Prescription drug prices in the US are more than 2.5 times as high as those in other similar high-income nations and are a leading health care concern among US residents. Given these factors, and in response to President Biden's executive order promoting competition, the US Department of Health and Human Services (HHS) released a comprehensive plan to address drug prices in September 2021. The plan highlighted 3 priorities: (1) making drug prices more affordable and equitable for all consumers and throughout the health care system, (2) improving competition throughout the prescription drug industry, and (3) fostering scientific innovation to promote better health care and improve health.

To support this agenda, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) conducts research on drug pricing, utilization, access, and innovation. For instance, a 2021 ASPE report found that more than 5 million Medicare beneficiaries reported difficulty affording medicines in 2019. A recent journal article projected that savings from biosimilars from 2021-2025 would total at least $38 billion and as much as $124 billion—or approximately 6% to 19% of total spending on biosimilars. A recent report on US and international generic drug utilization showed that US brand-name drug prices are 344% of prices in similar high-income countries, whereas US prices for generic drugs are actually lower than in comparator countries (84% of foreign prices). A series of projects are also examining the drug supply chain, including an overview of stakeholders and relationships. In addition, the HHS plans to publicly track large price increases in prescription drugs to improve drug price transparency.

Using evidence and research to guide this work, the HHS plan outlined actions that the Biden administration is taking to reduce high drug prices. One key agency in this work is the Centers for Medicare & Medicaid Services (CMS), which is addressing prescription drug costs in Medicare, Medicaid, and the health insurance marketplace. In Medicare, a rule finalized in April established that price concessions that Medicare Part D plans receive from pharmacies must get passed along to beneficiaries at the pharmacy counter, saving an estimated $26.5 billion between 2024 and 2032. For physician-administered drugs, paid for by Medicare Part B, the CMS implemented a provision from 2021 legislation that requires drug manufacturers without Medicaid drug rebate agreements to submit average sales price information for their Part B drugs, which will enable payment to be pegged to a lower rate than was previously in place for these drugs (including, for instance, common treatments such as hyaluronic acid injections, where payment may decline by ≥50% under this new rule). This change is projected to reduce Medicare costs by $3.5 billion over 10 years and produce significant savings to beneficiaries. In addition, Medicare is working with the US Food and Drug Administration (FDA) to share educational materials with clinicians about biosimilar and interchangeable biological products.

The HHS is also taking actions related to private insurance and Medicaid. In May 2022, the department finalized regulations designed to prevent health insurance marketplace plans from discriminating against beneficiaries with certain health conditions through the use of selectively designed drug formularies. The rule contained examples of how drug formularies might be discriminatory and how issuers can correct them, building on prior research that found that some insurers were putting all drugs from certain classes (for instance, antiretrovirals for HIV) on the highest cost-sharing tier. In Medicaid, a new regulation effective in July 2022 incentivizes manufacturers to offer states the same value-based purchasing arrangements for high-cost drugs.
that they offer to other insurers, and the CMS will also be launching a new learning collaborative in October 2022 to support state efforts on drug cost management and transparency. Medicaid is also working to encourage uptake of generic and biosimilar drugs through education to state drug utilization review boards.

Meanwhile, the FDA has established policies that support a competitive marketplace for generic drugs and biosimilar products, which can lower prices. Through its Drug Competition Action Plan and Biosimilars Action Plan, the FDA is working to help remove barriers to generic and biosimilar market entry, including through workshops and guidance to facilitate product development; initiatives to improve the quality of applications and enhance the efficiency of review by the FDA; and efforts to reduce "gaming" that delays competition and extends monopolies beyond what Congress intended. The agency has issued policy documents designed to ensure timelier generic drug approvals and earlier patient access by reducing the number of assessment cycles, facilitating prompt labeling updates, and providing advice on how to avoid common application deficiencies that lead to approval delays.

The FDA approved the first interchangeable biosimilar insulin product last summer, Semglee (insulin glargine-yfgn), which is biosimilar to its reference product, a long-acting insulin analog called Lantus (insulin glargine). As noted in the research discussed earlier, biosimilar and interchangeable products can reduce drug costs significantly, given that biosimilar prices average 15% to 35% less than their reference products.

Legislation remains a critical potential tool in reducing drug prices and costs, and the HHS plan released last fall highlights priorities such as drug price negotiation in Medicare, caps on out-of-pocket costs, and policies to slow price increases over time on existing drugs. While Congress continues to explore legislative options in this area, the Biden administration has been tackling these issues through its available regulatory tools. None is a silver bullet, but collectively they offer the potential for substantial improvements in drug affordability for millions of people in the US. Future research to assess these policies will be critical in efforts to address high drug prices to protect consumers and health care programs more broadly.