Insulin Shocks

Joseph White
Nicholas Corwin
Case Western Reserve University

Abstract Some of the news about insulin is shocking. In the United States, people have died because they were rationing a life-saving medication discovered in the 1920s. How could this happen? Perhaps a better question is why anyone should be surprised. The insulin story both illustrates and challenges many understandings of the problems with insurance, treatment, payment, and politics in the US health care system. It particularly highlights consequences of structuring price discounts as rebates to health plans or government instead of as lower individual prices to patients. Perversely, this encourages higher list prices, which, for patients without insurance or with high cost sharing, make insulin less affordable than it would be without the rebates.

Keywords insulin, health care, rationing, drug prices, PBM

The year 2021 marked the 100th anniversary of one of the signature discoveries of modern medicine: producing insulin for patients dying from diabetes because their own pancreases could not make it. The first product, created from the pancreases of cattle, was made by a team at the University of Toronto led by Frederick Banting and was first administered in January 1922, to a 14-year-old boy named Leonard Thompson. "Within 24 hours, Leonard's dangerously high blood glucose levels dropped to near-normal levels" (ADA 2019). News of the miracle treatment for what had been an incurable deadly disease sped across the globe. In 1923 Banting's team received the Nobel Prize in Medicine. The two MDs on the research team believed that to patent the product would violate the Hippocratic Oath; two other researchers initiated the patent but then sold the rights to the

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university for $1. In Banting's words, "insulin does not belong to me, it belongs to the world," and they wanted the treatment to be made accessible to all who needed it (Hegele 2017; T1International n.d.). The university licensed production to Eli Lilly in the United States and what would become Novo Nordisk in Europe. A death sentence became a treatable, though chronic and still very dangerous, disease.

As the 100th anniversary of insulin's discovery neared, however, this signature triumph of modern medicine became a symbol of the signal failures of the modern US health care system: exorbitant cost, insufficient access, and less effective care because "to receive quality care, people must have access to care" (Bodenheimer and Grumbach 2016: 118). It especially became an "unlikely symbol of America's problem with rising prescription costs" (Sable-Smith 2018).

This problem has two dimensions: the overall cost of drugs, which mainly affects premiums or government subsidy costs, and the cost for individuals. When total costs increase but patients pay a substantial amount out of pocket, that can have severe effects on patients. In the case of insulin, high out-of-pocket costs give patients a choice of either sacrificing other necessities of life or rationing by taking less than the prescribed amounts of insulin. Some who ration will later develop diabetes-related disease, such as retinopathy (Witt 2021). Others die. The case of Alec Smith—who aged out of his mother's health insurance when he turned 26, found that coverage he could get under the Affordable Care Act seemed pointless because of high deductibles, tried to get by on less insulin, and died a month after losing his mother's insurance–was widely publicized in the United States (Sable-Smith 2018; Stanley 2019) and internationally (France24 2019; Prasad 2019). One advocacy group kept a tally of deaths attributed to insulin rationing (Right Care Alliance 2019).

The issue attracted attention from policy specialists and policy makers as or even before it gained mainstream media prominence. A study conducted at Yale Diabetes Center in 2017 found that 25.5% of patients were rationing insulin; in one extreme case, a woman even let her blood sugars go far enough out of control to get her hospitalized so she could get insulin there (Caffrey 2019; for other data, see ADA 2018 and T1International n.d). This fit well with a Kaiser Family Foundation poll (2019a) which reported that 29% of respondents had either skipped or reduced doses of medicine in the previous year; but the potential consequences for the insulin-dependent are especially severe. Elisabeth Rosenthal (2019), editor-in-chief of *Kaiser Health News*, summarized the issue as "High Prices Cause Needless Death."

The Congressional Diabetes Caucus—the largest caucus in the House of Representatives, with more than 300 members ranging far across the

ideological spectrum—had begun an investigation of insulin prices in 2017, and its Republican and Democratic cochairs issued a report with findings and recommendations in late 2018 (DeGette and Reed 2018). As an aide who works on Diabetes Caucus issues puts it, "diabetes doesn't have a preference for one party or the other."[1] The Congressional Research Service issued a brief on insulin prices around the same time (CRS 2018). The Senate Finance Committee, chaired by Republican Charles Grassley, began a major investigation of insulin prices with a formal information request to the three major insulin manufacturers—Eli Lilly, Novo Nordisk, and Sanofi—on January 22, 2019 (Senate Finance Committee 2021). Senate Finance also made insulin a major focus of hearings on pharmaceutical prices that began a week later (Senate Finance Committee 2019). The House Energy and Commerce Subcommittee on Hearings and Investigations held a series of hearings named "Priced Out of a Lifesaving Drug" on April 2 and 10, 2019. That September the House Ways and Means Committee (2019) issued a devastating comparison of US and international prescription drug prices, with insulin as one of the major categories. President Trump, who had made lowering drug prices "a focus of his policy agenda . . . used strong language to criticize the pharmaceutical industry and its prices" (Sachs 2021: 1053) and promoted a mix of proposals (CMS 2020; DHHS 2018). He especially emphasized insulin in his reelection campaign (CMS 2020; Guarino 2020).

In early 2022, President Biden called for a cap of $35 per month on out-of-pocket insulin costs as part of his 2022 State of the Union message. *Kaiser Health News* reported that the cap was "Welcome, Popular, and Bipartisan. But Congress May Not Pass It Anyway" (McAuliff 2022). It passed the House on May 31, but as summer began, its future was uncertain.

How did the insulin crisis happen, why has it persisted, and what kind of relief (if any) is likely? A full analysis would require a very long article, so we will highlight a few dimensions that seem especially relevant for this special issue.[2] The most central is that price increases combined with

1. We interviewed, on the condition of no quotations or attributions, four individuals who have recently worked within Congress on diabetes issues for their experience and perceptions. We also consulted on the same basis with two senior participants in health and budgeting issues who have worked in both government and think tanks, both of whom one of the authors (White) viewed as offering policy and political expertise with more understanding of Republicans than he has.

2. We cannot cover the full complexity of some issues. For example, consider the availability of generic insulin. This involves technical and legal issues such as the difference between a "generic" and a "biosimilar" (Rajkumar 2020; White and Goldman 2019); the change over time in policies about biosimilars; complex twists such as the mainline manufacturers producing their own knockoffs (for a general analysis of that maneuver, see Feldman 2021); the peculiar difficulties of insulin manufacture; and reasonable doubt about whether biosimilars would actually be much less expensive or even offered considering the marketing dynamics explained below.

uninsurance and underinsurance to create the problem, but market forces and government policies that reduced payments through rebates to health plans, rather than making lower prices directly available to individuals, greatly exacerbated the crisis.

Politics and Problem Definition

Most of what has gone wrong with insulin is true of many other drugs, including other diabetes care products. But insulin became the most prominent example for good reason. First, millions of people need insulin—about 7.4 million in 2018 (Cefalu et al. 2018). Of those, about a fifth have type 1 diabetes, essentially an autoimmune disorder that strikes children or young adults (see Osborn 2020 on the diabetes types), so even people who oppose government programs on the grounds that they imperil individual responsibility cannot blame the victims. Yet the hook with which this article began may be even more important. The story of a miracle drug that was given away a century before and is suddenly unaffordable provides what Deborah Stone (2011) called one of the most powerful policy narratives. It is a narrative of decline, illustrated powerfully with numbers and highlighted by anecdotes that elicit empathy.

We see that decline in the titles of articles and reports that refer to "rationing a lifesaving medication discovered in the 1920s" (Fralick and Kesselheim 2019), mention how "way back when . . . insulin was cheap (and then it wasn't)" (Hoskins 2019), or refer to "the rising cost of a century old drug" (Senate Finance Committee 2021). And, for those who only care about government spending, the federal government also could save billions if the problem were fixed, both directly (e.g., subsidies for Medicare drug benefits) and indirectly (since better access to insulin would make diabetics less likely to progress to end-stage renal disease and then onto Medicare).

The insulin story therefore was invoked by advocates, analysts, and policy makers to illustrate the need for broader proposals such as H.R. 3, the Lower Drug Costs Now Act of 2019 (Pelosi 2019), and S. 2543, the Prescription Drug Pricing Reduction Act of 2019 (Adler et al. 2019). But there have also been proposals to address insulin alone, including by encouraging approval of generic or biosimilar products,[3] capping insured

3. Legislation listed in this and subsequent footnotes was derived by searching for "insulin" in the category "legislation" on Congress.gov for the 116th and 117th Congresses. Bills to reduce intellectual property barriers included, in the 116th Congress, S. 2103, H.R. 5444, H.R. 6155, S. 1140 and H.R. 2011, H.R. 8190, H.R. 4244, S. 2004, and H.R.4010.

and/or uninsured patients' payments for insulin products,[4] driving down prices through regulation or purchasing abroad,[5] or fixing the perverse effects of the rebate system.[6]

Most of the sponsors of these bills were Democrats, but there was a small cadre of Republican sponsors, and the size of the Diabetes Caucus also suggests diabetes-targeted bills should have more support than broader legislation to restrain pharmaceutical prices or to expand coverage by reducing cost sharing. This suggestion is supported by the fact that as of mid-2021 18 states, including deep-red states such as Alabama, Kentucky, Oklahoma, and Texas, had adopted limits on insulin cost sharing for the modest share of coverage they can regulate (NCSL 2021).

But here the unusual support for acting on insulin has ironic effects. President Biden highlighted insulin in his State of the Union address as part of a wider argument that, to counter inflation, policy should "lower your cost, not your wages" and, as part of that, to "first, cut the cost of prescription drugs" (*New York Times* 2022). He added that, as any reader of this special issue must know, "we pay more for the same drug provided by the same company in America than any other country in the world" and then used insulin to illustrate the problem (*New York Times* 2022). Biden has consistently promoted both passing at least some of the drug price regulation in his original Build Back Better Act and enacting the cost-sharing limits mentioned in the State of the Union address, which have been proposed separately in the Affordable Insulin Now Act (Briskin and Sainz 2022). If insulin is being used as the best illustration of the need for drug price regulation, as Biden used it in his State of the Union address, then "pulling the insulin measure from Build Back Better removes that powerful talking point" (McAuliff 2022). Moreover, the fact that insulin cost-sharing limits get very strong support in surveys (87% in favor vs. 8% opposed in one poll linked in McAuliff 2022) might not be enough to pass the cap as a stand-alone bill. It would likely need 60 votes to defeat a filibuster, and Republicans will worry, as one GOP aide said in a confidential interview, that "if we do fix it, and that shows government action can solve a problem, then maybe that shows that government can solve problems and should apply to more situations."

This tension between short- and long-term policy consequences makes action on insulin alone more difficult, though it remains possible because

4. Included in the 116th Congress are H.R. 5744, H.R. 7066, H.R. 366, and H.R. 7722, and the 117th Congress includes H.R. 2179, H.R. 4158, H.R. 4813, S. 1132, and S. 2815.

5. In the 116th Congress: S. 2817 and H.R. 5364, H.R.5744, and H.R. 1478.

6. In the 116th Congress: S. 2199 and H.R. 4906, H.R. 5382, and H.R. 7722; in the 117th Congress: H.R. 5623.

of the unusually strong case for action. But that brings us to the second obstacle. As the same aide added: "If you want more of a policy reason, I'd say it's complicated. . . . We've put together a system with the best intention over 20–30 years and the more you jiggle around with it the more you have misaligned incentives. . . . So to the extent we want to monkey around with the system, members are most afraid of unintended consequences . . . and you have such different ideas of what a solution would look like."

To the authors of this article, the major part of the story is the perverse effects of the amazingly complex system of pharmaceutical sales in the United States. But first we should look at an alternative concern: how insulin products have changed. From the perspective of the pharmaceutical companies, the comparison that drives outrage ignores massive improvement in the product. From the perspective of many analysts, the companies have frequently innovated, but their goal has been to maintain intellectual property protections and market advantages that allow them to extort unconscionable prices.

Two strains of health policy literature ascribe rising pharmaceutical costs to overpriced innovation. One strain argues that health care costs are too high because patients get unnecessary or inappropriate care. Insulin is so dangerous that very few people who use it (for long) might not need it. But using the newer products is commonly criticized as unnecessary. For example, many experts dispute whether short-acting insulin analogues have meaningful advantages (Davidson 2014; Fullerton et al. 2018; Grunberger 2014; Holleman and Gale 2007; Standt and Owen 2016). The other argument emphasizes that very marginal innovation—sometimes called "evergreening" (Feldman 2019)—allows pharma companies to receive patents and thus a period of market exclusivity that gives them market power. They then use presumptions that "new" must mean "improved" to convince doctors and patients to adopt the new drugs (CRS 2020; Martin 2021; Pew Charitable Trusts 2019). When products go off patent, brand-name pharmaceutical manufacturers discourage competition in many ways, which in extreme cases involves paying generic manufacturers not to enter the market (Fox 2017; Stolberg and Gerth 2000). This focus on abuse of intellectual property protections has some bipartisan appeal, as is shown by scholars from the conservative Cato Institute endorsing Democratic Senator Bernie Sanders' drug patent reform plan (Silver and Hyman 2018).

There is good reason to believe that manufacturers manipulate intellectual property protections to jack up prices and that product improvements have not justified price trends in the United States. Yet there is also

good reason to believe that insulin products have been improved in meaningful ways. These improvements may be especially visible to patients who have to cope with the difficult learning curve involved in using insulin to manage diabetes (Stanley 2019).

Although the early treatments saved lives, they had many disadvantages. Patients had to inject insulin into their bodies at the right time and in the right amounts. There was no direct way to measure insulin levels, so the treatments carried a risk of injecting too little or too much. The amount of insulin has to match the amount of food consumed, and injecting too much or eating too little could lead to low blood sugar (hypoglycemia), with severe symptoms and even death as a result (Mayo Clinic 2022) Conversely, just as rationing can lead to elevated glucose levels over time and thus serious complications such as diabetic retinopathy (Witt 2021), an accumulation of small errors over time can lead to similar results (Hirsch 2021).

The changes in how insulin is created and administered include, in rough chronological order: creation of longer-acting products; improving animal insulins to reduce formation of antibodies against them; creating biosynthetic human insulins, further reducing immune responses; creating analog insulins in which molecules are altered to shape the time profile of absorption of the drug (Hirsch 2021); and developing separate products to replace the ways in which the body would normally maintain a base (basal) level of insulin and to provide an extra boost (the bolus) for processing meals (Seed 2020). Related changes in diabetes treatment include better tests and other products for patients to monitor their blood glucose levels, most importantly through continuous glucose monitoring technology at the turn of the millennium (JDRF 2008), and insulin pumps, wearable devices that deliver small doses on a preprogrammed schedule, thus limiting both uncomfortable needle sticks and the chance that a patient will forget to treat herself, as well as the need for basal insulin (Cleveland Clinic 2021).

The developments above have made insulin available in a wide variety of forms that vary by how quickly they take effect, length of effect, when doses should be taken, and delivery system: needles, "pens," insulin pumps, and, recently, short-acting inhaled insulin (Cleveland Clinic 2021; Hirsch et al. 2020; WebMD 2020). These all make insulin management easier than in the past, but patients clearly differ in their comfort with particular methods, which is an argument for having alternatives (Oerum 2019).

Much of the product variation might seem like mere convenience. But in a world in which policy makers and pundits continually proclaim that

patients need to better manage their own conditions, diabetes—once a person is insulin-dependent—is an ironic case in which *self-management is not an alternative to high-tech treatment. Rather, the main point of technological advances is to improve self-management*. The advantages of newer products are illustrated by experience with "Walmart insulin": old-fashioned human insulin sold by Walmart as Novolin ReliOn for $25 per package.[7]

Analog products may not appear to perform better in some studies, but they act more quickly, so they make management easier. There should be patients, particularly some with type 2 diabetes, whose condition is manageable with the older products (Cefalu et al. 2018: 1307). But there will be many who cannot manage their condition as well with those products and thus need a lot of help, and the patients who have to buy Novolin ReliOn are also the patients with coverage shortfalls who therefore cannot get much help. "People who resort to Walmart insulins, especially those who transition to it after years of using analogs, often struggle with the lack of flexibility and more precise timing required when using older forms of the substance. If insulin does not absorb quickly enough, it leaves people imperiled" (Bennett 2019). This is how US diabetes patient Josh Wilkerson—who, like Alec Smith, aged out of his family's insurance instead of rationing his doses and tried the cheaper human insulin alternative—died (Olivo 2019).

In short, there are large differences between current products and the human insulin of the 1980s, easily noticed by anyone who has lived through the changes (Hirsch 2021). And quite neutral parties have concluded that the less costly alternatives are also less effective formulations compared to those used by "peers with private insurance or Medicaid" (Glied and Zhu 2020: 1).

We do not mean to suggest that all innovations are worthwhile, nor that they are properly priced. As in other countries (Soppi et al. 2018), US insulin costs have increased in part because of the transition to analog products and new delivery methods. But the cost per user of *both* human and analog insulins more than tripled from 2005–2007 to 2015–2017 in the United States (Zhou et al. 2020: 2398). Therefore, the biggest problems are prices and insurance coverage, not unnecessary use of newer products.

7. On June 29, 2021, Walmart announced a new analog product, ReliOn Novolog, also made by Novo Nordisk, which is to be sold for 60%–75% less than comparable list prices but still around three times more than Novolin Relion (Sommi et al. 2021). These discounts are still less than the difference in list prices between the United States and most other countries shown in table 21 of House Ways and Means Committee (2019).

Coverage and Prices

From one perspective, insulin-dependent people not being able to afford insulin is a coverage problem. For example, this is a much more serious concern in states that have not expanded Medicaid. The price only matters if people do not have insurance or if they have cost sharing that is a percentage of the price or that counts toward a high deductible (Glied and Zhu 2020). If insulin is covered without a deductible and with an affordable flat copay, the overall price does not matter to the patient. The Affordable Insulin Now Act (S. 3700, 117th Cong., 2022) would therefore make the price much less important for people who are insured, though it would not help the uninsured. Coverage can also be inadequate if a drug formulary excludes a version of insulin that is best for the patient, as part of the insurer's effort to lower the price it pays.

Coverage mandates could solve the *personal* affordability problem. The difficulty with coverage mandates is that if they are not linked to cost controls, they will make coverage for everybody more expensive. The not-so-hidden secret is that high cost sharing for insulin or other drugs in the short run *lowers premiums for healthy people at the expense of really sick people*.

For the system as a whole, therefore, good coverage should be combined with appropriate cost controls. Prices for pharmaceuticals, including insulin, have been rising in all countries, but trends have been especially severe in the United States (Morgan, Bathula, and Moon 2020; Mulcahy, Schwam, and Edenfeld 2020; OECD Directorate 2018).

The twist in the United States, however, is that *coverage determines price*, and in many cases *less coverage means higher prices*. Pharmaceutical pricing is one variant of what Uwe Reinhardt (2019: 47) called "the bizarre nature and role of prices in US health care," in which list prices are extremely high and the only buyers who ever pay the posted price are people who do not have insurance and thus do not have the "discounts."

As the American Diabetes Association explains, "pricing of drugs in general, and for insulin specifically, is very complex. Numerous stakeholders (i.e. manufacturers, wholesalers, pharmacy benefit managers [PBMs], pharmacies, health plans, and employers) are involved in the insulin supply chain, and the distribution and payment systems involve multiple transactions among these stakeholders. . . . While the medication itself takes a rather direct path from the manufacturer to wholesaler to pharmacy to patient, the flow of money is far less direct and transparent" (Cefalu et al. 2018: 1300).

Figure 1 provides a chart of payment for most drugs, including insulin (though the flow is a bit different for some public programs). Some parts of

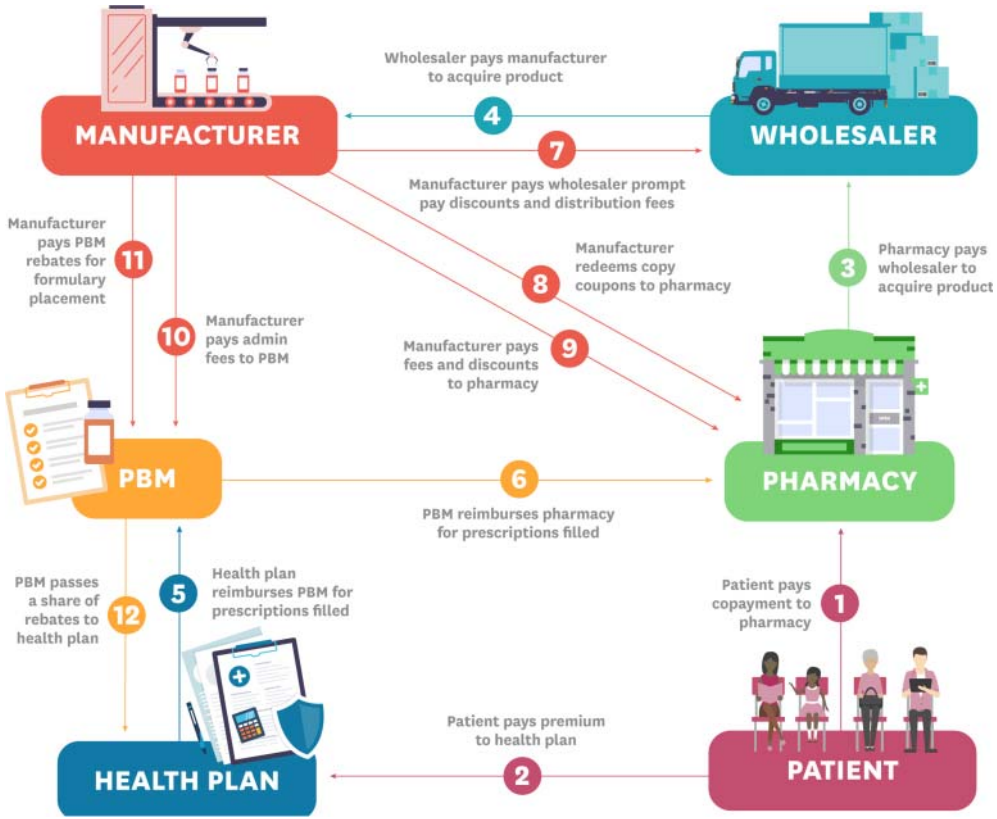

Figure 1 Untangling the price of insulin.

Notes: In arrow 1, *copayment* should more accurately be called *plan-specified cost sharing*.
Source: Van Nuys 2021.

the chart, such as arrows 3, 4, and 7 among manufacturers, wholesalers, and pharmacies, would exist in any system. In many countries patients pay premiums to insurers (arrow 2), and often there is some cost-sharing payment to the pharmacy (arrow 1). The cost sharing is where patients will face the greatest constraint (assuming they have insurance at all) and is especially large in the United States.

Other connections, especially the exchanges with PBMs, are uniquely American (Commonwealth Fund 2019). PBMs serve as intermediaries between insurers and manufacturers. PBMs can tell manufacturers that unless they discount their prices, the PBM will either not list the drug in its formulary (list of covered drugs) or will list it in a tier with very high cost sharing, which would cause the "covered lives" from health plans with which the PBM contracts to choose alternatives with lower net prices to the patient. The three largest PBMs—CVS Caremark, Express Scripts, and Optum Rx—control approximately 89% of the market and serve more than 270 million Americans (NAIC 2022).[8] As specialists in the field, they should know more than (or at least as much as) any insurer can about how products compare, while their size should give them more bargaining leverage than even the largest insurer possesses.

It is hard to see why PBMs should be more cost-effective than the price regulators in other systems, especially since, unlike the regulators, PBMs must extract profits. But what makes insulin unaffordable for some people is *how* PBMs lower prices.

Perverse Incentives and Effects of the Rebate System

Instead of lowering each nominal price, PBMs negotiate discounts as bulk rebates to plans (KFF 2019b). Manufacturers pay rebates to the PBM in return for favorable listing (arrow 11), and the PBM passes the vast majority on to the health plan while retaining enough to earn nice profits (arrow 12).[9] The manufacturer also pays an administrative fee to the PBM

8. Optum is a subsidiary of UnitedHealth, one of the largest insurers. CVS Caremark includes both CVS, the largest pharmacy chain, and Aetna, one of the largest insurers. We do not know what effects this has on contracting, but it is hard to believe cross-ownership has no effects.

9. It seems impossible to be sure of estimates on this topic. Figures range from the Government Accountability Office (GAO 2019) estimating less than 1% of rebates within Medicare Part D insurance were retained by the PBMs, to Caremark claiming that it retains 2% of total rebates (Fein 2018), to PBMs in Nevada retaining 6.59% of insulin rebates (Van Nuys et al. 2021), to the Pew Charitable Trusts (2017: 40) estimating about 9% of rebates being retained by the PBMs in 2016. Note that as rebates grew for reasons explained later in the text, we should expect the PBMs to be able to increase revenues even if they reduced their shares of the rebates. There is some reason to believe that the overall cut to middlemen increased dramatically in the past decade (Van Nuys et al. 2021), but the calculations seem so difficult that one should be cautious about large numbers.

(arrow 10). The health plan reimburses the PBM for prescriptions filled (arrow 5), and the PBM pays the pharmacy (arrow 6). In some cases the manufacturer seeks to eliminate patients' worries about cost sharing, and the effects of unfavorable formulary placement, by reimbursing part of that cost through copay coupons, although coupons are not allowed with Medicare Part D coverage (arrow 8; Gray 2020).

Manufacturers pay rebates to PBMs based on how much they sell, with greater discounts in return for larger sales volume (Cefalu et al. 2018: 1305). Sales, however, cannot be known at the time the patient buys the drug, so the rebate is calculated much later. Therefore, *at the point of sale the recorded price is the original list price for the drug*, also known as the wholesale acquisition price (WAC). Thus, *the "price" the patients sees—and to which cost sharing is applied if it is a deductible or coinsurance (but not a fixed copayment)—is normally the manufacturer's list price, not the average price paid by the health plan through the PBM* (Cefalu et al. 2018: 1306–7). This creates strong and perverse incentives for the manufacturer to raise the list price.

The first-order effect of the system is that patients may pay much more than the stated cost-sharing percentage relative to the actual (net) price. Twenty percent coinsurance applied to a $200 list price when the net price is $100 is actually 40% coinsurance. There can even be situations in which the rebate on a brand-name product is large enough that, combined with the cost sharing, a health insurer benefits from the patient choosing a branded product over a much cheaper generic (Alston, Dieguez, and Tomicki 2018).

But the system further inflates the list price. Normally, part of a PBM's income is a share of the rebate. If the final payment averages $100 as a discount from a WAC of $150, the PBM gets a small percentage of $50. If the WAC is $200 and the final payment is the same, the PBM receives the same percentage of $100, so twice as much. PBMs are also paid administrative fees that are normally calculated as a percentage of the WAC. Therefore, if manufacturers want PBMs to contract with them, it is better to raise their list prices while increasing discounts. Higher list prices with larger discounts drive up what patients have to pay through cost sharing. The Senate Finance Committee (2021) provided stunning evidence, including from internal manufacturer documents, of manufacturers choosing not to lower their WACs for fear of provoking retaliation from the PBMs (see also Hayes and Farmer 2020; Langa 2019; Roehrig 2018). This second-order effect makes drugs even less affordable for the uninsured and underinsured.

This dynamic is especially strong for insulins because the three major manufacturers offer products that are plausible substitutes for one another

(Hayes and Barnhorst 2020; WebMD 2020). This makes competition among makers for favorable treatment by the PBMs particularly strong. While the manufacturers were guilty of exploitation for raising prices until around 2011, since then list prices have risen even more quickly, but net prices have not risen at all (see, e.g., Cefalu et al. 2018: 1307; DeGette and Reed 2018: 10–12; Senate Finance Committee 2021: 46–47; Van Nuys et al. 2021). Any benefits of these savings are going to the middlemen (Van Nuys et al. 2021) or to reduce premiums, but not to sick people who need insulin.

The Government Angle

One part of American health care finance avoids these effects on patients: Medicaid (Glied and Zhu 2020). Medicaid charges very little cost sharing. Federal law requires that the Medicaid Prescription Drug Rebate Program receive the lowest price in the market for branded drugs (with a few exceptions). The formula also requires that a drug's price not increase faster than general inflation. States can negotiate additional rebates based on placement on a preferred list, particularly for some extremely expensive drugs, such as those for hepatitis C (Dolan 2019; MACPAC 2018). In general, though, the Medicaid system relies much less on restricted formularies, giving patients more choice of treatment. Manufacturers have to decide whether to sell any products or none to the 75 million Medicaid beneficiaries. They choose to sell.

Even in the Medicaid case, however, the savings rely on rebates rather than direct price-setting. It works for patients because of the low cost sharing. It also requires that the Centers for Medicare and Medicaid Services receive accurate reports about rebates paid to other purchasers. There is some fraudulent reporting (Maulden 2020), but as best as anyone can tell, Medicaid on net pays much less for drugs than any other federal program does (CBO 2021).

Unlike Medicaid, Medicare Part D is designed with high cost sharing. As three leading health policy scholars explain, "Higher list prices increase what patients pay out of pocket and reduce plan spending by an offsetting amount. . . . Patients using expensive, highly rebated drugs pay significantly more, while healthy enrollees save money from the reduced premium. In addition, increasing list prices expose beneficiaries to more risk and reduce the comprehensiveness of insurance coverage" (Lieberman, Ginsburg, and Trish 2020). Increasing list prices also raise government spending: "As the growth of rebates and other price concessions places

more of the burden on beneficiary cost-sharing," CMS explains, "Medicare's costs for these beneficiaries also grow." The reason is that the higher beneficiary cost sharing "results in the quicker progression of Part D enrollees through the Part D drug benefit phases and potentially leads to higher costs in the catastrophic phase, where Medicare liability is generally around 80 percent" (CMS 2017), which is much higher than in the other phases. This is the major reason why the reinsurance costs of Part D increased from $11.2 billion in 2010 to $46.3 billion in 2019, while total Part D spending only increased from $62.5 billion to $102.3 billion (Boards of Trustees 2020: 145).

A related subsidy issue occurs in the 340B drug pricing program. As the American Hospital Association (2021: 1) explains, "Section 340B of the Public Health Service Act requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to health care organizations that care for many uninsured and low-income patients." These especially include Federally Qualified Health Centers (FQHCs) but also numerous hospitals—especially federally defined "disproportionate share hospitals"—that have large low-income and indigent populations. The Trump administration noted that when these institutions sold either insulin or epinephrine to their patients, they frequently charged more than the discounted price. Following the principle that discounts should go to patients rather than institutions, Trump issued Executive Order 13,937 (85 *Federal Register* no. 146, July 29, 2020), requiring that patients with low incomes receive the full discount. But the implementing rule defined low incomes as 350% of the federal poverty guidelines (FPG) or below, while previously FQHCs had only extended discounts on a sliding scale to those with incomes below 200% of the FPG. FQHCs (and other 340B providers) protested that this was unfair because they relied on extra income from charging less poor patients more than the FQHC's cost, to subsidize their other activities (Rangavajla, Gellad, and Luo 2021). The Biden administration accepted these arguments and rescinded the Trump administration rule—which would have made insulin more affordable for some patients—on the grounds that overall it would do more harm than good (DHHS 2021; Wonder 2021).

Ironies and Lessons

The combination of uninsurance, underinsurance, and the link between rebates and higher list prices exacerbated an insulin affordability crisis that originated with what market analysts call "aggressive," and some might

call greedy, pricing by the manufacturers. Ironically, this is in part because in the case of insulin, *over the past 10 years competition among powerful payers—the PBMs—has reduced net prices to manufacturers*. This has been possible because both payers and manufacturers (though not all patients) have believed that equivalent products were available, and probably because profit margins for the insulin companies were so high that they could make money even with the resulting net price constraints (CRS 2018). In the United States, even when competition works it fails.

The complex supply or marketing chain siphons off substantial sums between the patient and the manufacturers. The system is so complex, however, that each highly profitable sector can blame the others. Intervening at any point risks nasty unintended consequences; for example, referring to what might be done about the PBMs, one very experienced respondent told us, "it's a nightmare figuring out how to regulate." We leave to the reader to conclude whether the right approach would be to blow up the complexity and do more straightforward price regulation.

Conclusion: A Worst Case of a Horrible System

The insulin affordability crisis illustrates everything that is wrong with how Americans pay for drugs. Even when competition sort of works, that just makes things worse for many sick people.

We have highlighted some lessons about the politics as well, such as the consequences of policy complexity and the trade-off between using insulin as an argument for broader legislation and focusing on individuals' costs for insulin alone. We have not emphasized the basic political situation: the vast majority of Republican legislators opposed price regulation or negotiation of any sort, while drug companies could swing enough Democratic votes to limit action in a tightly divided Congress (Sanger-Katz 2021, among many other sources). Those are among the reasons why Democrats in March of 2022 moved the Affordable Insulin Now Act forward. "If the effort to address drug prices ends with this plan to cap out-of-pocket costs for insulin," Larry Levitt commented, "it will amount to crumbs compared to Democrats' initial ambitions to allow the government to negotiate drug prices."

The Affordable Insulin Now Act passed the house on March 31 with unanimous support from Democrats and 12 Republican votes (Sanger-Katz 2022). In July it was folded into the draft reconciliation bill, renamed the Inflation Reduction Act, so as to be protected from a filibuster.

What then passed was both more and less than Levitt's "crumbs." The new law does include very limited provisions to allow the government to negotiate prescription drug prices for Medicare—but only Medicare—beneficiaries. Although negotiation would only begin in 2026, and only later reach a cap of 20 drugs, it still was projected to save more than $20 billion per year when fully implemented. It also limits price increases for drugs covered under Medicare Parts B and D, and it requires that the insurance plans and drug manufacturers cover 80% of the cost of drugs in the catastrophic phase of the benefit, with the federal share falling from 80% to 20%. It further capped Part D enrollees' out-of-pocket expenses (CBO 2022; Sachs 2022). All these changes will be good for Medicare beneficiaries, including diabetics, and for the federal budget.

But the Senate parliamentarian ruled that the $35 per month cap on insulin cost-sharing could not be applied to patients with private insurance. Senate Democrats included them in the bill text anyway, but 43 Senate Republicans voted to enforce a point of order and confine the Affordable Insulin Now provisions to Medicare beneficiaries (Halper and Romm 2022).

Democrats can hope this result gives them a good campaign issue—particularly against those Senate Republicans who voted to enforce the point of order. For now, however, a future Alec Smith or Josh Wilkerson could still be in danger. So will many people in states that have not expanded Medicaid and who are not eligible for ACA coverage or simply have the wrong employer-sponsored insurance. The market will remain perverse, and the United States a sad outlier, as to protection of the insulin-dependent.

■ ■ ■

Joseph White is the Luxenberg Family Professor of Public Policy with the departments of political science and population and quantitative health sciences at Case Western Reserve University. His work focuses on health care politics and policy and US federal budgeting, intersecting at the costs of health care programs. His health policy work especially emphasizes cross-national comparisons. He also edits the "Beneath the Surface" section of the *Journal of Health Politics, Policy and Law*.
jxw87@case.edu

Nicholas Corwin is a recent graduate of Case Western Reserve University. As a type 1 diabetic, he devoted both of his senior capstone projects to the issue of insulin prices in America, and he plans to attend law school in the fall in an effort to eventually work on resolving such drug pricing problems.

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