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FTC Holds Its First Listening Session on Practices and Regulations Impacting Pharmaceutical Generic or Biosimilar Competition

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On June 30, the Department of Justice (DOJ) and the Federal Trade Commission (FTC) held the first of three listening sessions focused on ways to lower Americans' drug prices through competition. The panels are being held as part of the agencies' implementation of President Donald Trump's Executive Order No. 14273, titled "Lowering Drug Prices by Once Again Putting Americans First." That order instructed the Department of Health and Human Services (HHS) secretary to conduct "joint public listening sessions with the [… DOJ], the Department of Commerce and the [FTC] and issue a report with recommendations to reduce anti-competitive behavior from pharmaceutical manufacturers."

In this first panel discussion, titled "Anticompetitive Conduct by Pharmaceutical Companies Impeding Generic or Biosimilar Competition," FTC Chairman Andrew Ferguson highlighted both that the new administration seeks to revisit previous policies and that the executive order's mandate was wide-ranging.

As discussed below, the 10 panelists focused on antitrust, patent trade office (PTO) reform, and legislative and regulatory action. Panelists also repeatedly referenced the role of pharmacy benefit managers (PBMs) in drug pricing. A more detailed discussion on that topic is scheduled for the second listening session on July 24.

Role of Antitrust

Panelists briefly addressed the role of antitrust — which, unlike PTO and legislative reform — is squarely in the enforcement purview of the FTC and DOJ. Some panelists focused on reverse payment agreements and product hopping as continuing barriers to competition. For example, Markus Meier, who investigated pharmaceutical and health care related antitrust issues with the FTC before retiring in 2023, advocated for further FTC study or investigations into current patent settlement practices.

Other panelists discussed the need for rigorous merger review and litigation challenging collusion, exclusive API supply agreements, and restricted distribution practices.

PTO Reform

Panelists debated the role of patent practices in driving high drug prices, with some arguing that excessive patenting stifles generic competition, and others defending the necessity of successor patents for innovation. The former group argued that successor patents provide incremental changes with little clinical benefit, that patent

thickets delay generic entry, and that the PTO should be allowed to more rigorously examine patent applicants, granting only patents that are truly novel and non-obvious. The latter noted that pharmaceutical companies are not obtaining materially more patents than other industries.

Legislative and Regulatory Action

Panelists proposed legislative reforms to streamline biosimilar approvals, particularly by eliminating the FDA's interchangeability suffix to boost competition. Interchangeability is a label the FDA gives to biosimilars that allows pharmacists to substitute those biosimilars for the reference biologic without the prescriber's intervention. Some panelists argued that obtaining this additional designation is burdensome and unnecessary, and that the designation creates unnecessary barriers to entry. They suggested that legislative reform to the BPCIA removing this designation would encourage increased production of biosimilars. Similarly, one panelist proposed elimination of the requirement for three-way pharmacokinetics study in cases where a European-sourced reference product is used. Another advocated for a clear and narrow definition of "specialty" that would lead to less steering and greater availability of drugs and biologics that do not meet the definition.

Other panelists also noted that unnecessary regulation has also imposed barriers to biosimilar adoption, and reminded that the FTC sought public comment on ways to reduce anti-competitive regulatory barriers. Those comments can be viewed here.

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Subsequent panels are scheduled for July 24 and August 4.

Devin Sengpiel, a 2025 summer associate with Troutman Pepper Locke who is not admitted to practice law in any jurisdiction, also contributed to this article.

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