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Department of Justice and Federal Trade Commission Host Second Listening Session on Lowering Drug Prices Through Competition, Focusing on Industry Entities and Regulatory Abuse

OVERVIEW

On Thursday July 24, 2025, the Department of Justice (DOJ) and the Federal Trade Commission (FTC), in coordination with the Department of Health and Human Services (HHS) and the Department of Commerce (DOC), hosted a listening session titled *Formulary and Benefit Practices and Regulatory Abuse Impacting Drug Competition*. The session gathered input from industry leaders and experts in two panel discussions. As part of implementing President Donald Trump's Executive Order No. 14273, *Lowering Drug Prices by Once Again Putting Americans First*, this was the second of three joint agency-led listening sessions focused on improving the affordability of prescription drugs through competition. The final session will be held on Monday, August 4, 2025, and will focus on *Turning Insights into Action to Reduce Drug Prices*. Per the Executive Order, listening sessions will inform the joint report to be issued by October 12, 2025, on recommendations to address anticompetitive practices in pharmaceutical markets.

A summary of key takeaways from the second listening session is provided below.

PANEL 1: BENEFIT AND FORMULARY PRACTICES AND REGULATIONS THAT HARM DRUG COMPETITION

Panelists:

- Cheryl L. Damberg, Director of the RAND Center of Excellence on Health System Performance; MedPAC Commissioner
- Time Dube, Senior Vice President for Policy and Regulatory Insights, Pharmaceutical Care Management Association

- Stacie B. Dusetzina, PhD, Associate Professor, Department of Health Policy, Vanderbilt University School of Medicine
- Kathleen Jaeger, Founder/CEO, Center for American Medicine Resiliency
- Joseph M. Shields, Esq., CEO, Transparency-Rx

This panel explored the complex relationships within the drug supply chain and their impact on competition and drug costs for health plan sponsors and patients. Panelists focused on how the market power of Pharmacy Benefit Managers (PBMs), Group Purchasing Organizations (GPOs), and Third-Party Administrators (TPAs) contribute to rising costs and limited access to lower-cost generics and biosimilars. Panelists shared mixed positions on PBMs, with some emphasizing their role in lowering costs and managing utilization, while others highlighted practices that distort incentives and require intervention. Across the discussion, panelists underscored the urgent need for greater transparency, accountability, and fair competition throughout the supply chain. Some of the key topics highlighted include:

***The Evolving Role of PBMs*:** Panelists identified PBMs as playing an essential role in negotiating drug prices and ensuring clinically appropriate use through contracting with pharmacies and building networks for health plans and employers. The panelist from PCMA emphasized that PBMs were created in a direct response to the monopolistic pricing power drug manufacturers have and that many entities rely on PBMs to negotiate better prices. However, many panelists raised concerns about problematic PBM practices, including:

- Charging more for drugs than the prices they negotiate with manufacturers,
- Reimbursing pharmacies below their acquisition and dispensing costs,
- Retaining rebates rather than passing savings to patients, especially those with deductibles or coinsurance based on inflated list prices,
- Overpaying for certain generics (e.g., specialty generics), leading to inefficient spending and sometimes higher out-of-pocket costs than if patients paid cash at a discount pharmacy without their coverage plan, and
- Lack of transparency in rebate flows, pricing methodologies, and contracts, which makes it difficult to track where healthcare dollars go.

***Vertical Integration and Market Consolidation*:** Panelists raised concerns that vertical integration among PBMs, insurers, and pharmacies reduces competition and increases pricing power. They noted a lack of transparency around contracting arrangements, rebate flows, pass-through fees, drug acquisition costs, and other financial flows that leave the system opaque and lacking transparency. Additionally, they noted that:

- Five of the six largest PBMs are vertically integrated with insurers and various pharmacy services, creating potential conflicts of interest and incentive misalignments.
- PBMs steer consumers to their own integrated entities, which disadvantage independent pharmacies and raise antitrust concerns.
- PBMs have affiliated with or created GPOs, turning them from intermediaries into profit centers and major decision-making entities that set terms for manufacturers.
- Vertical integration may help entities bypass medical loss ratio (MLR) rules through "intercompany elimination," which increases revenue without necessarily improving quality.

GPO and TPA Market Power and Pricing Influence: Panelists criticized predatory and restrictive practices by these entities, which may contribute to drug shortages and an unsustainable generic drug market, including:

- GPOs underpaying generic manufacturers and structuring punitive contracts that manufacturers would not agree to in a competitive market, and
- TPAs limiting employer choice, blocking market entry for generics, and advancing rent seeking.

Barriers to Biosimilar Uptake: Messaging by brand manufacturers around biosimilar safety and the interchangeability designation contribute to confusion and slower uptake among providers and patients.

Complex Financial Flows and Patient Cost Burdens: Multiple panelists noted that the supply chain is opaque with many baseless, arbitrary fees that disadvantage pharmacies and manufacturers, and ultimately contribute to high prescription drug prices for patients.

- Patients frequently pay coinsurance based on inflated list prices and do not benefit from rebates that lower the net price for health plans.
- The Medicare Part D market is trending towards a significant decline in standalone prescription drug plans, with consumers shifting to Medicare Advantage plans, due to advantages such as rebates, which create an unlevel playing field in the market and raise concerns about informed choice and market stability.

To address these challenges, participants shared several recommendations, including:

- **Increasing transparency of financial transactions** in the drug supply chain, including rebates, fees, acquisition costs, and reimbursements. Participants

noted the Inflation Reduction Act Drug Price Negotiation Program as an opportunity to create more direct savings and reduce complexity.

- **Increasing transparency on purchasing and contractual arrangements** between PBMs, manufacturers, pharmacies, insurers, GPOs, and TPAs, to address anticompetitive behaviors and better track the flow of healthcare dollars.
- Designing programs that incentivize insurers and different entities towards **biosimilar uptake in federal programs**, such as leveraging Star Ratings.
- **Establishing a reimbursement model that bases drug prices based on acquisition costs plus a dispensing fee**. These models must be inclusive of all pharmacy types, including independent and specialty pharmacies.
- **Eliminating the Food and Drug Administration's (FDA) interchangeability designation** to remove unnecessary regulatory barriers to biosimilar adoption.
- **Closing loopholes in the Hatch-Waxman Act** that enable brand-name manufacturers to delay generic and biosimilar competition.
- **Reassessing whether brand PBM rebates constitute anti-kickback violations** and considering restoring direct competitive pricing dynamics in the market.
- **Implementing a "generic-first" policy across all federal programs** to ensure generics are prioritized when clinically appropriate.
- **Ensuring fair procurement and reimbursement practices for generic drugs,** particularly addressing underpayments that destabilize the generic drug market.

PANEL 2: IMPROPER ORANGE BOOK LISTINGS AND OTHER REGULATORY ABUSE BY PHARMACEUTICAL COMPANIES TO IMPEDE COMPETITION

Panelists:

- Sarah D'Orsie, Senior Vice President of Global Government Affairs and Policy, Fresenius Kabi USA
- Adam Mossoff, Professor of Law, Antonin Scalia Law School, George Mason University
- Maryll W. Toufanian, Senior Vice President of Regulatory Strategy and Government Affairs, Amneal Pharmaceuticals

- Sarah Yim, MD, Director of the Office of Therapeutic Biologics and Biosimilars, Center for Drug Evaluation and Research, Food and Drug Administration

This panel examined anticompetitive practices by brand-name manufacturers that involve misuse of regulatory processes—such as improper Orange Book patent listings, sham petitioning, and efforts to obstruct biosimilar approval pathways. While panelists acknowledged the value of frameworks like the Hatch-Waxman Act and the U.S. patent system in promoting innovation, they stressed the need for stronger inter-agency collaboration to ensure these mechanisms function as intended and are not exploited to delay competition. Panelists were critical of both industry practices and regulatory shortcomings, emphasizing how such challenges ultimately delay patient access to affordable medications. Key issues raised include:

***Improper Orange Book Listings and Patent Misuse*:** Panelists agreed that brand-name manufacturers often list questionable patents in the FDA's Orange Book to delay generic or biosimilar competition beyond what Congress intended. For example, by initiating patent infringement litigation, manufacturers can trigger an automatic 30-month stay on generic approval, delaying market entry and generating more revenue.

Threats to Skinny Labeling: Although the statute allows generic applicants to carve out certain protected methods of use, referred to as skinny labeling, recent court decisions undermine the viability of this by potentially holding generic manufacturers liable for infringing a patent if they publicly describe its product as equivalent to the brand product. Panelists shared concern that this could chill competition and undermine savings, including for Medicare.

Patent Abuse and Double Patenting Concerns: Panelists agreed that patents drive pharmaceutical innovation and competition, citing the massive success of the Hatch-Waxman Act in fostering a generic drug industry. Panelists also agreed that patents offer protections that drive economic growth by ensuring secure, reliable, and effective property rights to innovators. However, there are many challenges to the US patent system from both the industry and regulatory side. They shared particular concern over the rising trend in double patenting and terminal disclaimers, which panelists said brought to question both the number and quality of US patents. These patents are often granted near "year 12" when biosimilars are preparing to launch, which serves as an obstacle for biosimilar entry.

Barriers to Biosimilar Entry: Several panelists called for eliminating the interchangeability designation for biosimilars, stating that it causes confusion among providers and patients and deters uptake. Despite meeting the same standards for safety and efficacy as their reference products, biosimilars face marketing-driven skepticism, limiting their use.

Sham Petitioning: Panelists noted that regulatory processes such as citizen petitions, which are intended to raise legitimate scientific or safety concerns with agencies like the FDA, are sometimes misused to delay the approval of generics or biosimilars. While petitioning is not a common practice, this tactic wastes FDA resources and ultimately delays patient access to more affordable medications.

To address these challenges, panelists shared the recommendations below:

- **Strengthening inter-agency collaboration**. The drug regulation environment spans multiple statutory and regulatory frameworks overseen by government agencies like the Food and Drug Administration (FDA) , Centers for Medicare & Medicaid Services (CMS), U.S. Patent and Trademark Office (USPTO) , DOJ, and FTC. Panelists emphasized the need to develop an understanding of the various statutory schemes and policy priorities to support sound policymaking and aligned policy positions.
- **Balancing incentivizing the development of new drug products and promoting competition** from lower priced generics and biosimilars.
- **Reforming the patent system** to eliminate double patenting and adopting bipartisan legislation that would allow brand manufacturers to assert only one patent per terminally disclaimed group against biosimilar/generic manufacturers.
- **Focusing reforms at the PBM level**, which participants noted can be efficient and eliminate actual harms linked to increased prices.
- **Eliminating the legal distinction between biosimilars and "interchangeable" biosimilars.**
- **Supporting "reality-matters" and evidence-based policymaking** rather than rhetoric-driven narratives about patents.
- **Streamlining FDA policies to reduce unnecessary regulatory barriers**, such as phase III clinical trials or routine/default switching studies for interchangeability, while ensuring approval of high quality, safe, and effective biosimilars.