Insulin — the new battleground for drug pricing

Outrage over the cost of insulin is driving drug-pricing reform. Industry must do more to support patients dealing with spiraling out-of-pocket costs for biotech medicines.

Insulin is in the headlines — but for all the wrong reasons. The biologic has become a lightning rod for anger over inequitable access to life-saving medicines. Allegations of price fixing and collusion between manufacturers have added to the chorus of criticism. In Washington, politicians frame insulin as the exemplar of all that is wrong with pricing. This has resulted in the inclusion of prescription drug provisions in the Build Back Better (BBB) Act and growing bipartisan support to provide financial relief to patients. With the US Food and Drug Administration's (FDA) recent decision to allow automatic interchangeability for an insulin biosimilar, increasing market competition is coming, auguring changes for other off-patent biologic drugs. Industry needs to recognize that its longstanding 'whataboutism' approach to drug pricing — sidestepping culpability by shifting the blame onto insurers and their middlemen — will no longer fly.

For ~7.4 million Americans living with diabetes, access to insulin is a matter of life and death. Patients have been hit with spiraling expenses for the drug, with insulin's average list price increasing 11% annually from 2001 to 2018. Of the uninsured, 68% pay the full price for insulin, which can be as much as $900 for a month's supply. As many as one in four patients in the country now ration insulin intake, placing them at risk for potentially fatal complications.

The US market is an oligopoly in which three companies — Eli Lilly, Novo Nordisk and Sanofi — share the spoils (31 more insulin manufacturers operate outside America, with lower pricing). The multinational triumvirate has a stranglehold on the US insulin supply, negotiating double-digit percentage price rises seemingly in lockstep.

Although pharmacy benefit managers (PBMs) — insurance company intermediaries — have been negotiating discounts to counter these increases, the perverse incentives of US healthcare mean that patients are increasingly left to foot the bill. Meanwhile, PBMs save money for insurers and employers while using the discounts to pad their own bottom lines.

To date, two insulin biosimilars have been approved: Semglee in July and Rezvoglar in December. Mylan Pharmaceutical's Semglee is the first biosimilar ever to be given 'interchangeable' status by the FDA — an important distinction allowing pharmacists to automatically substitute a cheaper biosimilar for the brand product. Until now, physician prescribing behavior has favored brands over biosimilars — due in part to originators' early scare tactics about biosimilar safety. Interchangeable status may thus be a game changer for biosimilar uptake.

Even so, insulin biosimilars face a battle for market share. They must contend with patent evergreening — Sanofi filed 74 patents for 'newer' versions of Lantus when its patent ran out in 1994. Lilly, Novo Nordisk and Sanofi have already launched their own 'authorized generics' (essentially their own brand drugs repackaged and marketed at a discounted price). And Rezvoglar is a biosimilar launched by none other than Lilly — hardly much incentive for competition. As PBMs can make more money from discounts to brand products, it also remains unclear whether they will de-prioritize biosimilars from inclusion in drug formularies.

The BBB legislation seeks to control patient cost-sharing for insulin by limiting it to no more than $35 per month from 2023. It would also require manufacturers to pay a rebate if drug prices increase faster than the rate of inflation. But the real sticking point for industry is a provision that allows federal government to negotiate prices on a small number of high-cost, single-source brand drugs or biologics lacking generic or biosimilar competition — up to 10 in 2025, 15 in 2026 and 2027, and 20 in 2028 and beyond.

Although the Biotechnology Innovation Organization is on the record as strongly supporting "legislation that reduces what patients pay out-of-pocket for their medicines," its complains that BBB would "weaken the innovation ecosystem" and "hurt patients." The trade group PhRMA went further, calling the Act "heavy-handed," with the potential to "make a broken insurance system worse and throw sand in the gears of medical progress." Even the non-profit 'No Patient Left Behind' initiative is concerned that BBB's market exclusivity limits unintentionally skew R&D incentives toward biologics instead of small molecules.

All this may be moot, anyway. As *Nature Biotechnology* went to press, Senator Joe Manchin (D-WV) withdrew his support, removing the voting majority needed to secure the bill's passage.

That does not mean the legislative impetus to put an end to predatory pricing will diminish. The cost of medicines is now one of those rare phenomena in Washington, DC: a bipartisan issue. And biologic therapies have a big target on their back. According to the consultancy RAND, they accounted for 38% of US drug spending in 2015 and for 70% of spending growth between 2010 and 2015.

Looking forward, the FDA's increasing use of accelerated approvals for non-oncology indications will mean payers will no longer accept predatory prices set by drug makers. The June green light for Biogen's Aduhelm (aducanumab) in Alzheimer's disease is a case in point. After approval with a startlingly broad label and equivocal evidence of efficacy, both public and private payers revolted, forcing Biogen to backtrack and halve its sticker price in December.

Of course, drug makers can simply continue to lobby lawmakers and block price-control legislation. But they would be well advised to instead put their house in order. That starts with stamping out price inflation, pay-for-delay tactics and anti-competitive practices — and supporting value-based pricing schemes, competition for off-patent medicines, and lowering costs for patients.

There are signs that an increasing number of biotech CEOs understand this. Already, 200 have signed the No Patient Left Behind letter to Congress. As the missive aptly puts it, industry doesn't "invent drugs to have them placed out of the reach of people who need them." ❐

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