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Containing the rising cost of insulin: select policy recommendations

Mary Titus, Lizheng Shi *

Department of Health Policy and Management, School of Public Health and Tropical Medicine, Tulane University, 1440 Canal Street, New Orleans, LA 70112, USA

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ABSTRACT

Diabetes is a chronic disease that affects over 30 million people in the United States. Of these, approximately 7.4 million use one or more formulations of insulin to manage their condition. There is a significant financial burden on diabetic individuals, as the price of insulin keeps increasing each year. Such consistent and drastic increase in the price of insulin is due to the complexities in the insulin supply chain, pricing mechanisms particularly due to pharmacy benefit managers (PBMs), and the dominance of a few insulin manufacturers in the market. This policy analysis has been undertaken independently and is based on information from peer-reviewed journals, government organizations and agencies, and credible news sources. Politicians and various stakeholders in the supply chain have made several policy recommendations on the pricing of insulin. From the data and information collected, we suggest basing a patient's co-payment on the net price instead of the list price of insulin, and that there should be real-time transparency in the negotiations between PBMs and pharmaceutical companies on rebates.

1. Introduction

Diabetes, the seventh leading cause of death, is a chronic disease that affects 30.3 million people in the United States (U.S.), or 9.4% of the population. This includes 23.1 million people who are diagnosed and 7.2 million who are undiagnosed.[1] There are three main types of diabetes: type 1, type 2, and gestational diabetes. In each type, the body's pancreas either does not produce enough insulin or cannot use the insulin it makes as efficiently as it should.[2] Insulin acts as a messenger allowing cells to absorb glucose, from the blood. In other words, without insulin, the body cannot use or store glucose for energy, and the glucose remains in the blood.[3] Type 1 diabetes, which affects approximately 5% of the diabetic population, or 1.5 million people, is caused by an autoimmune reaction that stops the pancreas from producing insulin. Type 2 diabetes, which affects approximately 90% of the diabetic population, is a condition in which the body does not use insulin properly and is unable to keep blood glucose at normal levels.[2] The remaining diabetic population is affected by gestational diabetes, which develops in pregnant women who have never had diabetes.

Of the 30.3 million Americans with diabetes, approximately 7.4 million use one or more formulations of insulin to manage their condition.[4] Type 1 diabetes patients need insulin to survive while for type 2 diabetes, insulin is often the only drug that can control the disease in patients.[5] In addition to the USD 327 billion annual costs incurred by the U.S. government to manage the health of diabetic patients,[4] there is a significant financial burden on the patients due to the consistent and drastic increase in insulin prices by the year. According to a study published in 2016, the average price of insulin in the U.S. almost tripled between 2002 and 2013.[6] Medicare Part D expenses for insulin have also increased. For example, Medicare spending on rapid-acting insulin registered a compound annual growth rate (CAGR) of 10% between 2006 and 2011, and a CAGR of 13% from 2011 to 2013.

This increase in spending on insulin has resulted in high out-of-pocket costs for patients. For Medicare Part D enrollees, such out-of-pocket costs have increased annually by 10% between 2006 and 2013. In contrast, medical care service costs only increased by 3.8% and spending on all prescription drugs increased by only 2.8% during the same time period. According to Beran's report, the out-of-pocket expenditure on insulin for insured adults in the U.S. increased by 89% between 2000 and 2010.[7] The World Health Organization has recommended that for the treatment to be considered affordable, the cost for a one-month supply should not exceed one day's salary of the lowest-paid government worker's (LPGW) salary.[7] The same report found that a month's supply of analogue insulin is more than 5-days' wages of the LPGW in Delhi of India, Hubei Province of China, and Sudan. Clearly, this is not an issue solely in the U.S.

The consistent and drastic change in the price of insulin is due to the complexities in the insulin supply chain, pricing mechanisms, and the dominance of few insulin manufacturers in the market. The insulin supply chain comprises the delivery of medicine from the manufacturer to wholesaler to pharmacy and finally to the patient. The manufacturers set the list price for each insulin product and typically sell their medications to wholesalers, who distribute them to individual pharmacies. However, in some cases, pharmacies deal directly with the manufacturer. When wholesalers buy the medications, they typically do so close to the list price and then sell to

* Corresponding author: lshi1@tulane.edu.

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pharmacies at little to no markup. Pharmacies then dispense the medications to individual patients and collect the cost-sharing amount as per the patient's health plan, if any. Finally, the pharmacies submit a bill to the patient's health insurance company (if any) for reimbursement of the cost of the medication less any cost-sharing collected, plus a dispensing fee.[4]

The flow of the money in the insulin supply chain is much less transparent. Pharmacy benefit managers (PBMs) are the stakeholders often managing the pharmacy benefit portion of a health plan on behalf of their clients. It is important to note that the clients of PBMs are health plans (private and government sponsored) and employers, not the actual patients. According to the Pharmaceutical Care Management Association (PCMA), the national association representing PBMs, the purpose of PBMs includes reducing prescription drug costs and improving the quality of drug benefit coverage for consumers.[8,9] For example, the PCMA's drug benefits solutions website states that PBMs save payers and patients an average of USD 941 per person per year. However, the lack of transparency comes into play with the drug rebates. Manufacturers negotiate with PBMs and give them discounts, called rebates, which are meant to be passed through to the payer and then to the patient, in the form of lower premiums.[10] PBMs also negotiate with pharmacies to determine how much the pharmacies will be paid for medications dispensed in the PBM client's health plan.[4] PBMs have significant negotiating power as the three major PBMs (CVS Caremark, Express Scripts, and OptumRx) manage about 70% of all prescription claims.[4] It is not clear how the rebates help consumers since the individual's co-pays are often based on the original list price than the cost after the rebate.[11] This "net price" that drug manufacturers receive is the list price less any fees paid to wholesalers, and/or discounts paid to pharmacies, and any rebates paid to PBMs or health plans.[4] In other words, sicker patients with costly drugs such as insulin end up paying higher out-of-pocket costs and do not really benefit from the lowered premiums.[10]

Finally, both the U.S. and the global market for insulin is dominated by three large multinational companies—Eli Lilly, Sanofi, and Novo Nordisk. These companies account for 96% of the total market by volume and 88% by global product registrations.[4] This three-company monopoly in the insulin market reduces competition that affects both affordability and availability. Notably, the patent for Sanofi's product, Lantus, the world's leading basal insulin, expired in 2016 and has opened up a testing ground for the development of insulin biosimilar drugs.[6] Biosimilars are developed to mimic the structural and clinical properties of biologic drugs, which are produced by living organisms such as bacteria or cultured cells.[6] It is yet to be seen whether biosimilars will reduce the cost to consumers and expand market competition.

Taking cognizance of all these factors, this policy analysis aims to compare different policy recommendations within the U.S. and the world for the benefit of patients with diabetes and prediabetes.

2. Methods

Only peer-reviewed journal articles published in 2014 or later, written in English with access to full text were selected as data sources for this analysis. This was supplemented with data from credible news sources and government agencies and organizations. The years before 2014 were not considered because of the rapidly changing nature of the issue at hand, and to account for the change in the U.S. presidential administration and the expiration of Sanofi's Lantus patent.

The PubMed database was utilized to retrieve many of the peer-reviewed articles used in this policy analysis. Commencing February 12, 2019, articles were accessed from PubMed using the keywords "rising costs of insulin." This resulted in several articles detailing the issue globally and in specific foreign countries. To narrow down the results, the keywords were changed to "rising costs of insulin in America." When combing through the search results, the importance of biosimilars became apparent; hence, the keywords for the search were further edited to "costs of biosimilars for diabetes." This search term was used to access articles on February 19, 2019. On the same date, the EBSCO database was also utilized to search the keywords "rising insulin prices."

It should also be noted that several articles were found in PubMed database that were not used in the policy analysis because of repetitive information, irrelevance to the topic, or not complying with the aforementioned criteria. Within the database, the keywords "costs of insulin," and "insulin patents" led to some interesting articles, but they were not used in this policy analysis. The JSTOR database was also consulted with the keywords "rising costs of insulin" and "increasing insulin prices." However, this did not yield any articles that were significantly different from the ones found in the PubMed and EBSCO databases.

On February 19, 2019, the Congressional Research Service (CRS) database was accessed through a Google search. The keywords searched in the CRS database were "drug prices." This resulted in an article titled "Frequently Asked Questions About Prescription Drug Pricing and Policy," updated April 24, 2018. Although the article provided important background information, it was deemed too general to be used in this policy analysis. The search term "biosimilars" was also used in the CRS database, which yielded an article titled "Biologics and Biosimilars: Background and Key Issues," published October 27, 2017.[12] This article was utilized as it provided a detailed information on the U. S.' Food and Drug Administration (FDA) approval process for biosimilars and its current status.

The Google search engine was utilized to retrieve most of the general statistics on diabetes and policy recommendations referenced in this policy analysis. On February 19, 2019, the term "CDC diabetes" was searched on Google, which yielded the National Diabetes Statistic Report for 2017.[1] The Google search engine was used again on March 30, 2019 to search "proposed policy changes for high insulin costs," which led to the publication "Report 7 of the Council on Medical Service" on insulin affordability published by the American Medical Association (AMA).[5] For more general information, the search terms used on Google included: "what is diabetes," "how does insulin work," "pharmacy benefit manager," and "how pharmacy rebates work." The two government policy proposal documents used in this analysis resulted from the Google search terms "pros and cons of Medicare Negotiation and Competitive Licensing Act" and "Trump's new drug rebate proposal."[13] Finally, on March 30, 2019 and March 31, 2019, the phrase "US Senate debate with Pharma CEOs" searched on Google yielded a new article and a government policy proposal, respectively, which were referred in the policy analysis. The cited articles/documents are summarized in Table 1, Table 2 and Table 3.

3. Results

There have been several policies proposed by politicians, stakeholder organizations, and the authors of the various referenced journal articles. On February 7, 2019, the U.S. Congressman Lloyd Doggett and the U.S. Senator Sherrod Brown proposed a patient-first legislation called the Medicare Negotiation and Competitive Licensing Act.[14] This legislation would authorize the Secretary of Health and Human Services (HHS) to negotiate drug prices. If drug companies refuse to negotiate in good faith, the Secretary would be able to issue a competitive license to another company to produce the medication as a generic. Doggett and Brown argue that "the purpose of medicine is to help people, not to line the pockets of Big Pharma executives. Our bill would … demand prescription drug companies offer fair prices, or be boxed out." Senator Amy Klobuchar, one of the original co-sponsors of the bill, further argued that "Medicare is one of the largest drug purchasers in the country. It should not be restricted from negotiating the best deal with drug manufacturers" (2019).

In a similar vein, the Centers for Medicare and Medicaid Human Services proposed a rule on November 11, 2018 on the federal register government site. The proposed rule would amend the Medicare Advantage program (Part C) and Prescription Drug Benefit Program (Part D) regulations to provide them the flexibility to negotiate lower drug prices and reduce out-of-pocket costs for Part C and D enrollees. This proposed rule would change many things that affect PBMs, including the definition of negotiated price.[16]

President Donald Trump's administration, specifically the Office of Inspector General (OIG) and the HHS, proposed a rule on February 6, 2019

Table 1
Summary of cited policy recommendations from peer-reviewed journal articles.

Title of article or document	Author(s)	Published time	Source	Major policy recommendation(s)	Reference number
Biosimilars for insulin: a cost-saving alternative?	McCall C	August 11, 2018	Pubmed	Foster a mature biosimilar market in the U.S. to lower costs overall	6
Insulin Access and Affordability Working Group: Conclusions and Recommendations	Cefalu WT, Dawes DE, Gavlak G, et al.	June 2018	EBSCO	• Cost sharing for insured people with diabetes should be based on lowest price vailable • List price should more closely reflect net price •PBMs and payers should use rebates to lower costs at point of sale	4

Table 2
Summary of cited policy recommendations from the government and other organizations.

Title of article or document	Author(s)	Published time	Source	Major policy recommendation(s)	Reference number
Dogget, Brown Announce Bicameral Medicare Drug Price Negotiation Bill	Congressman L. Doggett, Senator S. Brown, Senator A. Klobuchar	February 7, 2019	Google	Medicare Negotiation and Competitive Licensing Act would authorize the Secretary of HHS to negotiate drug prices	14
Fraud and Abuse; Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees	Office of Inspector General and Department of HHS	February 6, 2019	Google	End the practice of PBM rebates in the Medicare and Medicaid programs	15
Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses	Centers for Medicare and Medicaid Human Services	November 30, 2018	Google	Amendment to the Medicare Advantage and Prescription Drug Benefit programs to reduce out-of-pocket costs for Medicare Part C and D enrollees	16
PCMA Issues Guiding Principles, Policy Solutions to HHS on Reducing Prescription Drug Costs	PCMA	July 18, 2017	Google	• Eliminate the use of risk evaluation and mitigation strategies to delay competition • Allow FDA accelerated approval of brand drugs • Require biosimilars to bear identical labeling and naming • Encourage more use of generics for Medicare Part D enrollees	8,9
Report 7 of the Council on Medical Service - Insulin Affordability	AMA	2018	Google	• Encourage FTC to monitor insulin pricing and market competition • Prohibit contract clauses that bar pharmacists from telling consumers about less expensive options • Ensure private health insurance companies declare which medications are on formularies by October 1 of preceding year	5

PBM: pharmacy benefit managers; FDA: Food and Drug Administration; HHS: Health and Human Services; FTC: Federal Trade Commission; AMA: American Medical Association; PCMA: Pharmaceutical Care Management Association.

targeting "backdoor drug rebates." The proposed rule would end the practice of PBM rebates in the Medicare and Medicaid programs as of January 1, 2020.[15] Consequently, the discounts that PBMs negotiate with drug manufacturers would have to apply to the "list price" that patients pay, instead of being transmitted in the form of rebates that reduces the premium amount.[10] This would lead to lower out-of-pocket spending and better patient adherence to medications, as the list prices start to look more like the net prices. The end of the rebates would also lead to higher utilization of low-cost generic and biosimilar drugs, since PBMs will not have the incentive to favor brand name drugs in their formularies. Two scenario analyses published by Jake Klaisner, Katie Holcomb, and Troy Filipek from Milliman suggest that this new rebate rule could reduce federal spending on government programs by USD 78 billion to USD 98 billion over the next ten years, and reduce out-of-pocket and premium costs to Part D enrollees by as much as 11%.[10]

In an American Diabetes Association statement in *Diabetes Care*, the Insulin Access and Affordability Working Group provides several recommendations based on their research, which is referenced throughout this analysis. Some notable ones related to policy include: "cost-sharing for insured people with diabetes should be based on the lowest price available,"

Table 3
The cited policy recommendations from news article.

Title of article or document	Author(s)	Published time	Source	Major policy recommendation(s)	Reference number
Pharmaceutical Company CEOs Face Grilling in Senate Over High Drug Prices	Kodjak A. for NPR	February 26, 2019	Google	Senator R. Wyden argued with Pharmaceutical Company CEOs that "lowering list prices is the easiest way for consumers to pay less at the pharmacy counter"	13

CEO: chief executive officer; NPR: National Public Radio.

"list price should more closely reflect net price, and rebates based on list price should be minimized," "PBMs and payers should use rebates to lower costs for insulin at the point of sale," and "the FDA should continue to streamline the process to bring biosimilar insulins to the market".[4] At the time of the CRS report on Biologics and Biosimilars (October 27, 2017), the FDA had approved seven biosimilars for marketing in the U.S., but sales of five of those had been delayed, or alleged to have been adversely impacted by actions of the brand manufacturers.[12]

At the 2017 Interim Meeting, the House of Delegates referred to Resolution 826, "Improving Affordability of Insulin," which was sponsored by the American Association of Clinical Endocrinologists and the Endocrine Society, and directed the AMA to pursue solutions and recommendations for the insulin affordability issue in association with the various stakeholders. Some notable recommendations related to policy include: "encourage the Federal Trade Commission (FTC) and the Department of Justice to monitor insulin pricing and market competition and take enforcement actions as appropriate," "prohibit 'clawbacks' and standard gag clauses in contracts between pharmacies and PBMs that bar pharmacists from telling consumers about less-expensive options for purchasing their medication," "support drug price transparency legislation that requires public notice by pharmaceutical manufacturers when certain price increase triggers are reached," and "legislation or regulation to ensure that private health insurance carriers declare which medications are available on their formularies by October 1 of the preceding year, and that drugs may not be removed from the formulary nor moved to a higher cost tier within the policy term".[5]

Interestingly, the PCMA's policy recommendations on their drug benefit solutions website mentions nothing on the subject of rebates. Their recommendations include: "eliminate the use of risk evaluation and mitigation strategies to delay competition," "allow for FDA accelerated approval of brand drugs that have the potential to create competition," "require substitutable biosimilars to bear identical labeling and naming," and "encourage greater use of generics for Medicare Part D low income subsidy enrollees".[8,9]

As mentioned before, this problem of insulin affordability is not unique to the U.S. In Finland, for example, the per capita expenditure on insulin increased by 86% from 2003 to 2015 which translates to a total spending of EUR 50 million (about USD 56 million).[17] According to the article, the main drivers were the increase in the number and size of purchases, and a shift in use towards newer and therefore more expensive drugs. A similar problem has been occurring in India—the sales of insulin recorded a growth of 44% between 2008 and 2012, 114% between 2012 and 2014, and 80% between 2014 and 2016.[18] However, the biosimilar market has grown much more in Europe and India compared to the U.S. While the FDA took longer to approve some biosimilars, Europe's major pharmaceuticals regulator, the European Medicines Agency (EMA) has clarified that, in principle, it has no issue with the use of biosimilars. In 2014, Eli Lilly, in partnership with Boehringer Ingelheim, was the first to obtain market authorization from the EMA for its biosimilar insulin glargine called Abasaglar in Europe. Furthermore, the Indian generic drugs manufacturer Biocon and the U.S. drugs specialist Mylan are now marketing Semglee, a biosimilar insulin glargine in India. Biocon's CEO, Arun Chandavarkar, stated "We have a mature biosimilar market in India with biosimilars providing access to critical therapies to millions of patients who otherwise would have been limited in their treatment options." The Indian drug company also argues that the cost reduction caused by the production of biosimilars will help patients who are not able to afford the patent drugs. However, many experts argue that biosimilars do not offer much cost benefit in the short-term because of the high production costs arising from specialized equipment and development of the drug.[6] The regulatory process for insulin biosimilars is also more painstaking than that of generics or other biosimilars.[19] In fact, the price reductions for insulin biosimilars in the U.S. are only predicted to be approximately 20% to 40%, which is much less than the price reductions of 80% or more for most small-molecule generic drugs.[19] Finally, it is not guaranteed that patients would want to use insulin biosimilars. As Japanese endocrinologist, Mitsuru Ohsugi, said, "some patients simply trust the originator brands more and are reluctant to switch to a biosimilar".[6]

4. Discussion

There is a bias that exists in many of the aforementioned policy recommendations. Trump's new policy proposal first surfaced only in May 2018, as part of the "American Patients First" campaign, just six months before the Senate and House of Representatives elections, and was clearly a push to keep his constituents happy and keep Republican control of both sections of the U.S. legislative branch. The American Diabetes Association and AMA obviously have individual patient's best interests at heart, but this is also a bias against the pharmaceutical companies and the PBMs. Finally, the PCMA does not offer any policy recommendations on more transparency or the halt of drug rebates. When the Trump administration first announced their proposed change of discontinuing drug rebates, the PCMA argued that rebates do not distort incentives for utilization of low-cost drugs. The PBM trade association also stated in a legal analysis that it "raises significant concerns as to whether there are any viable alternatives to rebates, in light of drug manufacturers' inability to offer up-front discounts under current antitrust case law.[10]

However, in a debate between the U.S. Senate and Pharmaceutical Company CEOs on February 26, 2019, the leaders of "Big Pharma" deflected blame onto the insurance industry, government, and PBMs.[13] The CEO of Sanofi, Oliver Brandicort, argued that, "we want these rebates, which lower net prices, to benefit patients" and "unfortunately, under the current system, savings from rebates are not consistently passed through to patients in the form of lower deductibles, co-payments or co-insurance amounts." Senator Ron Wyden countered that "lowering list prices is the easiest way for consumers to pay less at the pharmacy counter".[13] In contrast to the opinion of the PCMA, several of the pharmaceutical company leaders support the Trump's administration proposal. On the other hand, they do not want the government negotiating drug prices directly through Medicare, as proposed by the *Medicare Negotiation and Competitive Licensing Act.* Brandicort contested that "the government should not directly control the price of medicines either through federal government price controls or worse, outsourcing prices to other countries".[13]

5. Conclusion

From this analysis, the policy recommendation should be that an individual's co-payments be based on net price instead of list price, and that there should be real-time transparency of the negotiations between PBMs and pharmaceutical companies on rebates. Although the Trump administration's proposal on completely nixing the rebates is valid, it is unclear whether it will actually save money for patients, since their premiums would most likely increase if rebates were made illegal. In general, it makes much more sense for a patient's co-payment to be based on the net price rather than the list price since the net price is the list price less the rebate, and the rebates are meant to benefit the patients financially. Furthermore, almost every stakeholder mentioned in this analysis can agree on the fact that more transparency is necessary, especially the ones with the patient's best interests in mind, the American Diabetes Association and the American Medical Association. Although the pharmaceutical companies could also be forced into lowering their list prices, more transparency with the rebate process seems like a strong and more achievable start.

Competing interests

The authors declare no competing interests.

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