TEN KEY FACTS ABOUT THE MARKET FOR INSULINS

A century ago, patients were treated with insulins from pigs and cattle. Today, biopharmaceutical companies produce insulins that operate at the molecular level, which more closely resemble insulin released naturally in the body and more effectively manage diabetes. The range of options available today provide patients with the tools and flexibility necessary to better manage the disease and stay healthy – saving costs throughout the health care system.

However, these advances are meaningless if patients can't afford their insulin and other medicines at the pharmacy. While net prices for brand diabetes medicines have been falling, the amount insurers ask patients to pay out of pocket for these medicines has been on the rise in recent years. Increasing use of deductibles and coinsurance mean that more patients pay their cost sharing based on the undiscounted list price of medicines. This allows health insurance plans to shift more of the cost of health care onto a small proportion of patients with diabetes, subjecting them to high out-of-pocket costs at the pharmacy counter.

1. Factoring in discounts and rebates from manufacturers to health plans and middlemen, net prices for brand diabetes medicines declined by **10%** last year, continuing a trend of decreasing or flat net price increases over the past five years.

2. Insulins have experienced significant net price declines in recent years. For example, since 2014 net prices for long-acting insulins **declined** by 50%, on average, and net prices for rapid-acting/mixed insulins have **declined** by 40%. In fact, net prices for both of these commonly used classes of insulins are **lower today** than in 2007.[i]

3. Insurers and middlemen in the biopharmaceutical supply chain known as pharmacy benefit managers (PBMs)—three of which manage more than **74%** of all prescriptions filled in the United States—leverage robust competition among a broad range of long- and rapid-acting insulins to negotiate deep discounts from companies in exchange for preferable formulary placement. These dynamics lowered the net price of insulins by **83%** on average last year.[ii]

4. However, it does not feel that way to the patients who are not benefiting directly from these negotiated discounts and rebates. Health plans' benefit designs **increasingly** subject medicines to deductibles and/or coinsurance, which are typically based off of the undiscounted list price of a medicine, exposing a small proportion of patients to significant out-of-pocket costs. In fact, these patients pay 3.4 times more than patients not subject to a deductible for diabetes medicines.

5. **A small share** of insulin scripts filled by diabetes patients last year cost more than $35 in out-of-pocket costs, but these scripts accounted for the majority of total patient spending on insulin. This is not how insurance should work.

6. Every biopharmaceutical company that produces insulin **offers** patient assistance and cost-sharing assistance programs to help with the out-of-pocket costs of insulin as well as other diabetes medicines, which have become a crucial lifeline for many patients.

7. Last year, average out-of-pocket spending for patients taking brand diabetes medicines would have been more than twice as high without cost-sharing assistance from biopharmaceutical companies. Another analysis finds, patients just beginning treatment with brand medicines are nearly **three times** as likely to abandon medicines at the pharmacy counter without this assistance.

8. Many biopharmaceutical companies have taken additional steps to expand their **assistance programs** to help patients maintain access to therapy during the current public health emergency, including for those who need access to emergency insulin or who may have lost employment due to COVID-19.

9. Historically, the U.S. Food and Drug Administration was unable to approve generic insulins because of the scientific challenges and limitations on the scope of data that can be used in a generic drug application. However, as of March 2020, manufacturers are now able to seek regulatory approval **for biosimilar or interchangeable insulins**. These new products are expected to fuel additional competition in the insulin market.

10. It is important to note that manufacturers have previously brought "follow-on" insulins to market, which have driven tremendous competition among long- and rapid-acting insulins. For example, in the two years following the introduction of the first "follow-on" long-acting insulin in 2016, the net price across the class fell by **30%**.

LEARN MORE AT LETSTALKABOUTCOST.ORG/INSULIN

THE SYSTEM NEEDS TO WORK BETTER FOR PATIENTS WITH DIABETES

More of the significant discounts, rebates and other price concessions paid by biopharmaceutical companies should be shared with patients to lower costs at the pharmacy counter. Some insurers in the commercial market have already begun to do just that. One **analysis** found passing through rebates to patients in the commercial market could save certain diabetes patients as much as $800 annually while increasing premiums by just about 1%. Another **study** found that if discounts were passed directly on to patients at the pharmacy counter, a typical Part D patient with diabetes taking five medicines, including insulin, could see their out-of-pocket spending decrease by more than $900 a year.

More patients should be able to access insulin without worrying about deductibles. Some insurers have begun to provide first dollar coverage for insulin in high deductible health plans (HDHPs), which can dramatically improve patient affordability. **Research** has shown that transitioning to first dollar coverage of preventive medicines, such as insulin for diabetes patients enrolled in HDHPs, leads to substantial out-of-pocket savings. One **study** found if all patients with diabetes in HDHPs had first dollar coverage for insulin, out-of-pocket costs could be 2.4 – 3.7 times lower. In fact, exempting insulin from the deductible could save certain patients more than $1,500 annually in out-of-pocket costs while also allowing them to spread these costs more evenly throughout the year.

The Centers for Medicare & Medicaid Services recently announced it is taking steps to address seniors' out-of-pocket costs through a new voluntary demonstration program that would lower cost sharing for certain insulin to a maximum of $35 copayment for a 30-day supply. Three manufacturers and over 1,600 Medicare Part D plans will participate to offer lower out-of-pocket costs for patients through the demonstration for the 2021 plan year. These efforts represent important steps to improve affordability and predictability for patients who rely on insulin.

However, given that insurers and PBMs receive deep discounts and rebates on insulin, we believe more can be done to improve insulin affordability for patients and realign and strengthen incentives in the health care system. Other key policy changes to improve patient affordability include:

- Delinking supply chain payments from the price of a medicine
- Modernizing Medicare Part D coverage by establishing an annual cap on out-of-pocket costs and allowing patients to spread cost throughout the year
- Providing flat copays for insulin for patients in commercial health plans and those receiving cost-sharing subsidies in the Exchanges
- Counting out-of-pocket costs paid through third-party discount programs and cost-sharing assistance toward deductibles and out-of-pocket limits

[i] PhRMA analysis of SSR Health, October 2020: Includes long-acting insulin analogs (50% decline in class average annual net price between 2014 and 2020) and rapid-acting insulin analogs/mixed insulins (40% decline in class average annual net price between 2014 and 2020). These classes align with classifications reported in analysts' reports.

[ii] PhRMA analysis of SSR Health, October 2020