FTC Workshop: Update Pharma Merger Guidelines

Lower HSR Threshold, Merger Activity Impacts R&D, PBM Role Called Out

Today & tomorrow, the Federal Trade Commission (FTC) & Department of Justice (DOJ) are hosting a public workshop to examine pharmaceutical mergers and examine antitrust enforcement in this arena **(here).** Speakers include FTC Chair Lina M. Khan and Assistant Attorney General Jonathan Kanter, as well as a keynote delivered by Commissioner Rebecca Slaughter who formed the Multilateral Pharmaceutical Merger Task Force.

FTC MEETING HIGHLIGHTS

- **Commissioner Rebecca Slaughter, who is most strident in her messaging that pharma mergers are largely anticompetitive, noted the following high points at today's meeting.** Some highlights from other antitrust speakers can be below.
  - Competition promotes access to drugs; and prices for prescriptions are quite high (Slaughter)
  - Drug spending per capita has increased 7-fold over the last 40 years (Slaughter)
  - When there is a competitive market there is a robust amount of R&D…. Mergers can impact competitive R&D space, because as players are reduced then innovative research may also decline (Slaughter)
  - FTC's Multilateral Pharmaceutical Merger task force is working with international organizations (Slaughter)
  - Competition can save lives, a lack of competition can threaten lives (Kanter)
  - Research & development (R&D) behind modern medicine has transformed society (Khan)

- **FTC hailed its win in a case regarding an "HIV drug priced with 4,000% increases"** This was of course the Martin Shkreli (Daraprim) 2015 issue, where the pill went from $13.50 to $750 overnight. FTC touted case progress on pay for delay and price fixing. On the latter, DOJ and States have brought and won cases on Rx price fixing.

- **Ongoing PBM study will inform FTC Pharma merger work.** The antitrust authorities recognize that pharma does not operate in a vacuum. "Root causes" may lie in the entire supply chain, according to Commissioner Lina Khan. A PBM investigation was opened last week; we had said this was likely the case after a Senate hearing in early May on PBM and transparency/formulary issues.

- **Breast cancer therapy innovation touted by Lina Khan**. Chairwoman Khan, formerly counsel to House Judiciary Committee and a professor at Columbia Law School, noted the recent HER2-low experimental therapy clinical data that demonstrated interim results. We deduce this to be trastuzumab deruxtecan, Enhertu, being developed by Daiichi Sankyo and AstraZeneca. This is the type of innovation that the agencies want to foster, and antitrust authorities want to continue this type of life-saving progress where they can.

- **Panelists applaud lowering the HSR threshold for merger scrutiny**. Recall that the HSR Act requires most of the proposed transactions that affect commerce in the United States over a certain size to be reviewed by the FTC or the Department of Justice. Either agency can take legal action to block deals that it believes would "substantially lessen competition."

BACKGROUND & NEXT STEPS

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- **Small-ball FTC bills could pass as a part of BBB, if a slimmed-down version moves forward ahead of 9/30 (and it very well could)**. A lack of competition in the pharmaceutical industry is blamed as a factor in drug pricing and the administration is hoping for any kind of a win in drug pricing reform. We have previously noted that anti-competitive FTC/patent practice provisions may be seen in a slimmed down BBB. These bills were scored by CBO last week and could save the government <$2 B over 10 years. (pay for delay, product hopping)

- **Recall FTC has authority over Pharmaceutical and Hospital industries.** DOJ has authority over health plans & PBMs. Both agencies operate under the same regulatory & statutory framework, but have expertise in different industries.

- **Big Pharma notes appetite for M&A, and we note some recent activity**. Since Q4 of 2021, pharmaceutical executives (IPN, GSK, PFE, TEVA to name a few) have noted willingness to engage in M&A for cheap(er) biotech assets. Pharmaceutical companies appear more interested in tuck in acquisition than mergers. Some recent announced transactions include PFE's acquisition of Biohaven (May 2022), GSK's acquisition of Sierra Oncology (April 2022), Hikma's acquisition of Custopharm (April 2022), AbbVie acquisition of Syndesi Therapeutics (March 2022), and Ligand Pharma's merge with Avista Public Acquisition (March 2022).

- **Recall also that FTC is also investigating PBMs, and commissioners note important supply chain role in Rx prices.** Last week, the FTC announced that it will investigate the six largest PBMs (Caremark; Express Scripts, OptumRx, Humana, Prime Therapeutics, and MedImpact Healthcare Systems). The study aims to gather information on scrutinized practices including PBM control over formularies, pressure on independent pharmacies, and spread pricing. Consolidation in the PBM market is also expected to be addressed in this investigation. Companies have 90 days from the order to respond and we expect the investigation to take several more months.

- **NEXT STEPS**: This is a 2-day public workshop. Day 2 will examine the innovation aspects of pharmaceutical mergers and how conduct by pharmaceutical companies affect merger analysis. On Thursday June 16th, Capitol Street will host a Biopharma & PBM antitrust outlook webinar with antitrust expert Seth Bloom at 10:30 am ET. Please RSVP to Rasheda White at Rasheda@capitol-street.com for webinar details. Chair Lina Khan noted the agency will update its biopharma regulations/HSR standards for mergers that have impact beyond traditional horizontal merger overlap. Separately, we also look to an updated BBB for FTC bill inclusion, as well as potential Part D restructuring, CPI penalties and limited Part B&D negotiation. We expect statements/tweets from FTC/DOJ over the coming months, which has created significant headline risk since the start of the Biden administration.

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