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Second FTC and DOJ Listening Session Focuses on Formulary and Benefit Practices and Regulatory Abuse in the Pharmaceutical Industry

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On July 24, the Department of Justice (DOJ) and Federal Trade Commission (FTC) held the second of three listening sessions focused on competition in the pharmaceutical marketplace as part of the agency's implementation of the president's Executive Order No. 14273, titled "Lowering Drug Prices by Once Again Putting Americans First."

At the beginning of the listening session, FTC Chair Andrew Ferguson noted the agency's aggressive approach to combating anticompetitive practices related to pharmaceuticals. Specifically, he pointed to FTC warning letters sent to pharmaceutical companies disputing the propriety of more than 200 patent listings in the Food and Drug Administration's (FDA) Orange Book. He also made clear that the agency plans to complete its 6(b) study of pharmacy benefit managers (PBM), which should inform potential legislative and future enforcement actions aimed at combating anticompetitive conduct in the prescription drug markets. Finally, Ferguson stated that incumbent PBMs and manufacturers appear to use government laws and regulations, designed to promote competition and reduce costs, to shield themselves from competition, resulting in higher costs for consumers.

As described below, the two panels then discussed various structural issues affecting competition, including increased consolidation, lack of transparency, and overlapping regulatory structures.

"Benefit and Formulary Practices and Regulations that Harm Drug Competition"

The first panel discussed business relationships among pharmaceutical manufacturers, PBMs, group purchasing organizations (GPOs), and health care payors.

Many panelists voiced concerns about the lack of transparency in PBM pricing and negotiations, noting how PBMs may be incentivized to favor products with higher list prices and higher rebates. One panelist discussed PBMs' use of offshore GPOs, contending that the GPOs do not comply with industry standards. Another panelist suggested that pharmacy reimbursements should be tied to acquisition costs. The panelists generally encouraged increased transparency at all levels of the supply chain, especially at the PBM level, and favored pass-through pricing models.

The session also addressed growing vertical consolidation in the pharmaceutical supply chain, with a focus on the vertical integration of PBMs with insurers, administrative services organizations, and GPOs. In recent years, all three of the largest PBMs have integrated with major health care insurers, administrative services providers, and

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pharmacies. Some panelists expressed concern that vertically integrated healthcare entities may disadvantage industry rivals by steering business to their integrated PBMs and pharmacies through exclusive contracting. They suggested that such steering should subject vertically integrated entities to antitrust scrutiny. Further, panelists expressed concerns that GPOs "engage in predatory practices" by overcharging and underpaying generic manufacturers.

"Improper Orange Book Listings and Other Regulatory Abuse by Pharmaceutical Companies to Impede Competition"

The second panel focused on the Hatch-Waxman regulatory scheme and how pharmaceutical manufacturers may exploit a complex regulatory system to delay or deter competition. One panelist focused on improper Orange Book listings, a hot topic in recent litigation and a focus of the FTC. She explained how improperly listed patents can harm competition by subjecting generic companies to an automatic 30-month stay of regulatory approval.

The panelists also discussed so-called "patent thickets" — dense groups of overlapping patents used to cover a single product — especially in the biologic space. While one panelist argued that patents are no more prevalent in life sciences than in other industries, another highlighted that those other industries are distinguishable because of cross-licensing, and focused on the expense and delay that arise when a brand enforces multiple nearly identical patents for the same product. That panelist highlighted current legislation that would allow brands to assert only one patent per terminally disclaimed group.

Some panelists also asserted that branded drug manufacturers improperly use Citizen Petitions to the FDA to attempt to delay or deter generic competition. They expressed that, while Citizen Petitions can constitute constitutionally protected speech, and may be appropriate to raise legitimate safety concerns, sham petitioning can delay generic competition and usurp FDA time that would otherwise be devoted to helping generic products reach the market.

Throughout the session, panelists reflected on the many overlapping regulatory schemes and responsible agencies that govern pharmaceutical patenting, approval, and competition, and how manufacturers may be able to exploit areas of overlap due to knowledge gaps among agencies. They noted that, given the wealth of specialized agency knowledge in this field, overlapping regulatory schemes may be a strength — so long as the various agencies understand each other's work and form strong inter-agency lines of communication.

Focus on Biologics

Participants across both panels were generally united on one issue: the need to reform the regulatory process and educate patients and providers to promote the use of biosimilars and interchangeable biosimilars as alternatives to expensive brand biologics. The panelists generally opined that the distinction between biosimilars and interchangeable biosimilars is unnecessary or counterintuitive. They called for a single regulatory pathway for biosimilars that would allow approved biosimilars to be automatically substituted by pharmacies, without prescriber intervention. Further, panelists emphasized the need to educate patients and prescribers about the safety and efficacy of biosimilars.

The third and final joint session will take place on August 4. The final session is expected to highlight the most

impactful takeaways from the previous two sessions and discuss other potential strategies to reduce drug pricing.

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