FEATURE ARTICLE

Bipartisan Federal Legislation to Address Insulin Access and Affordability

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Insulin access and affordability affect the well-being of millions of Americans. In the 116th Congress (2019–2020), seven bipartisan bills were introduced to address this issue. In this article, the authors group the seven bills into five categories (enhancing price transparency, limiting cost-sharing, changing biosimilar regulations, certifying prices, and permitting importation), summarize the main content of these bills, and discuss their implications. Understanding the bipartisan insulin pricing policy proposals can facilitate the development of a feasible legislative agenda to improve insulin access and affordability.

In 2018, 88 million adults in the United States were estimated to have prediabetes, representing more than one-third of the adult population, and 34 million Americans, or about 10% of the population, had diabetes (1). Among these Americans, ~0.2 million children and adolescents, as well as 1.4 million adults, were living with type 1 diabetes and using insulin (1). Prices of commonly used forms of insulin in the United States have been rising rapidly; the average wholesale acquisition cost (WAC) of insulin pens and vials experienced a 15–17% compound annual growth rate from 2012 to 2016 (2). Moreover, prices of insulin in the United States can be several times higher than prices in other developed countries. For example, 10 mL of insulin glargine costs about $200 in the United States but less than $50 in Canada, France, Japan, Korean, Sweden, Switzerland, and the United Kingdom (3). High insulin prices limit access to these life-saving therapies and threaten patients' health outcomes (2,4).

Insulin access and affordability issues have received broad attention by federal and state policymakers in recent years. In the 116th Congress (2019–2020), 23 bills were introduced to address access and affordability of insulin specifically or of prescription drugs in general, with a mention of insulin. Among them, seven bills have received bipartisan support (Table 1) (5–11). Given the very small majorities in both chambers of the 117th Congress, the legislative proposals in these seven bills are likely to have greater political feasibility than those in the bills that do not have bipartisan support.

In this article, we group these seven bills into five categories based on their main approach to enhancing insulin access and affordability—enhancing price transparency, limiting cost-sharing, changing biosimilar regulations, certifying prices, and permitting importation—and discuss their implications. Our objective is to provide health care professionals, policymakers, and the public with an overview of the insulin pricing policy proposals that have bipartisan support to facilitate the development of a feasible legislative agenda.

Enhancing Price Transparency

Two bipartisan bills propose measures to enhance price transparency of insulin.

H.R. 7722–Matt's Act would require insulin manufacturers to publish quarterly on their websites the average net price for the previous quarter (defined as the drug price net of all prospective or retrospective rebates, discounts, concessions, and other price adjustments offered to a plan). Failure to disclose would result in not receiving payment for insulin products sold to federal programs.

S. 2004–Emergency Access to Insulin Act of 2019 would establish that the Inspector General of the U.S. Department of Health and Human Services (HHS) collect quarterly price (median WAC per unit), sales volume, and gross revenue information from insulin manufacturers for each of their insulin products and issue annual reports to the public and the Internal Revenue Service. These reports would disclose price spikes—defined as increases in WAC above the

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TABLE 1 Summary of Insulin Bills Introduced in the 116th Congress With Bipartisan Support

Title, Date, and Committee	Sponsor and Cosponsors	Main Provisions
H.R. 1478—Affordable Insulin Act of 2019, 28 February 2019, House Energy and Commerce	Peter Welch (D-VT) Francis Rooney (R-FL)	*Permitting importation* • Permit the importation of qualifying insulin from Canada • Prohibit manufacturers from price discrimination against the United States
S. 2004—Emergency Access to Insulin Act of 2019, 27 June 2019, Senate Finance Committee	Tina Smith (D-MN) Kevin Cramer (R-ND)	*Enhancing price transparency* • Disclose price spikes and impose a price spike tax *Limiting patient cost-sharing* • Fund states, Indian tribes, and tribal organizations to cover cost-sharing for uninsured or underinsured individuals *Changing biosimilar regulations* • Shorten the biological product market exclusivity period from 12 to 7 years
S. 2103—Affordable Insulin Approvals Now Act, 11 July 2019, Senate Health, Education, Labor, and Pensions Committee	Richard Durbin (D-IL) Tina Smith (D-MN) Jeanne Shaheen (D-NH) Doug Jones (D-AL) Sherrod Brown (D-OH) Jeff Merkley (D-OR) Gary Peters (D-MI) Kyrsten Sinema (D-AZ) Kevin Cramer (R-ND) Cindy Hyde-Smith (R-MS) Shelley Capito (R-WV) Mitt Romney (R-UT) Lisa Murkowski (R-AK) Mike Braun (R-IN) Roger Wicker (R-MS) John Hoeven (R-ND) Cory Gardner (R-CO)	*Changing biosimilar regulations* • Require the continued review and approval, as appropriate, of pending applications for insulin biological products under section 505 of the Federal Food, Drug, and Cosmetic Act filed no later than 31 December 2019 beyond the 23 March 2020 cutoff date previously established by the Biologics Price Competition and Innovation Act • Deem applications for insulin drugs to be considered a license for a biological product under section 351 of the Public Health Service Act
S.2199—Insulin Price Reduction Act, 22 July 2019, Senate Finance Committee	Jeanne Shaheen (D-NH) Susan Collins (R-ME) Thomas Carper (D-DE) Kevin Cramer (R-ND)	*Certifying prices* • Prohibit insurance plans and pharmacy benefit managers from receiving price concessions from insulin manufacturers who certify to the HHS that their insulin list prices are rolled back to the level of 1 July 2006 • Require insurance plans to waive deductibles for certified insulin products • Reduce manufacturers' Medicaid rebates for certified insulin products
H.R. 5444—Lower Insulin Costs Now Act, 17 December 2019, House Energy and Commerce Committee	Lauren Underwood (D-IL) Janice Schakowsky (D-IL) Andy Levin (D-MI) Brett Guthrie (R-KY) Mike Kelly (R-PA) Brian Fitzpatrick (R-PA) Scott Perry (R-PA)	*Changing biosimilar regulations* • Same as for S.2103 • Require insulin to be identified as a listed drug during the transition and as a biological product after the transition and applications for insulin to contain a patent certification or statement
H.R. 7722—Matt's Act, 22 July 2020, House Energy and Commerce Committee; House Education and Labor Committee	Jeff Fortenberry (R-NE) Angie Craig (D-MN)	*Enhancing price transparency* • Require net price disclosure *Limiting patient cost-sharing* • Limit cost-sharing for patients enrolled in Public Health Service Act or Employee Retirement Income Security Act plans • Allow patients enrolled in high-deductible plans would access insulin drugs for free • Allow uninsured patients to access the drug at the average net price plus the average charges for distributing and dispensing • Define net price as the list price net of all prospective or retrospective rebates, discounts, concessions, and other price adjustment offered to the plan • Require that the charges for distributing and dispensing be no more than 10% of the average net price of the drug
H.R. 8190–Biosimilar Insulin Access Act of 2020, 8 September 2020, House Energy and Commerce Committee	Glenn Grothman (R-WI) Michael San Nicolas (D-GU)	*Changing biosimilar regulations* • Deem biosimilar insulin to be interchangeable with the reference product • Shorten the market exclusivity for the first interchangeable product

Related bills have been excluded.

inflation rate—and the resultant revenues obtained by manufacturers. An annual price spike tax and/or a cumulative price spike tax would be imposed on insulin manufacturers, with a tax rate linked to the magnitude of the annual or cumulative price increase.

Limiting Cost-Sharing

Two bipartisan bills aim to expand access to insulin through reducing out-of-pocket costs to patients.

H.R. 7722–Matt's Act is intended to limit the cost-sharing of insulin for patients with diabetes enrolled in Public Health Service Act or ERISA (Employee Retirement Income Security Act) plans, as well as uninsured patients. It caps the net price and the distribution and dispensing charges. Specifically, insured patients would pay cost-sharing at the lowest of the following rates: *1*) 10% of the average net price of the drug plus the charges for distributing and dispensing, *2*) patient's current coinsurance amount, or *3*) $20. Patients enrolled in a high-deductible health plan would have no cost-sharing. Uninsured patients would access the drug at the average net price plus the average charges for distributing and dispensing. The charges for distributing and dispensing would be capped at 10% of the average net price of the drug.

S. 2004–Emergency Access to Insulin Act of 2019 specifies that the Centers for Disease Control and Prevention would provide grants to states, Indian tribes, and tribal organizations to create programs to help individuals obtain insulin at no out-of-pocket cost. These programs would support eligible uninsured or underinsured patients, for example, by providing insulin cards allowing patients to fill a prescription at no cost. For patients enrolled in high-deductible health plans, payments made by these programs would count toward their deductible. The bill would require insulin manufacturers to pay annual fees to HHS based on their insulin market share each year to fund these programs.

Changing Biosimilar Regulations

Two bipartisan bills promote competition in the insulin market by changing regulatory policies. Two other bipartisan bills aimed to streamline the regulatory transition of insulin products (implemented in March 2020) from approval as drugs to approval and licensure as biological products.

S. 2004–Emergency Access to Insulin Act of 2019 would shorten the biological reference product market exclusivity period from 12 to 7 years, allowing follow-on competitor products such as insulin biosimilars to enter the market sooner.

H.R. 8190–Biosimilar Insulin Access Act of 2020 would allow all biosimilar insulins to be interchangeable with the reference product without the need for additional studies. Therefore, all biosimilar insulins could be substituted for the corresponding reference product at the pharmacy counter without the need for a new medical prescription. The bill would also shorten the market exclusivity for the first interchangeable product to allow more interchangeable products to enter the market sooner.

S. 2103–Affordable Insulin Approvals Now Act would require the U.S. Food and Drug Administration to continue review and approval of pending applications for insulin products filed before the regulatory transition of 23 March 2020. In addition, if approved, such applications for insulin drugs would receive a license for a biological product even if they were originally filed as a drug product. Because the regulatory transition was implemented in March 2020, these provisions are no longer relevant.

H.R. 5444–Lower Insulin Costs Now Act would incorporate the same provisions as in S. 2103, with additional requirements that applications for insulin products shall comply with related requirements concerning any timely filed patent information, including providing a patent certification or statement describing whether there are any relevant patents on the reference (listed) drug and, when there are, whether such patents are expired, invalid, unenforceable, or will not be infringed by the new product.

Price Certification

One bipartisan bill would provide incentives to manufacturers to reduce insulin list prices to 2006 levels.

S. 2199–Insulin Price Reduction Act would allow manufacturers to certify insulin products by setting list prices to no more than the rates as of 1 July 2006. For insulin products without available list prices from 2006, the weighted average list price in 2006 for the specific insulin category could be used. Manufacturers that raised insulin prices by more than the medical CPI (consumer price index) would lose certification. For certified insulin products, manufacturers would not pay rebates or discounts to health insurance plans or pharmacy benefit managers, the patient's deductible would be waived, and the Medicaid rebates would be adjusted down.

Permitting Importation

One bipartisan bill would permit the importation of qualifying insulin to the United States from other countries.

H.R. 1478–Affordable Insulin Act of 2019 would allow for importation of insulin from Canada (potentially including other countries after 2 years). In the United States, importation of insulin would be allowed by wholesale distributors, pharmacies, and individuals. HHS would publish a list of certified foreign sellers and approved laboratories to conduct random testing of the chemical authenticity of the imported products. The bill would also prohibit drug manufacturers from price discrimination against United States purchasers. Specifically, it would be unlawful for drug manufacturers to charge a higher price for an insulin product sold to a foreign seller who will eventually sell it to U.S. importers than for the same product sold to a foreign seller who will not eventually sell it to U.S. importers.

Discussion

The bills introduced in the 116th Congress with bipartisan support reflected five bipartisan approaches taken by federal lawmakers to enhance insulin access and affordability: improving price transparency, limiting out-of-pocket costs, changing biosimilar regulations, certifying prices, and permitting importation.

Improving price transparency in the pharmaceutical market has become a bipartisan legislative focus because of the rapid growth of some drugs' list prices, as well as an increasing disconnect between list prices and net prices of insulin (2,12). List prices, determined by drug manufacturers, are growing faster than net prices actually paid by insurers (i.e., the negotiated prices after rebates and discounts) (2,4). List prices are often used to calculate cost-sharing for insured patients and reflect the prices charged to uninsured patients (2,13). Net prices can be substantially lower than list prices and are kept confidential because of contractual agreements between insurers and manufacturers (13). The disconnect between list prices and net prices imposes undue financial burdens on uninsured patients, those enrolled in high-deductible health plans, and all other patients whose cost-sharing is based on list prices. Price transparency would facilitate insulin price oversight from governments, private payers, and the public, as well as deter manufacturers from imposing price spikes. However, legislative efforts to improve price transparency often face substantial legal challenges from drug manufacturers on the grounds that price information can be a trade secret (14).

The cost-sharing burden on patients with type 1 diabetes who need insulin to survive can be substantial. It has been estimated that in 2018, for privately insured patients, the cost-sharing for insulin was, on average, $435 a year and could reach >$2,000 a year for many patients depending on their clinical needs and benefit design (15). Capping cost-sharing would limit patients' financial exposure, encourage insulin adherence, and improve health outcomes. The Part D Senior Savings Model, initiated by the Center for Medicare & Medicaid Services in 2021, limits Medicare beneficiaries' cost-sharing to $35 per month in the deductible, initial coverage, and coverage gap phases (16). In addition, basing the cost-sharing cap on net prices, accompanied with net price transparency, would reduce the relevance of list prices, motivate net price–based supply chain contracting, and discourage list price increases. The unintended consequences could include higher premiums to compensate for lower patient cost-sharing. Because the increase in total premiums needed to cover the decrease in payments for patients with diabetes would be spread across all beneficiaries, the incremental financial burden (due to higher premiums) on individual beneficiaries would be of much smaller magnitude than the incremental financial relief (due to lower cost-sharing) for individual patients with diabetes.

Regulatory policy for insulins underwent a recent transition; as of March 2020, insulin approval and licensure are implemented through the biologics pathway rather than the conventional drugs pathway. This transition, established by the 2010 Biologics Price Competition and Innovation Act, has added market entry barriers and uptake barriers for follow-on insulin products (17). Granting interchangeability to all insulin biosimilar products (without the need for additional studies, as is currently required) and allowing automatic interchangeability across biosimilar insulins and reference products by pharmacies (without the need for a new medical prescription) would address these issues (17). Increased interchangeability would promote competition, drive down prices, and benefit patients and insurers, similar to the experience of the conventional generics market.

Rolling back insulin list prices to 2006 levels can lead to significant relief in patient cost-sharing and plan spending. By prohibiting rebates or discounts, the annual certification process can create incentives for manufacturers to voluntarily participate. However, it is unclear how often manufacturers would find it financially beneficial to certify their insulin products. In addition, because pharmacy benefit managers would not retain any rebate from certified insulin products, they may disfavor these products on formulary placement, thus discouraging manufacturers from certifying their products.

Allowing drug importation from other developed countries that have stronger price regulation mechanisms has long been

proposed as a means to bring down drug prices in the United States. However, a recent state-led initiative has proven unsuccessful (18). Fundamentally, the feasibility and effectiveness of insulin importation remain limited. For example, importation is unlikely to address the entirety of insulin pricing problems in the United States because of the significantly larger size of the U.S. market relative to the size of Canada and any other foreign markets. It would also be challenging to monitor and oversee foreign pharmacies and wholesalers that claim Canada as the country of origin for their insulin products.

Enhancing insulin affordability and access will likely become a legislative focus of the 117th Congress. As lawmakers embark on seeking various approaches to achieving this goal, understanding what legislative approaches introduced in the 116th Congress have obtained bipartisan support will help build a feasible policy agenda.

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AUTHOR CONTRIBUTIONS

Both authors researched data and wrote and edited the manuscript. G.B. is the guarantor of this work and, as such, had full access to all the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

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