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Perspective

A Radical Treatment for Insulin Pricing

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On July 28, 2021, the Food and Drug Administration (FDA) approved the first interchangeable biosimilar insulin product, Semglee, which pharmacies can substitute for insulin glargine for patients with diabetes when the brand-name version (Lantus) is prescribed. Acting FDA Commissioner Janet Woodcock heralded the "momentous day for people who rely daily on insulin" because of the potential of interchangeable biosimilars to substantially reduce spending on biologic products, just as generics have done for many small-molecule medications. But when deductibles were reset on January 1, 2022, it was hardly a momentous day for patients filling prescriptions for insulin glargine: the list price of Semglee was barely 5% less than that of Lantus.[1]

Semglee was introduced into a complex ecosystem full of intermediaries that benefit from maintaining high prices. Although it's too early to tell whether and how far the price of Semglee will fall over time, brand-name insulin manufacturers have a long history of resisting price competition. It has become increasingly clear that relief for patients whose out-of-pocket costs depend on list prices will require more than biosimilar manufacturers pursuing typical business strategies; a regulatory or disruptive business fix is needed.

Such a fix could be on the horizon for insulin. It derives from the private, rather than the public, sector. (Congress may yet act on insulin pricing, but any final legislation seems likely to focus more on reducing out-of-pocket spending for insured patients than on addressing high list prices, which could benefit uninsured patients and contain total spending.) The potential business fix comes in the form of a new entrant — a private, nonprofit company called Civica — which announced that it intends to bypass the traditional supply chain and sell interchangeable biosimilar insulin products at substantially reduced prices, beginning in 2024.[2] If this approach leads to a sustained drop in insulin prices, it will illuminate the pathophysiology of market failure in the U.S. pharmaceutical industry and provide proof of concept for a radical treatment.

The primary reason a regulatory solution or disruptive business innovation is necessary to reduce insulin prices relates to the chain of intermediaries involved in determining the amount that a patient pays for insulin. A patient with prescription-drug insurance has coverage for the insulin products that are included in the plan's formulary. The out-of-pocket cost for the patient depends on the plan's benefit design, which may include a deductible and either a fixed copayment or coinsurance (in which the patient pays a percentage of the product's price).

Of course, the for-profit manufacturers of current insulin products have an incentive to charge prices that maximize profits, and given strong demand and the lack of government intervention (e.g., price negotiation) in the United States, these prices are much higher than insulin prices in other high-income countries. But intermediaries between the manufacturer and the patient add complexity to U.S. pharmaceutical markets, and various stakeholders have perverse incentives to keep prices high. Intermediaries include pharmacy benefit managers (PBMs), which aggregate demand among multiple insurers and employers and negotiate discounts (called rebates) off brand-name drug prices. Rebates are generally set at a percentage of a drug's list price, so PBMs and plan sponsors (which split the rebates) can benefit from high prices.[3]

In theory, plan sponsors — either insurers or employers — could pass rebates on to enrollees. One option for doing so would be to calculate out-of-pocket costs using postrebate prices, thereby providing "point of sale" rebates. But this approach is rarely adopted because insurers and plan sponsors often prefer to use the savings for other purposes, such as to reduce plan premiums or defray spending for other benefit-related programs or administrative costs. The pot of money involved is quite large: rebates for insulin are especially high — 50 to 80% of list prices — and they are commonly used medications.[4] Other intermediaries in the supply chain, such as distributors and pharmacies, also tend to benefit when list prices are high. This system benefits many parties, but not patients who pay the list price, or a portion of it, at the pharmacy counter.

With this complex and perverse system working so well for many stakeholders, it's unsurprising that Semglee hasn't changed the landscape for patients. Its manufacturer, Viatris (which was formed by the merger of Mylan and Pfizer's Upjohn), has set a list price of $404 for five 3-ml insulin glargine pens — about $20 below the list price for Lantus.[5] An unbranded version of Semglee, which is priced at 65% less than Lantus, doesn't appear to be included in the formulary for the three largest PBMs. The result is that a century-old drug is still often unaffordable to millions of patients who need it.

The insulin sector has attracted nontraditional entrants before. Walmart began offering low-priced, private-label versions of human insulin in 2010. Targeting a "low-end" market segment that brand-name manufacturers have ignored and offering a very competitive price is a classic move for would-be disruptors, who ultimately aim to move into higher-end segments and claw away at the market shares of major players. Indeed, in 2021, Walmart introduced a short-acting insulin analogue priced at $86 for five pens. But Walmart's partners are brand-name insulin manufacturers Eli Lilly and Novo Nordisk. Although this approach cuts out PBMs, it doesn't introduce a new rival to current manufacturers. The plan announced by Civica — whose mission is "to make quality generic medicines accessible and affordable to everyone" — is intended to heighten competition and cut prices more deeply.

Civica has experience with the effects of dysfunction in the pharmaceutical market. Launched in 2018 by seven health care delivery systems (including Intermountain Healthcare, which I advise on unrelated issues) and three philanthropic groups, Civica initially set out to address chronic shortages of generic drugs that are essential to inpatient care, such as broad-spectrum antibiotics, anticoagulants, and intravenous sedatives. Today, Civica sells more than 50 generic sterile injectable drugs to more than 1500 hospital members.

In March 2022, Civica announced plans to develop and commercialize interchangeable biosimilar versions of three types of insulin — aspart, lispro, and glargine, which account for about 80% of insulin prescriptions in the United States. Civica plans to create a direct line from manufacturers to retail buyers. It will make its insulins available to all U.S. pharmacies at the same wholesale price and on identical terms. It won't offer or receive rebates, and it will publish wholesale prices and include the manufacturer's suggested retail price (MSRP) on its packaging. Civica has announced that its MSRP for a pack of five insulin glargine pens won't exceed $55, as compared with a list price of $425 for Lantus, $404 for Semglee, and $148 for unbranded Semglee.[2,5]

This plan is straightforward: sell a drug at cost and at the same price to all buyers. Having no profit motive is one key ingredient. Another is targeting a high-volume, high-rebate drug: there is enough margin being captured by intermediaries and plan sponsors to enable Civica to cover its

costs and still give patients a good deal. Civica will face important barriers to executing this plan, though. In addition to the usual implementation and regulatory challenges, intermediaries threatened by its approach may introduce new obstacles; for example, they might pressure pharmacies not to carry Civica's insulin products. It's also possible that intermediaries won't try to block Civica's end run and will instead promote new diabetes agents that would be subject to the existing system. If Civica does deliver on its plan, however, it will disrupt the status quo for an important set of drugs and establish a path for reducing prices for other biologic medications whose market-exclusivity periods have passed.

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