Agenda for Lowering Drug Prices EO Listening Sessions

Listening Session 1: Anticompetitive Conduct by Pharmaceutical Companies Impeding Generic or Biosimilar Competition (June 30 at 2 p.m.)

1. **Panel 1: Anticompetitive Conduct to Delay, and Forestall Competition From Lower-Priced Alternatives**

   This panel will focus on strategies employed by incumbent manufacturers to delay or exclude generic or biosimilar competition. It will provide an overview of recent trends in pharmaceutical patent settlements as well as other strategies employed by these manufacturers to preserve their market share. Specific potential anticompetitive practices to be discussed include:

   - Current trends around potential pay-for-delay agreements
   - Exclusive agreements for API supply and restricted distribution

2. **Panel 2: Anticompetitive Conduct to Impede and Reduce Competition from Lower-Priced Alternatives**

   This panel will focus on strategies employed by incumbent manufacturers to preserve their market share even after generic or biosimilar entry. Specific potential anticompetitive practices to be discussed include:

   - Product hopping
   - Rebating strategies
   - Generic drug price-fixing and collusion

Listening Session 2: Formulary and Benefit Practices and Regulatory Abuse Impacting Drug Competition (July 24 at 2 p.m.)

1. **Panel 1: Benefit and Formulary Practices and Regulations that Harm Drug Competition**

   This panel will focus on the business relationship between drug manufacturers and PBMs that may impact drug competition, resulting in higher drug costs for health plan sponsors and patients. This panel will also focus on how applicable regulations distort competitive incentives or encourage firms to focus on rent seeking, rather than price and quality. The panel will address a variety of topics, including:

   - Impact of vertical integration of the health insurer, PBM, and specialty pharmacy on incentives to reduce drug costs
   - Formulary design and rebating practices
   - Private label biosimilars
   - Medicare policies and regulations
   - Interchangeability of biosimilars

2. **Panel 2: Improper Orange Book Listings and Other Regulatory Abuse by Pharmaceutical Companies to Impede Competition**

   This panel will discuss the anticompetitive concerns from improper Orange Book listings and sham litigation. The panel will describe the interplay between the various agencies tasked with overseeing this conduct (e.g., FDA, PTO, FTC, and DOJ) and suggest how these agencies can better collaborate to combat potential anticompetitive conduct.

   - Improper Orange Book listings or sham petitioning to FDA
   - Misuse of the REMS process
   - Disparaging the safety and efficacy of generics, biosimilars and interchangeability to hinder the uptake of lower-priced alternatives.

Listening Session 3: Turning Insights into Action to Reduce Drug Prices (Aug. 4 at 2p.m.)

This session will highlight the most impactful discussion from the previous two sessions. It will also include discussion of other potential strategies to reduce drug pricing in the United States.