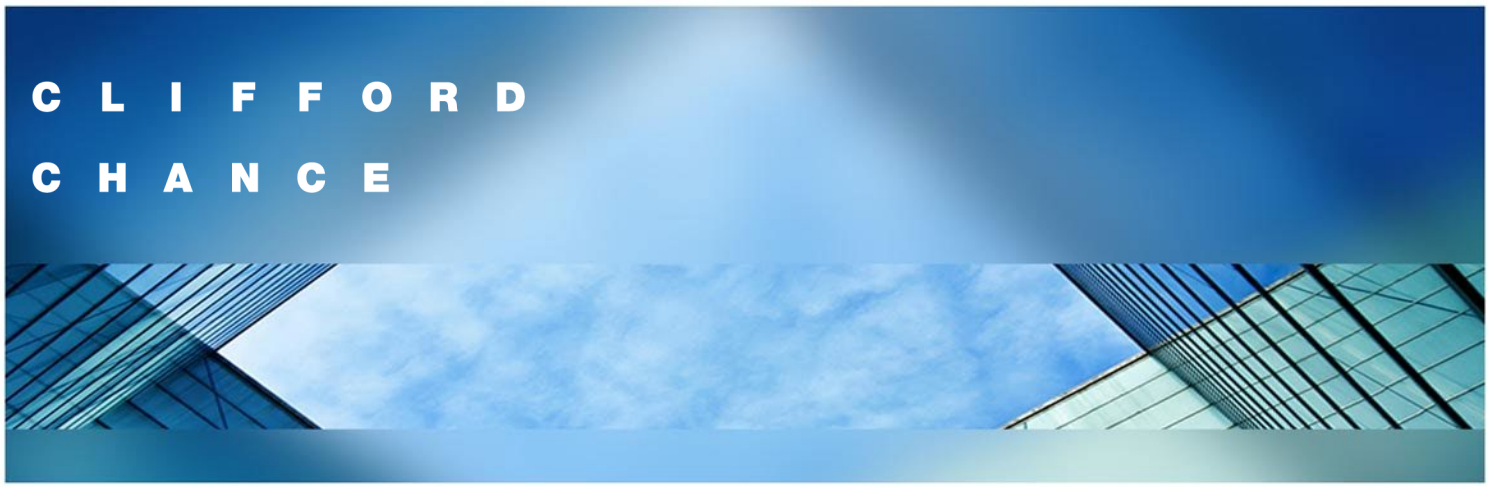

DRUG PRICING CHECK-UP: A DEBRIEF OF THE FTC AND DOJ'S FIRST JOINT LISTENING SESSION ON LOWERING AMERICANS' DRUG PRICES THROUGH COMPETITION

INTRODUCTION

On June 30, 2025, the U.S. Department of Justice's Antitrust Division (DOJ) and the Federal Trade Commission (FTC) jointly hosted one of three planned "listening sessions" on drug pricing, as mandated by President Trump's executive order, titled "Lowering Drug Prices by Once Again Putting Americans First."[1] The session brought together government officials, patient advocates, academics, and industry representatives as panelists.[2] The agencies framed the series as a hunt for purported "regulatory abuse" and "gamesmanship" that has the potential to impede generic or biosimilar competition. They will reconvene on July 24 for a panel titled, "Formulary and Benefit Practices and Regulatory Abuse Impacting Drug Competition," and will conclude on August 4 with a solutions-focused panel titled, "Turning Insights into Action to Reduce Drug Prices."

Assistant Attorney General Gail Slater, in her introduction, noted that Americans—because of high drug costs—are facing a choice: either to "skimp on life's necessities" or forgo their prescription drugs altogether. In her view, competition is vital to lowering existing drug prices and bringing forth innovative drug treatments. But to ensure competition, the agencies must first understand the "crucial difference between supporting innovation and gamesmanship," and "not condone rent seeking that blocks or raises the price of generic or biosimilar treatments," urging the agencies to "be vigilant that regulatory barriers do not unnecessarily favor incumbents or make markets susceptible to [] rent seeking." Her comments

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

2 Panel 1 consisted of Shashank Upadhye (Partner, Upadhye Tang LLP), Sneha Dave (Executive Director, Generation Patient), Marcus Meier (former Assistant Director of Healthcare Division, FTC), Hans Sauer (Deputy General Counsel & VP, Biotechnology Innovation Organization), and Stephen Schondelmeyer (Professor, University of Minnesota). Panel 2 consisted of Alex Brill (Senior Fellow, AEI), Michael Carrier (Professor, Rutgers Law School), James Gelfand (President & CEO, ERISA Industry Committee), Julie Reed (Executive Director, Biosimilars Forum), and Jocelyn Ulrich (VP, Pharmaceutical Research & Manufacturers of America)

reflect the antitrust agencies' continued focus on the pharmaceutical industry, and the healthcare and life sciences industries more broadly.

Below is a summary of the topics discussed by the panelists.

1. EXCLUSIVE SUPPLY AGREEMENTS AND PAY-FOR-DELAY AGREEMENTS

- The panel discussed the potential for competitive effects associated with exclusive contracts with key intermediaries, such as manufacturers of critical ingredients where supply is exclusive to approved DMF holders, or where medications are dependent on certain physical characteristics.
- Generic manufacturers of inhalers—because the FDA requires inhalers to have similar plume geometry, particle size distribution, and spray pattern—often face barriers caused by exclusive contracts. When exclusive contracts exist, generic companies don't always have the option to use another device, resulting in an uphill battle or denial from the market altogether.
- Shashank Upadhye opined that these types of contracts "may warrant further scrutiny," but any proposed solutions need to be fair and ensure predictability for both the brand and generic stakeholders.

2. PATENT AND REGULATORY BARRIERS

- Several panelists described pay-for-delay agreements and the proliferation of secondary and continuation patents as barriers to genuine competition. Marcus Meier, a former Assistant Director of the Health Care Division at the FTC, referred to them as a "disturbing trend" that reflects "a sharing of monopoly profits." Other panelists called for the FTC to further investigate these practices.
- The panel conducted an examination of issues concerning "patent thickets," a collection of patents that cover, and occasionally overlap on, a single product. Sneha Dave suggested that "patent thickets" create competitive obstacles by increasing the risk of infringement lawsuits, and "effectively keep[] our drug prices high, and the cost of our therapeutics unaffordable." She endorsed legislative solutions that enhance "USPTO-FDA collaboration to ensure better data sharing," helping to prevent patent abuse and incorporate patient input prior to Patent Trial and Appeal Board decisions.
- Regulatory exclusivities (e.g., orphan drug, three-year market, and pediatric exclusivities) and the complexity of the drug approval process (e.g., three-way pharmacokinetic studies and biosimilar suffix requirement) were also identified as barriers to entry for biosimilar and generic products. Alex Brill proposed streamlining the approval process "to foster competition across a wider array of biologic drugs—particularly smaller biologic drugs."

3. CONCERNS ABOUT PHARMACY BENEFIT MANGERS (PBMS)

- The panel also suggested that PBMs limit access to lower-cost biosimilars, citing the FTC's published report[3] on their rebate structure.
- Julie Reed expressed concern that PBMs "prefer the highly rebated, full-priced, fully loaded brand drug" over biosimilars that are 80% discounted. Similarly, Jocelyn Ulrich, Vice President of PhRMA suggested "PBMs have increasingly excluded biosimilars from their commercial formularies."
- Joclyn Ulrich proposed reforming the 340B Drug Pricing Program and PBM rebate structure to incentivize the adoption of biosimilars and reduce costs to consumers. Similarly, Stephen Schondelmeyer called for standardizing the specialty drug market and assigning preferred status to lower-cost products on formularies, such as biosimilars, since "limited distribution drugs limit access . . . and allow [manufacturers] to engage in price maintenance and schemes."
- The upcoming session on July 24th is expected to discuss benefit and formulary practices of PBMs further.

4. THE DOWNSIDE OF "PRODUCT-HOPPING"

- The panel discussed "product-hopping," noting that the practice of shifting patients to new, more expensive formulations right before generic entry continues to concern enforcers. Alex Brill opined that "these strategies create uncertainty and are unequivocally inefficient…add[ing] cost to the system with little to no benefit."
- Professor Carrier called for robust legislation and scrutiny by the courts to combat the harms caused by product-hopping.

5. ISSUES ASSOCIATED WITH THE FDA'S INTERCHANGEABILITY DESIGNATION

- The panel examined the issues stemming from the FDA's interchangeability designation for biosimilars, particularly the confusion it creates among healthcare providers who might mistakenly believe that non-interchangeable biosimilars are inferior, thus affecting the overall adoption of biosimilars.
- James Gelfand referred to the interchangeability designation as a legislative "poison pill" that is duplicative, unnecessary, and costly. Because there is no clinical difference between the biosimilars and the reference drugs, he suggested eliminating this regulatory hurdle to keep drug prices low.

[3] Fed. Trade Comm'n, Specialty Generic Drugs: A Growing Profit Center for Vertically Integrated Pharmacy Benefit Managers (Jan. 2025), https://www.ftc.gov/system/files/ftc_gov/pdf/PBM-6b-Second-Interim-Staff-Report.pdf.

CONCLUSION

Stakeholders should continue to monitor upcoming listening sessions through our client alerts. The listening session—and the plan to do everything possible to tackle the problems mentioned—underscores not only the agencies ongoing scrutiny of the pharmaceutical industry but also their readiness to engage in litigation in this particular space. Stay tuned for the next debrief.

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