On Wednesday, November 8, 2017 the Federal Trade Commission (FTC) hosted a workshop seeking to explore the general question of why the cost of prescription drugs has risen greatly in recent history. The Workshop was framed around industry development in the time since the enactment of the Hatch-Waxman Act in 1984.

Acting Chairman Maureen Ohlhausen gave the first keynote address. Chairman Ohlhausen was quick to note that after a branded drug’s patent expires, the first generic drug entry into the market offers a 20-30% discount, with subsequent entries lowering the price up to 85% or more. She questioned how to best encourage greater entry into the generic marketplace, particularly when the demand for a drug is not sufficiently high. Ms. Ohlhausen touted the Agency’s recent history with enforcement actions, but cautioned those in attendance not to draw conclusions about the FTC’s forthcoming plans. Instead, Ms. Ohlhausen framed the workshop as an opportunity to explore potential solutions to difficult problems. In closing, she asserted that the antitrust process works best when it focuses on eradicating harms to the competitive process, and if the FTC does take enforcement actions in this space, it will be based upon the specific facts of a case, rather than as a blanket admonition of certain practices.

Dr. Scott Gottlieb, FDA Commissioner made the second keynote speech, and discussed the FTC and FDA’s shared goal of ensuring that consumers benefit from greater competition in the prescription drug market. Dr. Gottlieb noted that while there have been many advancements in pharmaceutical products, consumers may only see benefits if they are able to afford them. Dr. Gottlieb believes that the “root cause” of high drug prices is lack of competition, and advocated for brisk competition when exclusivity periods on patented drugs expire. With respect to generic drugs, Dr. Gottlieb espoused his concern that branded companies often make it difficult for generic firms to buy the doses they require in order to appropriately test their products to bring to market.

The panels that followed discussed a variety of issues, beginning with a general discussion of drug supply and demand, and then discussing the issue of intermediaries, including Pharmacy Benefit Managers (PBMs) and Group Purchasing Organizations (GPOs). The panels included great minds from many types of firm, including researchers, economists, trade associations, law firms, and policy advocates.

Panel 1: Generic Drug Competition: Understanding Demand, Price and Supply Issues

One of the hot topics of the Workshop was the issue of increasing competition in the generic drug market. Throughout the presentations, there was one consensus among panelists: entry into the market is affected by profitability. Factors affecting generic drug use that were discussed included: (1) advertising/promotion of brand name drugs; (2) patient/physician skepticism as to effectiveness; (3) cost/availability of generic drugs; and (4) consolidation in the marketplace. Due to these factors, niche patient populations are rarely sought after for development of generic alternatives, where demand is simply not great enough to warrant the significant investment required of bringing a generic drug to market. Multiple panelists throughout the day emphasized that generics operate in a deflationary market, leading generic drug manufacturers to market hundreds of products with varying levels of profitability. This is in stark contrast to the model for “branded” drugs, where companies market a small number of highly profitable products. During the panel discussion, one interesting alternative was raised with respect to drug shortages not resolved by new market entrants. A panelist suggested temporary importation for these periods while generic firms navigate through the typical FDA approval process. Such a strategy would attempt to avoid the rent-seeking behaviors the industry has seen, for example, when Turing Pharmaceuticals raised the price of its antiparasitic drug Daraprim from approximately $13.50 per dose to $750.

Panel 2: Understanding Intermediaries: Pharmacy Benefit Managers

The next panel was the first of two related to intermediaries in the prescription drug marketplace—PBMs. One repeated theme was the concentration of the PBM market. Notably, the three largest PBMs, Caremark, OptumRx, and Express Scripts have approximately 75% market share in the space. This market makeup was compared to the pharmaceutical drug manufacturers, where even the largest of manufacturers control only 6-7% market share. The value of these PBMs was hotly debated. For example, a general proposition was espoused that for every $100 spent on prescription drugs, PBMs keep approximately $5. Therefore, consumers must ask whether PBMs bring at least $5 of value to the market.

Panelists also advocated for the continued use of PBMs. These organizations provide for improved access and choice for consumers. Instead of PBMs being responsible for the rising cost of prescription drugs, one panelist placed the greatest blame on pharmaceutical industry’s shift from producing drugs that may cost ~$3 per day to “blockbuster” drugs that may
cost upwards of $1,000 per day. In fact, one panelist also provided statistics to show that in the face of the growth of PBMs, there has been a modest cost growth per capita as pertains to prescription drugs. These statistics were criticized by others on the panel as including generic drug pricing, which cost substantially less than “branded” drugs.

Panel 3: Understanding Intermediaries: Group Purchasing Organizations

The third panel centered around Group Purchasing Organizations, organizations that allow healthcare providers, including hospitals, nursing homes, etc., to realize cost savings by aggregating purchase volume and negotiate discounts with manufacturers and distributors. Overall, the panelists were in agreement that GPOs are, in general, a good thing. The pros and cons of the organizations were best summed up by the panel moderator, the FTC’s Markus Meir, Acting Deputy Director of the Bureau of Compliance. He asserted that GPOs reduce transaction costs, increase their members’ bargaining power, and secure volume discounts that might otherwise be unavailable to the hospital members. But, critics say that GPOs are fraught with conflicts of interests (principal-agency problems) and that GPOs have played a role in creating drug shortages.

One panelist in particular began his talk with a stipulation: “GPOs do great things. The relevant question is whether they would do even greater things if they didn’t face a conflict of interest when it comes to their compensation?” In essence, he pondered aloud what incentives GPOs have to further lower drug prices if they are paid based on a percentage of the price of the drug – one would believe they would seek to maximize revenue, and therefore benefit from higher prices.

Panel 4: Potential Next Steps to Encourage Entry and Expand Access through Lower Prices

The final panel was a summary panel of two individuals. It was repeated that the high and continually growing price of prescription drugs are a problem for many stakeholders, but most importantly for patients. It was asserted throughout the day, and during this session that “Big Pharma” often pursues monopoly pricing, and there is little that can be done (or has been done) to combat these practices. There are no “silver bullets,” and even well-intentioned solutions can result in bad consequences. The panelists suggested a more aggressive antitrust investigative power and enforcement be utilized by the FTC.

Conclusion

In her closing remarks, FTC Deputy Director from the Office of Policy Planning, Suzanne Munck, was grateful for the robust participation throughout the day. Ms. Munck believed that it was particularly helpful to see the panelists back their arguments up with data, which is most helpful from a policymaker’s perspective.

While the FTC Workshop did not answer all of the industry’s questions, it was undoubtedly a step in the right direction for opening up a dialogue, and may shed light on the FTC’s future agenda, although Acting Chairman Ohlhausen cautioned against any such inferences. Slides from the day’s presentations can be found here and speaker bios can be found here. Public comments may be submitted until December 8, 2017.