On May 11, President Trump delivered remarks about his administration’s new plan to help lower drug prices. The President blamed “soaring drug prices” on “everyone involved in the broken system,” including “the drug makers, insurance companies, distributors, pharmacy benefit managers, and many others,” such as “middlemen,” “special interests” as well as “the government.”

As steps “to get prices under control,” the President noted that his administration has “reformed the Drug Discount Program for safety net hospitals to save senior citizens hundreds of millions of dollars on drugs this year alone” and is “also increasing competition and reducing regulatory burdens so drugs can be gotten to the market quicker and cheaper.”

Among the more specific reforms mentioned by the President, the administration’s plan “gives Medicare Part D plans new tools to negotiate lower prices for more drugs, and make sure that Medicare Part D incentives encourage drug companies to keep prices low”; “bans the Pharmacist Gag Rule, which punishes pharmacists for telling patients how to save money”; and “will also speed up the approval process for over-the-counter medicines so that patients can get more medicines without prescription.” Other possible reforms mentioned by the President include “ending Obamacare’s twisted
incentives that actually encourage higher drug prices”; “end[ing] the dishonest double-dealing that allows the middleman to pocket rebates and discounts that should be passed on to consumers and patients”; and “end[ing] the global freeloading once and for all” where “foreign governments extort unreasonably low prices from U.S. drug makers, [causing] Americans [to] have to pay more to subsidize the enormous cost of research and development.”  The President also suggested that the plan may involve reforms to the patent system, stating: “We are getting tough on the drug makers that exploit our patent laws to choke out competition. Our patent system will reward innovation, but it will not be used as a shield to protect unfair monopolies.”

The President concluded his remarks: “In the coming weeks, we will work with Congress to pass legislation that will save Americans even more money at the pharmacy. For that, we need the help of Congress, and we think it will be forthcoming.”

Shortly after the President’s speech, FDA Commissioner Scott Gottlieb released a statement “applaud[ing] President Trump for making this one of the Administration’s priorities and introducing a bold plan that puts patients first in advancing actions to address the rising list prices of prescription medicines.” According to the press release: “The FDA shares the goal of ensuring that American patients have access to quality and affordable care that meets their needs. This is why we’re prioritizing actions to encourage the timely development and approval of generics and biosimilars.”

Several industry groups and organizations also published their reactions to the plan. Generally, but with some exceptions, the reactions were cautiously optimistic, commending the President for his remarks but noting some concerns or additional reforms that may be necessary. Below are some highlights from the reactions: (see the links below for the full press releases)
• Association for Accessible Medicines (AAM): “President Trump’s embrace of generic and biosimilar competition as a key to lowering brand-name drug prices is an important step forward for patients coping with skyrocketing health care costs.”

• Biotechnology Innovation Organization (BIO): “We look forward to working with the administration on solutions that help provide all patients access to prescription drugs with out-of-pocket costs they can afford. However, we have concerns that some of the ideas proposed today could, if adopted, hurt patient access to the medicines they need today and the future cures and treatments they’re desperately waiting for America’s biopharmaceutical innovators to discover.”

• Biosimilars Forum: “We were pleased that the plan specifically notes the Food and Drug Administration’s recently launched education initiative, demonstrating that it prioritizes raising awareness about the potential of biosimilars to lower costs while providing the same safety and effectiveness as their reference biologic drugs.”

• America’s Health Insurance Plans (AHIP): “We commend President Trump and his Administration for their focus on this essential issue. Insurance providers have every incentive to lower drug prices for consumers, and we share the goal of getting the most clinically effective drugs into the hands of patients at the lowest cost.... We are concerned that some proposals would actually lead to higher costs for Americans, because they would weaken the ability of plans to negotiate lower prices.”

• Pharmaceutical Care Management Association (PCMA): “While PCMA is still reviewing the Administration’s plan, we support its call for greater flexibility in benefit design to encourage better price negotiations, including allowing Medicare Part D plan sponsors to promote lower cost
generics and biosimilars.... Getting rid of rebates and other price concessions would leave patients and payers, including Medicaid and Medicare, at the mercy of drug manufacturer pricing strategies. PBMs have long encouraged manufacturers to offer payers alternative ways to reduce net costs. Simply put, the easiest way to lower costs would be for drug companies to lower their prices.”

**Academy of Managed Care Pharmacy (AMCP):** “AMCP has long supported several of the recommendations contained in the President’s blueprint, including the need to foster a competitive generic and biosimilars marketplace, and greater flexibility in benefit design for the Medicare program. However, AMCP also believes some of the elements outlined in the President’s blueprint require further consideration and broad stakeholder input to ensure that they are sustainable solutions to decreasing medication costs without resulting in unintended consequences that may disrupt patient care.”

**CVS Health:** “We commend the Trump Administration’s focus on reducing the cost of prescription drugs, and we agree more can and needs to be done.”

**BlueCross BlueShield Association (BCBS):** “We look forward to evaluating specific proposals as they become available, and we will continue to work with the administration and Congress to reduce barriers to competition and consumer choice, increase transparency, promote innovation and strengthen patient education so that people can access the drugs they need at a more affordable price.”

Stay tuned to Big Molecule Watch for further developments.