The Myth Of 'Price Disconnects' In US Pharma Markets

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A number of recent antitrust lawsuits involving pharmaceuticals allege schemes by branded manufacturers to convert prescriptions from an older branded product that is facing generic competition to a newer version of the branded product. In these lawsuits, the improvements in medical benefits offered by the newer version are typically disputed[1]. These scenarios, referred to as "product hopping," allegedly impair generic competition and allow branded pharmaceutical companies to charge supracompetitive prices on newer, but only marginally superior, products. Recently, some antitrust analysts have weighed in against pharmaceutical manufacturers in these scenarios. In so doing, they argue that such anti-competitive actions are enabled by "uniquely complicated" characteristics of the pharmaceutical markets in the U.S., pointing specifically to a "price disconnect" that exists because prescribers, patients and insurers do not make the fundamental trade-off between prices and quality[2].

Assessment of the extent of such a price disconnect is often an important, albeit not always dispositive, part of the economic analysis of competitive effects of new product introductions. Accordingly, what follows is a closer look at the evidence concerning price disconnects in the U.S. marketplace for pharmaceuticals.

Prescription Drug Purchasing: Mechanisms that Connect Price and Quality

The purchase of a prescription drug in the U.S. involves a number of different entities including, at a minimum, a physician and a patient. Insurers and pharmaceutical benefit managers (PBMs) also typically have a role in the purchase for insured patients. Some have argued that the involvement of many different entities in the purchase of a prescription drug leads to market failures because physicians choose medically appropriate products for their patients but do not pay for the product, and consumers purchase the product but are not always knowledgeable buyers[3]. However, this feature alone is insufficient to demonstrate that "[n]o one makes the price/quality decision or trade-off that ensures that manufacturers sell products at competitive prices[4]." In particular, the insurance companies and PBMs that provide prescription drug benefits are sophisticated entities that are attuned to trade-offs between prices and quality among alternative drugs. These entities employ a number of tools to achieve cost-efficient prescription drug use:

- **Formularies and Pharmacy and Therapeutic (P&T) Committees** — Health insurance providers frequently use drug formularies or lists of approved and preferred drugs that are covered under the prescription drug benefit. These formularies are routinely updated and are developed and managed by committees comprising physicians, pharmacists, nurses, administrators and quality assurance directors, among others[5]. As new products are introduced, including drugs named in alleged product hopping schemes, P&T committees review available evidence regarding their benefits. To the extent a product is not considered favorably in terms of the trade-off between its incremental cost and quality relative to preexisting products, the committee can adjust the benefit design accordingly.
- **Formulary Tier Benefit Design** — Formulary "tiers" are associated with different cost-sharing provisions between the insurance provider and the insured patient. Insurance providers use this tool to steer patients to cheaper alternatives or to pass on costs for more expensive drugs[6]. Formularies with more tiers may help insurers incentivize patients to choose preferred medications and avoid drugs that do not offer a favorable price/quality trade-off. In 2015, one industry survey found that over 80 percent of covered workers received a prescription drug benefit with a cost-sharing formula of three or more tiers[7].
- **Prior Authorization, Step Therapy and Quantity Limits** — Other utilization tools that influence the dispensing of particular drugs are also used by insurers. Prior Authorization prohibits reimbursement for a particular drug unless specified conditions are met. This often requires additional work on the part of the prescriber to demonstrate that a patient meets the relevant conditions. Step therapy requires that a patient first try and fail on an alternative, typically less expensive, therapy in order to obtain reimbursement for the drug in question. Quantity limits impose restrictions on how much of a drug will be reimbursed in a given period of time. All of these tools can help an insurer steer patients and physicians to particular drugs

that have the preferred price/quality trade-off. These tools are also frequently used. A 2015 survey of 302 employers offering prescription drug benefits found that 84 percent used prior authorization, 69 percent used step therapy and 81 percent used quantity limits[8].

These industry practices suggest that not only do parties involved in prescription drug purchasing have the means by which to make relevant price/quality trade-offs, but that in practice these methods are employed frequently. Furthermore, numerous studies have found that these management tools result in reduced drug utilization and drug costs[9]. As a result, if a branded manufacturer attempted a product hopping strategy and introduced a new branded product at a supracompetitive price, insurance providers would be expected to implement one or more of these utilization management tools to disincentivize physicians from prescribing the product and disincentivize patients from purchasing the product. In turn, the branded manufacturer's response would be to lower its price closer to competitive levels.

Conclusion

There is no question the U.S. healthcare system is complicated. As more time progresses, insurers and patients will continue to evaluate and modify prescription drug benefit options, looking for better ways to meet patients' needs while helping to control costs. The insurer mechanisms for shaping patients' and physicians' prescription drug choices outlined above, while frequently employed, do not mean that prescribers, patients and insurers have perfect information or can react immediately to every change in the market. As a result, the connection between prices and quality may be imperfect and adjustments to new pharmaceutical developments may take time. These imperfections are not unique to the market for pharmaceuticals. Moreover, the pattern of introducing "new and improved" products for consumers to evaluate and respond accordingly over time, is common to many markets. For all of these reasons, it is wrong to single out the pharmaceutical market as one where price/quality trade-offs are not occurring when new products are launched. At a minimum, the demonstrated ability of insurers to make tangible connections between prices and quality in prescription drug markets needs to be taken into account when assessing the competitive effects of new product introductions.

Endnotes

1 Complaint, CVS Pharmacy Inc.v. Warner Chilcott Public Limited Co., No. 1:16-cv-00164 (D.R.I. April 5, 2016); Complaint, FTC v. Endo Pharmaceuticals Inc, No. 2:16-cv-01440-PD (E.D., Pa. March 30, 2016).

2 Michael A. Carrier and Steve D. Shadowen, "Product Hopping: A New Framework," Notre Dame Law Review, 2016 (forthcoming) (hereafter, "Carrier and Shadowen, 2016"), pp. 3,11, 21.

3 Carrier and Shadowen, 2016, p. 12.

4 Carrier and Shadowen, 2016, p. 12.

5 Robert P. Navarro et al., "Pharmacy & Therapeutics Committees in Managed Care Organizations," In Robert P. Navarro, (ed.), Managed Care Pharmacy Practice, 2nd Edition, Sudbury, MA, Jones and Bartlett Publishers, 2009, Chapter 13.

6 Kaiser Family Foundation and Health Research & Educational Trust, "Employer Health Benefits: 2015 Annual Survey," p. 160.

7 Ibid, p. 162. Eighty eight percent had a tiered cost-sharing formula of any type.

8 Pharmacy Benefit Management Institute, "Prescription Drug Benefit Cost and Plan Design Report," 2015-2016, p. 31.

9 For a survey of this literature, see Dana P. Goldman et al., "Prescription Drug Cost Sharing: Associations With Medication and Medical Utilization and Spending and Health," The Journal of the American Medical Association (JAMA), Vol. 298, No. 1, July 2007, pp. 61-69, E1-E18.