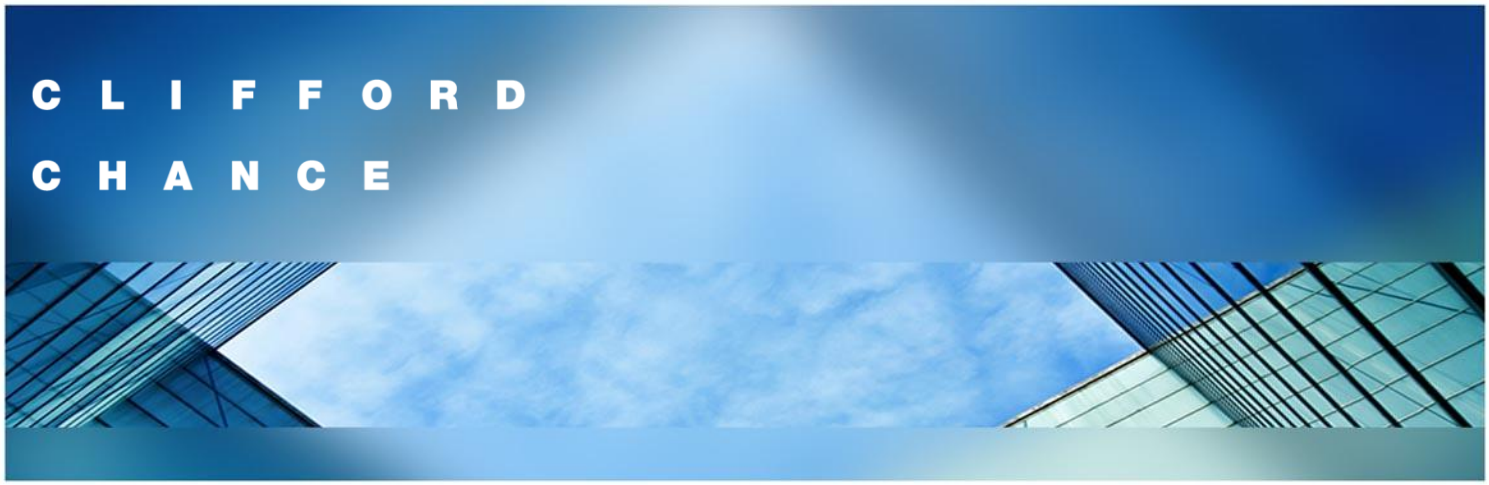

DRUG PRICING CHECK-UP: A DEBRIEF OF THE FTC AND DOJ'S SECOND JOINT LISTENING SESSION ON LOWERING AMERICANS' DRUG PRICES THROUGH COMPETITION

On July 24, 2025, the Federal Trade Commission (**FTC**) and the U.S. Department of Justice's Antitrust Division (**DOJ**) jointly hosted the second of three mandated "listening sessions" on drug pricing.[1] This session titled, "Formulary and Benefit Practices and Regulatory Abuse Impacting Drug Competition," focused primarily on what Chairman Ferguson perceived to be the three potential causes of reduced competition in the drug market:

- The business relationship between PBMs and drug manufacturers;
- The misuse of the U.S. Food and Drug Administration (**FDA**)'s Orange Book and drug safety programs; and
- Government regulations that disincentivize competition on price and product quality.

Chairman Ferguson showed his hand during his introduction, taking fire at incumbents in the industry, who "engage in regulatory arbitrage or 'lawfare' to edge out rivals." "Rather than increasing one's market share through genuine innovation," he claimed that incumbents engage in "competition in rent-seeking." By letting the rent-seeking activity continue, he believes that "companies [are able to] reap financial rewards that are entirely out of proportion to their contribution to genuine innovation in pharmaceuticals." He also highlighted the FTC's work in the area, placing special emphasis on the FTC's ongoing investigation into PBMs and its efforts to address improper listings in the FDA's Orange Book. His comments, and the FTC's recent actions in the pharmaceutical space, reflect the antitrust agencies increasing scrutiny on the practices of the industry and raise a vital question—Will the increasingly hostile rhetoric *actually* turn into more enforcement action and policy changes?

[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/.

Below is a summary of the topics discussed by the panelists.[2]

1. The Evolution of the PBM and its Downsides

- The panel discussed the potential anticompetitive effects stemming from the horizontal and vertical integration of PBMs, which result in a handful of firms holding significant market power. While the discussion centered on the actions of PBMs that increase costs for pharmacies and consumers, Stacie Dusetzina pointed out that without PBMs, [] Americans [might] pay more for their medications than they currently do."
- Cheryl L. Danberg opined that the consolidation in the industry "improves the ability of the PBMs to negotiate better prices with drug manufacturers, who themselves have market power," but the potential cost-savings are downplayed by increasing prices and profit-maximizing in other areas. For example, after the implementation of the medical loss ratio (**MLR**) regulations—which mandated that a certain percentage of premium revenue incurred by health insurances be spent on quality improvement activities and health care claims, allowing customers to receive value for their premium—PBMs found a workaround through intercompany eliminations, thereby PBMs could earn more than "15 to 20% [of what] the MLR allows" and this workaround has since become a "significant source of revenue for vertically integrated companies."
- Kathleen Jaeger flagged how PBMs are "steering formularies toward[s] their own private-labeled products and granting them favorable treatment" but admitted that PBMs are only half the story. GPOs, with the three largest controlling over 90% of the US market in generic purchasing, also engage in similar practices that raise costs for consumers.
- Panelists agreed on the need for transparency but disagreed about the best policy and enforcement measures for regulating the industry. Several proposals were made, such as incentivizing insurance plans to select lower-cost drugs, creating payment models that reimburse pharmacies based on drug acquisition cost plus mandate a set dispensing fee, and utilizing federal enforcement actions.

2. Limited Choice in Insurance Plans

- Panelists raised concerns regarding the decline in standalone Part D plans. Cheryl L. Danberg referred to the trend as "a worrisome sign and something that policymakers need to be paying attention to," while Stacie Dusetzina stated that it was a sign that the "market is not a level playing field." To ensure access to affordable and comprehensive medical drug coverage, panelists argued that choice is needed to protect consumers

[2] Panel 1 included Cheryl L. Damberg (Director, RAND Center of Excellence on Health System Performance), Tim Dube (Senior Vice President for Policy and Regulatory Insights, PCMA, a trade association representing the interests of PBMs), Stacie Dusetzina (Professor of Health Policy and an Ingram Professor of Cancer Research at Vanderbilt University School of Medicine), Kathleen Jaeger (President and CEO, MEDSecurean LLC), Joe M. Shields (CEO, Transparency-Rx). Panel 2 included Sarah D'Orsie (Senior Vice President, Fresenius Kabi USA LLC), Adam Mossoff (Professor of Law, George Mason University School of Law), Maryll Toufanian (Senior Vice President for Regulatory Strategy and Government Affairs, Amneal Pharmaceuticals Inc.), and Sarah Yim (Director, Office of Therapeutic Biologics and Biosimilars in the Office of New Drugs at FDA's Center for Drug Evaluation and Research).

from unreasonable premiums, and this may eventually require regulatory intervention.

- Joe M. Shields noted that employers are harmed by the consolidation of the insurance industry, since they face extensive barriers when they attempt to shop for the best insurance. For instance, employers who try to carve out PBMs to avoid high drug prices may face financial penalties, higher administrative fees, or denial in access to integrated medical networks. He urged the FTC to prohibit tying PBM services to networks and ban retaliatory fees that deter PBM carve-outs.

3. Methods Used to Delay Generic Competition

- Several panelists discussed the FDA's Orange Book and its impacts on market competition, including the overlisting or mislisting of patents (and the creation of patent-thickets), which can lead to unreasonable delays in generic entry and higher costs. Chairman Ferguson advised that "just last month, [the FTC] sent warning letters to pharmaceutical companies disputing the propriety of over 200 patent listings in the FDA’s Orange Book across 17 different name-brand drug products" in an effort to halt some of the more predatory practices.
- According to the panel, brand name companies sometimes attempt to insert new barriers in legislation or by using the regulatory process. For instance, Maryll Toufanian opined that citizen petitions are too often used to prevent generic entrants. When the government has to review each one, it takes bandwidth away from the staff, who could "otherwise support[] generic drug approvals," since "the same small cadre of experts who are working on generic drug development have to put their resources into the ultimately unsuccessful citizen petitions."
- Several other panelists mentioned that the same issues arise with serial litigation, when multiple, duplicative lawsuits over similar patents force generics/biosimilars into costly settlements or delayed launches.

CONCLUSION

Following the second panel, Taylor C. Hoogendoorn, Deputy Director of the FTC's Bureau of Competition, noted that the listening sessions highlighted how the "healthcare industry is rife with misaligned incentives, dominant oligopolies, and market structures that are opaque by design." It seems evident that under President Trump, the FTC will continue to prioritize competition in all parts of the healthcare and life science sector. Tune in after August 4th for the final listening session debrief.

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