Advancing Biopharmaceutical Innovation in Diabetes Research and Development

November is American Diabetes Month – an important time when communities across the country and around the globe come together to bring awareness to diabetes. Throughout this month, it is important to recognize the critical role biopharmaceutical innovation has played – and continues to play – in transforming diabetes care. Diabetes is a complex, chronic condition that affects each patient differently and is often related to a range of other chronic illnesses, requiring a diverse range of treatment options.

The two most common forms of diabetes are **type 1 and type 2**.

Type 1 diabetes is an autoimmune condition where the immune system attacks insulin-producing cells in the pancreas, leading to little or no insulin production. It typically appears early in life and requires insulin therapy.

Type 2 diabetes occurs when the body becomes resistant to insulin or doesn't produce enough of it. This form of diabetes is often linked to different risk factors — though genetics also play a role — and usually develops later in life. It can sometimes be managed with lifestyle changes, though insulin may be needed with greater disease severity as the disease progresses over time.

Over the past decade, significant advances in therapies for both type 1 and type 2 diabetes have improved patient outcomes and quality of life, and there is promising pipeline of new medicines on the horizon that are offering hope for delaying or even preventing diabetes. For policymakers, understanding and supporting these innovations is key to improving access and ensuring the best possible care and quality of life for millions of Americans living with diabetes.

Insulin: Continued Progress Improves Treatment Outcomes for Patients

More than 100 years ago, insulins were derived from cows and pigs and their effects lasted only about six hours. Today, advanced insulin analogs more closely resemble insulin as it is naturally produced in the body, leading to more stable management of blood glucose, less frequent injections and convenient dosing options.

More recent treatment advances include ultra-long-acting insulins, which provide coverage for 24 hours or longer and ultra-rapid acting insulins which can be dosed directly before or even after meals — rather than in anticipation of meals. A wide range of insulin pen and pump options today also offer greater convenience, including some that reduce injections for patients requiring high doses or improve ease of use in children. Collectively, these treatment advances provide enhanced flexibility in dosing, reduce barriers to treatment adherence and offer better health outcomes for patients.

Comprehensive Solutions to Address a Wide Range of Chronic Diseases

New classes of medicines for type 2 diabetes have emerged over the past decade which not only improve glycemic control but effectively treat a wide range of chronic illnesses commonly affecting patients with diabetes. For example, GLP-1 receptor agonists and SGLT2 inhibitors not only manage blood sugar but also offer cardiovascular and kidney health benefits. GLP-1 receptor agonists have also been approved to treat obesity, a highly prevalent chronic illness in the U.S. and one that commonly affects those with type 2 diabetes.

The Future of Diabetes Care: Delaying and Preventing Disease Onset

Biopharmaceutical research is moving toward preventing and delaying the onset of diabetes through immunotherapies and other cutting-edge treatments. In a landmark development, the FDA recently approved the use of a monoclonal antibody shown to delay the onset of stage 3 type 1 diabetes in high-risk individuals. In addition, thanks to new innovative autoantibody testing programs, type 1 diabetes can now be detected before symptoms are even noticeable. These types of groundbreaking advancements stand to fundamentally alter the course of the disease, reducing the long-term burden on patients and the health care system.

Looking to the future, prevention is also a key focus: efforts are underway to develop a vaccine to prevent type 1 diabetes by halting the autoimmune attack on insulin-producing cells, and for type 2 diabetes, research into precision and personalized medicines is offering tremendous promise for more targeted treatment approaches.

From once-weekly insulin formulations, which are in the very late stages of development, to next-generation combination therapies, future treatments aim to improve adherence, enhance efficacy and more comprehensively address diabetes-related complications.

Innovative Examples in the Pipeline

A DNA immunotherapy is in development for the treatment of **type 1 diabetes**. The therapy, a recombinant plasmid that encodes pre-proinsulin, is thought to help in the preservation of pancreatic beta cell function (insulin-producing cells).

A medicine in development for the treatment of **type 2 diabetes** acts on three different receptors in the body that are involved in the release of insulin and controlling hunger. The subcutaneous injectable combines a glucagon-like peptide 1 (GLP-1) receptor agonist, a gastric inhibitory polypeptide (GIP) receptor agonist and a glucagon receptor agonist. Collectively, these receptor agonists encourage the release of insulin, slowing the process in which food moves through the body and signal to the brain that a person is full. Together, these effects help to lower blood sugar and can lead to weight loss.

Policy Implications and Opportunities

As biopharmaceutical researchers drive progress in diabetes care, it's critical that patients can access these life-changing treatments to effectively manage their disease. From novel insulin options that more closely resemble insulin as it naturally produced in the body, to therapies that protect the heart and kidneys, and new approaches that delay or prevent disease onset, these medical advancements offer better treatment outcomes for millions of people living with diabetes.

Unfortunately, insurers and their pharmacy benefit managers (PBM) are shifting more costs onto patients through the use of high deductibles and coinsurance, often forcing patients to pay based on the full list price for brand diabetes medicines, not the lower, negotiated price. In fact, patients with deductibles and coinsurance taking brand diabetes medicines paid 3.5 times more out of pocket, oon average, in 2021 compared to patients with only fixed copays.

A growing share of PBM compensation is tied to the list prices of medicines, which incentivizes PBMs to prefer medicines on formularies with higher list prices and large rebates over lower cost alternatives. In fact, in recent years the big three PBMs, which control 80 percent of the market, have denied coverage of lower cost biosimilar and authorized generic insulins in favor of high list priced versions, which would have offered patients with diabetes lower out-pocket costs.

Policymakers must take additional measures to lower the cost of care for diabetes patients by supporting common-sense solutions to fix the misaligned incentives in the system that pad profits for middlemen and drive up costs for patients, including making sure savings are shared directly with patients at the pharmacy and breaking the link between the price of medicines and the fees middlemen receive. Reforms like these, which crack down on abusive PBM and insurer practices, are supported by nearly 90% of insured Americans.

PhRMA remains dedicated to collaborating with policymakers to advance these critical efforts and deliver better, more affordable care for the millions of Americans living with diabetes.