemir (Novo Nordisk) are two long-acting insulins. These graphs show the list price for competing brands of insulin, which have risen together

This phenomenon likely stems from limited market competition. Each part of the insulin delivery chain is controlled by a small number of entities. For example, only three manufacturers produce insulin in the United States. Similarly, the three largest wholesalers control about 85 percent of the drug distribution market.[7] The PBM market also suffers from lack of competition with only a handful of corporations holding significant market share. This market concentration throughout each part of the insulin delivery chain precludes competitive forces typically present in other commodity markets that could exert a downward pressure on insulin prices.

Additional Price Impacts

Patent Extensions i.e. Evergreening

As discussed earlier in this paper, since the discovery of insulin, three manufacturers have produced brand name insulin formulations without generic competition. In addition, these

insulin manufacturers have protected their brand name formulations by garnering repetitive patents on the same drugs, a practice known as *evergreening.* Some of these patents were extended to pharmaceutical companies for incremental innovations in insulin formulas. Industry analysts told us that recent insulin innovations appear to be more incremental than past breakthroughs. This trend has raised disagreements among stakeholders about whether recent patents justify increases in list prices.

Formulary Changes

Formularies, as discussed previously in this paper, are dynamic and can be changed without much notice during the year. These list revisions are made for a variety of reasons, including new drug approvals by the FDA, changes to insulin usage instructions, and safety issues. Health plans indicated that they generally try to minimize the impact of these changes on patient care by providing advance notices of formulary changes and developing transition plans to help patients find similar drugs. However, despite insurer insistence of minimal mid-year formulary disruption, providers and patients both still report significant concerns with formulary changes. The subsequent sections will summarize provider and patient concerns about formulary changes and how they potentially raise insulin costs for patients.

Providers

Unlike in the past, providers are more seriously taking prescription costs into consideration before prescribing drugs to their patients. Study after study, and common sense, tells us that patients are more likely to remain on their provider-prescribed insulin care plans if their prescriptions are affordable.

Before prescribing a brand of insulin, many clinicians consider its cost, in addition to which formula works best for the patient. This evaluation requires that providers consult formularies, some of which do not provide easily accessible cost-sharing information for each patient's insurance-covered prescription drugs. In addition, providers frequently must consult multiple formularies since their patients have varying insurance and drug coverage. Formulary changes during the calendar year can force providers to revisit this laborious process, diverting time and resources away from patient care. Further, taking cost into consideration during the prescription process can push providers and patients to decide to follow more cost-conscious treatment routes, instead of which form of insulin is best suited for a patient's medical needs.

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> Patient appeals can be made. But they too often take too long to be resolved, and insurance plan 'rules' often trump patient and physician judgment.
>
> **- Patient Advocate**

Patients

When formulary changes are made mid-year, some health plans offer patients the opportunity to petition these changes through an appeals process. These insurers claim that the appeals process minimizes the impact of formulary changes on patients. However, patient advocates reported that these processes are confusing, time-consuming, cumbersome, and the process generally dissuades patients from filing appeals.

When a formulary is changed, some patients choose to stay on their specific insulin formulation and opt not to go through the formal appeals process. This results in most patients losing coverage of their preferred insulin, making the drug even more unaffordable. In these cases, some patients have resorted to rationing or skipping insulin doses, which can cause debilitating, expensive, and dangerous complications.

Patients with High-Deductible Health Plans

The proliferation of high-deductible health insurance plans have increased out-of-pocket costs for patients, requiring them to pay a greater share of their insulin costs. High-deductible health plans that use co-insurance systems to base out-of-pockets costs instead of co-pays have had a greater impact on patients. Unlike co-pays, which are fixed amounts, co-insurance varies because it is an out of pocket payment percentage based on insulin's price. Consequently, co-insurance rises with increasing insulin prices. Sometimes the co-insurance percentage is tied to insulin's list price rather than the negotiated rate determined by the patient's PBM. High-deductible health plans, especially those with co-insurance requirements, disproportionately affect patients with chronic conditions like diabetes.

Patient Assistance Programs, Drug Discount Cards and Patient Resources

When patients lose their insurance coverage, have their drug coverage changed, or choose to go without insurance altogether, some can access discounted insulin through patient assistance programs (PAPs), drug discount programs/cards and by using pricing databases.

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Patient Assistance Programs

Through our investigation of PAPs, we found that all three brand-name insulin manufacturers operate some type of PAP, but two of them administer the programs through separate 501(c)(3) foundations. In arrangements involving foundations, the drug manufacturer donates insulin to the 501(c)(3) which then distributes it to eligible patients.

The eligibility criteria for these programs was nearly identical across the reporting insulin manufacturers. The length of a patient's enrollment in a PAP is dependent upon their type of insurance coverage. However, all of the insulin manufacturers reported that they do not have caps or limits on the number of times a patient can re-enroll in their PAP. Though, some PAPs limit the amount of free insulin a patient can receive in a given year.

Drug Discount Cards

In addition to PAPs, insulin manufacturers reported that they operate and manage drug discount card programs. These cards can greatly reduce patient's out-of-pocket insulin costs. In some cases, these discount cards can help bring a patient's cost of insulin down to $15 per month. To receive these cards or participate in similar savings programs, patients must have commercial coverage. Drug discount cards cannot be used in federal health insurance programs such as Medicare or Medicaid.

Concerns

Through this inquiry, we uncovered some ethical considerations with the use of patient assistance programs and drug discount cards. These programs cover a patient's out-of-pocket costs; therefore, they can encourage patients to use expensive medications when cheaper alternatives exist. Some stakeholders worry that this can unnecessarily increase prescription drug spending. To account for this potential overutilization, health insurers might raise premiums for drug coverage plans, which in turn could increase costs for the entire health care system.

We also found that these financial assistance programs can potentially place patients in vulnerable situations. Though these assistance programs help patients access lifesaving medications, patients become dependent on these programs. As a result, manufacturers can potentially wield significant influence over patients, particularly by keeping them on the most expensive and/or branded products.

Community & Online Resources

Apart from PAPs and discount cards, some organizations provide information or searchable databases that patients can use to find cheaper prices for their prescriptions. For example, the National Council on Aging provides resources for seniors with limited incomes and resources through a website called BenefitsCheckUp.org. In addition, websites like GoodRx.com and RxAssist.org provide patients with comprehensive, searchable databases listing pharmaceutical program for patients who need help.

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In addition, local pharmacies and local community health clinics often also offer help for patients in need of assistance in finding affordable insulin. Some large retail stores like Walmart also offer discounted insulins, some even without prescriptions. However, it is important to note that these discounted insulins are typically older insulin formulations, and not more advanced brand-name insulins.

Though not ideal, and sometimes dangerous, some patients are forced to depend on charitable donations of insulin from other diabetics through online forums and other means.

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Policy Recommendations

Introduction

In conducting this insulin inquiry, we have concluded that lowering the price of insulin for patients will require several policy changes. These changes include increasing the transparency in insulin pricing, curbing the inflationary effects of rebates, mitigating the impacts of formulary changes, and promoting increased market competition. The subsequent sections of this paper offer approaches that Congress and regulatory agencies could take to achieve these goals. We believe that taken together, the implementation of these recommendations could help stabilize the insulin market and lower prices.

Combatting Upward Price Pressures

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

As discussed in this inquiry paper, rebates create incentives that raise insulin's list price. Value-based contracts (VBC), however, are a delivery-based contract that can bring down costs. VBCs are arrangements between different entities along the supply chain that pay higher rates for better patient health outcomes, instead of for higher sale volume. The implementation of these contracts could eliminate current volume-based incentives by tying payments to successful patient outcomes.

For example, under an insulin VBC, manufacturers might only be reimbursed if their insulin formula helps patients better manage their diabetes. Should an insulin not meet a minimum efficacy standard under an insulin VBC, manufacturers would have to refund patients for their insulin purchases. To promote the use of these contracts, lawmakers could direct the Centers for Medicare and Medicaid Services (CMS) to pilot outcomes-based pricing arrangements in Medicare. Lawmakers could also introduce pilot legislation allowing private insurers to take part in VBC models through managed care contracts or on the individual marketplaces. Some respondents to our value-based contracting letters of inquiry suggested the need to reform the Anti-Kickback Statute and the Medicaid Best Price Rule, in order to confidently engage in VBCs.

> "Value-based contracting has the potential to connect pharmaceutical reimbursement structures with real world patient outcomes, helping the related health care industries make a leap forward towards value-based care."
>
> **- Manufacturer**

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2. **Promote the use of payment arrangements between insulin makers and wholesalers that involve standardized fees instead of rebates.**
   Encouraging the use of unit-fee models or volume-based systems could eliminate the need for rebates, based on list price, in shipping contracts, helping remove a driver of rising insulin prices. To enact this change, policymakers could introduce legislation that requires wholesalers participating in Medicare and Medicaid or the individual and employer marketplaces to use these alternative payment models.

3. **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.**
   Rebates can be used to lower premiums for patients. Under the current drug pricing system, however, independent entities, including our offices cannot verify that rebates are being used for this purpose. Congress could require drug plans in federal health insurance programs to disclose their use of rebates throughout the supply chain.

4. **Link patient out-of-pocket costs to negotiated prices instead of list prices.**
   As previously discussed, some patients' out-of-pocket costs are based on insulin's list price. As a result, patients do not benefit from the discounts and negotiated prices generated by rebates. Lawmakers could introduce legislation that requires health plans and PBMs to base out-of-pocket expenses on negotiated prices.

Changing Competitive Market Forces

1. **Encourage the development of follow-on insulin drugs by addressing patent extensions.**
   In 2015, the FDA approved a generic insulin product. It is important to note that the agency does not classify this product as true generic insulin since its chemical structure is slightly different than its brand name equivalent. For this reason, all generic insulins, including the 2015 product, will be considered follow-on insulins.

> "Incremental changes to branded products are often used for the purposes of extending branded monopolies rather than improving patient outcomes. Branded manufacturers use such changes to shift large patient populations from one branded drug to an incrementally different new one prior to the patent expiry of the legacy product in order to insulate themselves from generic competition. This practice is commonly referred to as 'product hopping' or 'evergreening.'"
>
> **- Manufacturer**

However, creating a pathway for follow-on insulin products will require addressing anti-competitive practices such as *evergreening*. Congress could pursue legislation requiring drug manufacturers to show that new formulations of insulin result in improved disease

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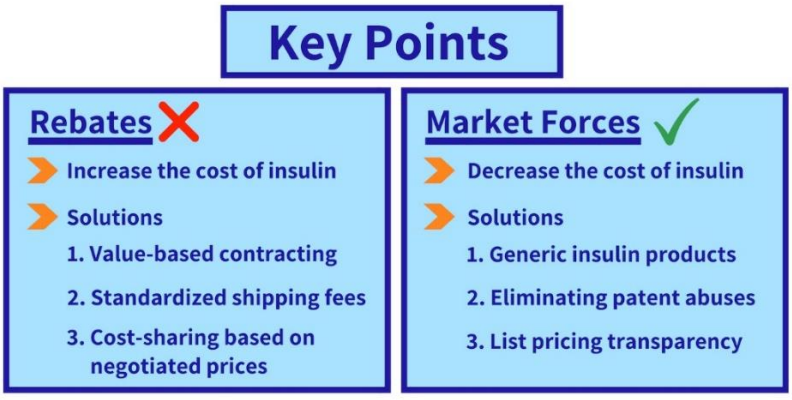
management when compared to current insulin formulations. This would ensure that market exclusivity is only given to manufacturers when their improvements to existing insulin formulations are value-based and warrant a patent extension. Experts predict that follow-on insulins could cost 20 to 40 percent less than their brand name equivalents, creating savings for patients.[8]

2. **Allow generic manufacturers to produce older, off-patent insulin formulations.**
As insulin manufacturers are awarded new patents, they often stop manufacturing older forms of insulin products. Allowing generic manufacturers to produce these older formulations, as long as they are safe, could expedite the development of a robust and competitive insulin market. However, because insulin is made from living cells instead of specific chemicals (like regular prescription drugs) it is considered a biosimilar drug. Because they are made with living cells, biosimilar drugs are more difficult to replicate, especially when it comes to testing how these biosimilar drugs will interact with the patient's body. As such, biosimilar drugs must meet stricter parameters for FDA approval. Congress could direct the FDA to make exceptions or allow fast-track approval for certain biosimilar insulin formulations, if they meet certain quality and comparative effectiveness standards.

   Congress, however, might also need to address industry practices that dissuade generic pharmaceutical companies from producing older formulations of insulins. For example, some brand name manufacturers use what are called pay-for-delay agreements. Under these arrangements, generic manufacturers are paid by the expired patent-holding manufacturer not to produce older, off-patent drugs. By enacting legislation outlawing such agreements, Congress could assist in encouraging additional generic manufacturers to produce older insulin formulations without interference by brand-name manufacturers.

3. **Require manufacturers to disclose their insulin's list pricing process.**
Congress could introduce transparency legislation requiring drug manufacturers to disclose how they set their insulin prices. This measure could place potential downward pressure on list prices by preventing insulin makers from setting list prices that do not reflect the operational and business costs of manufacturing insulin.



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Formulary Changes

1. **Standardize the process for requesting exemptions or filing appeals from formulary changes.**
   Standardizing the appeals and exemptions processes for patients to challenge formulary changes would alleviate some of the administrative or procedural challenges encountered by patients. To help develop a universal appeals procedure, Congress could convene working groups composed of patients, providers, PBMs, and health insurers to develop a patient-centric appeals system. This system could then be phased into all federal health programs such as the Children's Health Insurance Program and Medicare. This action would help ensure that patients stay on their insulin regimens and avoid expensive complications.

2. **Standardize drug formulary disclosure of patient cost-sharing information.**
   Medical pricing information is generally confusing for patients and providers. Additional transparency regarding service and medication costs by insurers is something that could help patients and providers decide on the right medications. To promote this effort, Congress could introduce legislation directing the Centers for Medicare and Medicaid Services (CMS) to develop a series of standard formulary designs that provide cost-sharing information in an accessible manner. As a condition of participation in Medicare Part D, the legislation could require insurers to use these standard formulary templates. These templates could help insurers simplify formulary development across their different health plans and provide patients and clinicians with cost awareness when developing treatment plans.

3. **Limit the number of changes an insurer is permitted to make to a formulary each year.**
   As we discussed earlier in this paper, changes to formularies many times put patients in challenging predicaments. Congress could pursue legislation that would cap or limit the number of changes an insurer could make to a formulary in a given year. These restrictions, however, should not be limiting, as PBMs and health plans need some flexibility to account for innovations that are approved during the year. An outright ban on formulary changes would make it difficult for patients to get new diabetes therapies as health plans would not be able to cover the new innovations through their formularies.

Additional Recommendations

1. **Cap out-of-pocket expenses for prescription drugs that are needed for chronic conditions.**
   Chronic conditions like diabetes are long-lasting diseases that can get worse over time. As a result, patients with chronic conditions must take prescription drugs throughout their lives to manage their conditions.

   Without insulin, diabetic patients can experience severe health outcomes such as heart attacks, vision problems, kidney failure and death. When patients do not adhere to their prescribed chronic condition treatment plans, they often times make unnecessary visits to the hospital, where they receive expensive care. Some of these hospital visits can be

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avoided by ensuring patients have affordable access to their life-sustaining medication. Capping out-of-pocket costs for life-sustaining drugs like insulin could help patients better manage their diabetes and avoid adverse outcomes leading to unnecessary hospitalizations.

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Acknowledgements

Representatives DeGette and Reed would like to thank each of the entities who submitted contributions during this insulin inquiry process. Without each organization and patient's feedback, we would not have been able to compile this thorough report.

Patients

Our deepest thanks go to the patients from our districts and across the country who originally brought the issue of insulin affordability to our attention, and bravely shared their stories with us. We greatly appreciate the following organizations for sharing the patient perspective, which was the impetus for this inquiry: Patients for Affordable Drugs, T1 International, Juvenile Diabetes Research Fund, the American Diabetes Association, the Diabetes Patient Advocacy Coalition, Diabetes Advocacy Alliance, and the American Association of Retired Persons.

Providers

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Industry

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