PBMs Are Innovating to Increase Affordable Access to Insulin

As a result of insulin patent protection leading to limited competition and severe concentration in manufacturing, the average list price of insulin – discovered in 1921 with a patent sold for $1 – has skyrocketed, nearly doubling between 2012 and 2016 from $2,841 to $5,705 per person annually.[i,ii] Today, insulin prices in the United States can be hundreds of dollars for a one-month supply, nearly five and a half times the global median price.[iii]

Manufacturers are blocking competition by taking advantage of loopholes in the U.S. patent system to extend drugs' patent protection ("patent evergreening").

- Uniquely, insulins have very limited generic or biosimilar competition because brand manufacturers have made incremental improvements that have kept insulin under patent from 1923 onward.[iv]
    - **Brand manufacturers have used multi-drug combination products as an effective strategy to extend the life of older insulin brands by developing new brands (with new patent protections).** Novo Nordisk's Fiasp and Fiasp Flextouch are a new combination of insulin with nicotinamide (vitamin B3) and an amino acid, which have market exclusivity (patent protection) until 2030.
    - **Brand manufacturers have extended patents by patenting *delivery mechanisms*** (e.g., insulin pens, auto-injection, dose-setting limiters, etc.). For example, Eli Lilly applied a new triple-screw thread feature to its Humalin and Humalog insulin products, which allowed for an additional 9 years (through 2024) of market exclusivity.
- These anticompetitive practices spare brand manufacturers from the competition that comes from having multiple insulin manufacturers that would help lower costs for patients.
- Rather than ending their own anticompetitive practices, brand manufacturers are deflecting blame for skyrocketing prices by falsely claiming the high prices they themselves set are a "coverage" problem.

PBMs are innovating to increase affordable access to insulin. Real solutions should build on these efforts and hold brand manufacturers accountable.

- Pharmacy benefit managers (PBMs) are innovating to reduce financial barriers for patients—in some instances outright eliminating patients' out-of-pocket costs.
    - A one-month supply of insulin for one health plan's enrollees cost $41.50 on average in 2018.
    - Last year, a PBM and health plan introduced a program to cap out-of-pocket insulin costs at $25 for a one-month supply for nearly 1 million eligible health plan enrollees, lowering their monthly out-of-pocket costs by 40% or more.
    - More recently, another PBM announced it could provide access to diabetes drugs, including insulin, at no out-of-pocket costs to health plan enrollees and at a savings to plan sponsors.
- **The private sector is working to help reduce out-of-pocket costs for patients, but manufacturers, not employers and taxpayers, must be held accountable for list prices.**

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[i] Ninety-six percent of total insulin market volume is concentrated between Eli Lilly, Novo Nordisk, and Sanofi SA.
[ii] Xinyang Hua, Natalie Carvalho, et al. Expenditures and Prices of Antihyperglycemic Medications in the United States: 2002-2013. JAMA. 2016; 315(13).
[iii] Nuala Moran. Analysis by UK startup Medbelle highlights extent of drug pricing disparity. Bioworld. November 21, 2019.
[iv] Jeremy A. Greene, Kevin R. Riggs. Why Is There No Generic Insulin? Historical Origins of a Modern Problem. NEJM. 2015; 372(12).