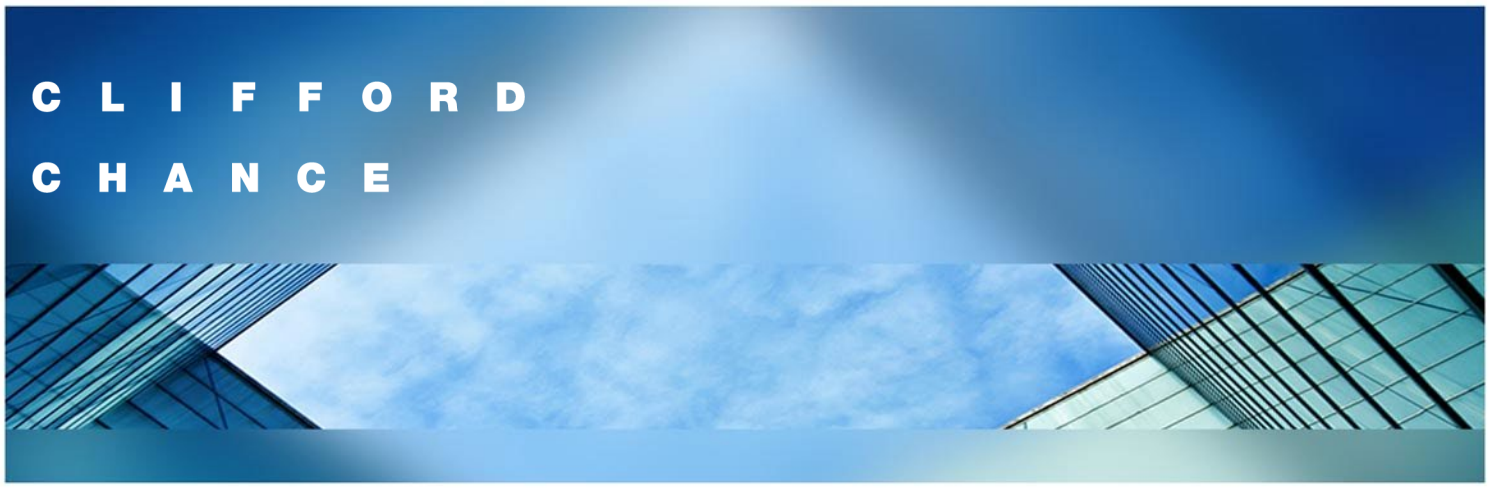

DRUG PRICING CHECK-UP: A DEBRIEF OF THE FTC AND DOJ'S THIRD AND FINAL LISTENING SESSION ON LOWERING AMERICANS' DRUG PRICES THROUGH COMPETITION

On August 4, 2025, the U.S. Department of Commerce joined the U.S. Department of Justice and the Federal Trade Commission in hosting the final listening session on drug pricing, as mandated by President Trump's executive order, titled "Lowering Drug Prices by Once Again Putting Americans First."[1] The session, "Turning Insights into Action to Reduce Drug Prices," brought together congressional staffers representing their members, who discussed the issues affecting drug pricing and proposed possible solutions.[2]

Coke Morgan Stewart, Acting Under Secretary of Commerce for Intellectual Property and Deputy Director of the U.S. Patent and Trademark Office, began the panel by encouraging efforts to promote fair competition in the United States and globally, noting that "for far too long the United States has paid more than its fair share for drugs." Despite the purported call to action, she cautioned that without patents and intellectual property rights, "innovation would cease." She advised that "a world with fewer patents may look like a utopia of open markets and free access to innovations, [but] in reality, it would destroy the very incentives that promote competition and access to medications." Any initiatives aimed at reforming the current system should ensure that "those efforts do not damage the very system enshrined in the constitution that makes the United States the most innovative place on earth." While the executive branch continues to underscore the significance of lowering drug prices, her comments suggest a reluctance

1 Executive Order 14273, Lowering Drug Prices by Once Again Putting Americans First (Apr. 15, 2025), https://www.whitehouse.gov/presidentialactions/2025/04/lowering-drug-prices-by-once-again-putting-americans-first/.

2 Panelists: Franci Rooney Becker (Chief Counsel on the Senate Judiciary Committee to Senator John Cornyn), Thomas DeMatteo (Chief Counsel on the Senate Judiciary Committee to Senator Mike Lee), J. John Lee (Chief Counsel for Intellectual Property on the U.S. House of Representatives, Committee on the Judiciary), Peter-Anthony Pappas (Director of Intellectual Property Policy for the Senate Committee on the Judiciary to Senator Thom Tillis), Nicholas D. Pottebaum (Health Policy Advisor for Senator Chuck Grassley), and Peter Stein (Senior Policy Advisor to U.S. Representative Diana Harshbarger).

toward pursuing substantial legislative measures that could affect the existing patent framework.

The level of bipartisan support for substantial reform remains unclear. Additionally, the composition of the panel may have limited the range of solutions discussed and diminished the depth of the overall conversation. Regardless, below is a summary of the topics discussed by the panelists.

1. ELIMINATE REGULATORY OBSTACLES THAT ENCOURAGE ANTI-COMPETITIVE BEHAVIOR

- Thomas DeMatteo addressed the issue of limited transparency in drug pricing, adding that "this problem is compounded by the labyrinth of regulation and a web of intermediaries, such as insurance companies, PBMs, and drug wholesalers." Though he acknowledged that there are benefits, many intermediaries can become "mere toll collectors along the drug supply chain" and use the complex regulatory system to their advantage. He referenced two pieces of legislation—the Biosimilar Red Tape Act and the Short on Competition Act—both designed to facilitate expedited reviews for specific categories of products or circumstances.
- J. John Lee pointed out that the current system is "off-balance." There is a need for clear and robust patent protection, as patents can encourage innovation, but limitations are necessary because, in some cases, patents may hinder innovation. There are some possible solutions to address this balance either through litigation or through legislation aimed at removing obstacles to competition.

2. PROMOTE LEGISLATIVE SOLUTIONS TO PREVENT PBM'S "GAMESMANSHIP"

- Nicholas D. Pottebaum referenced a recent congressional investigation that showed how pharmacy benefit managers (PBMs) "encourage drug markets to spike drug costs," specifically insulin, through their rebate practices and formulary placement strategies at the expense of patients. While the complexities of drug pricing and the role of PBMs in it are still being explored, he pointed to the Bipartisan PBM Transparency Act as a potential legislative solution currently under consideration. This bill prohibits PBMs from engaging in deceptive or unfair pricing practices, such as spread pricing—where PBMs charge health plans more for prescription drugs than they reimburse pharmacies—and the practice of arbitrarily clawing back reimbursement payments.
- Peter Stein called upon Congress to break apart PBMs through legislation, pointing to the railroad and banking industries as places where it has successfully been done before.

3. SAFEGUARD PATENTS WHILE STREAMLINING BIOSIMILAR MARKET ENTRY

- Panelists focused on the need to secure the strength of the current patent system; however, panelists disagreed on whether any change was needed. Peter-Anthony Pappas, for instance, expressed the view there is insufficient data to show misuse of the patent system or that any change is needed, while

other panelists referenced legislative proposals that would safeguard the current system while simultaneously reducing barriers for new entrants.

- Franci Rooney Becker referenced the Affordable Prescriptions for Patients Act as a possible solution to deter the misuse of patent thickets in the patent dance. The bill, in specific circumstances, would restrict the number of patents that a biological product manufacturer may assert in a patent infringement lawsuit against a company intending to market a biosimilar version.
- She also mentioned the Drug Competition Enhancement Act, a piece of legislation that, if enacted, would expand the Federal Trade Commission's authority by designating anticompetitive product hopping as an antitrust violation. The goal of the bill would be to facilitate market entry for generics and biosimilars, driving down costs for consumers.

CONCLUSION

This panel showed that scrutiny is likely to continue for the duration of the current administration. As of now, Daniel Guarnera, Director of the FTC's Bureau of Competition, emphasizes that "the challenges to bringing down drug costs are significant, but so is the commitment by President Trump and those [] serving in his administration, as well as [their] colleagues in Congress, to confront these challenges head on." Dina Kallay, Deputy Assistant Attorney General for International Policy and Appellate at DOJ's Antitrust Division made clear that the "work under President Trump's Executive Order to Lower Drug Prices has only just begun." Stakeholders should continue to stay informed as Congress considers the proposed reforms, and the agencies apply their newly acquired insights to enforcement.

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