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Panel 2

Generics Exclusion: What Conduct Crosses the Lines?

Do Pharmaceutical Mergers Harm Consumers?

Webinar, 1 July 2020

*Interview with Patricia Danzon (Wharton) by George Rozanski (Bates White)**

Prof. Patricia Danzon *(Professor of Health Care Management, The Wharton School, University of Pennsylvania), has been interviewed by* ***Dr. George Rozanski*** *(Partner, Bates White Economic Consulting) in anticipation of the* ***Antitrust in Life Sciences*** *webinar, to be held on 1 July 2020. This webinar was originally a conference that would take place on 23 March 2020. However, due to the COVID-19 outbreak, it has been transformed into a webinar.*

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Dr. George Rozanski: **Market definition: Antitrust agencies and plaintiffs typically assess effects on competition by first defining markets. In the case of pharmaceuticals, the FTC has defined markets for generic drugs quite narrowly – based on the molecule, form, and strength. In the case of drugs that are still on patent, drugs intended to treat the same condition and with similar indications may be considered to be in the same market, even though they may be differentiated in terms of side effects or in other ways that are significant for some patients.**

When this is the case, what methods and types of evidence are available to assess the extent of substitution between two different drugs, especially given that consumers and their doctors may not respond to prices or even be faced with prices?

Should market definition rely on evidence of substitution or steering by agents for payers, such as insurance companies and PBMs?

Prof. Patricia Danzon: Market definition for pharmaceuticals is not easy. For generic drugs, the narrow definition using molecule, form and strength makes sense, at least for the short run, because this defines the scope within which pharmacies can substitute bioequivalent generics without seeking permission from the prescribing physician. For drugs that are still on patent, a starting point for market definition is drugs that are indicated (FDA-approved or potentially approvable) to treat the same medical condition(s). In some cases it may be appropriate to also consider other factors that limit substitutability e.g. drugs that have very different mechanisms of action or different routes of administration (injection vs. oral) may differ systematically in side effects, convenience etc.

However, reliance on actual substitution data is problematic for several reasons. First, substitution is typically greater for new patients than for established patients who may be reluctant to switch from a drug that is familiar and working for them, so substitutability increases with time but this varies across therapeutic categories; second, to the extent that patients face prices, these are usually co-payments that are a small fraction of the full price and depend on the formulary decisions of their PBMs or insurers, which may only be revised annually; third, these formulary decisions made by PBMs are influenced by their own financial incentives, in terms of rebates and other margin payments.

These financial incentives or "prices" faced by payers are generally unobservable to analysts. Thus structuring an empirical analysis to measure substitution is conceptually complex (which decision-makers and which prices) and empirically problematic (unobservability of prices, controlling for promotion and other non-price influences on demand). If one or more of the potential competitors has not yet been approved, empirical measurement is not even a possibility.

Innovation markets: Concerns about pharma mergers sometimes extend to possible effects on R&D competition. When they do, an important issue is to identify the participants in the market and to assess their competitive significance, in order to determine if a proposed merger is likely to have a "substantial" or "significant" effect on competition. Competitors may be identified on the basis of R&D assets, patents, or experience in a particular therapeutic category.

What do we know about the specificity of R&D assets, and hence our ability to identify which firms are important competitors to innovate a new drug in a therapeutic class, especially in early stages of the R&D process?

Has the task of identifying possible sources of innovation become more difficult with the advent of new technologies that may allow startup firms to compete effectively, e.g gene editing technology?

I do not know of any research that identifies particular assets or experience that predisposes particular firms to be consistently important R&D innovators over time. It is certainly true that there has been remarkable stability over time in the identity of the top ten pharma-biopharma firms in terms of sales, and persistence in their dominance in particular therapeutic categories, despite some shifting of rankings over time. However, this dominance of sales is not associated with dominance in R&D innovation.

Small firms are now estimated to account for roughly 70 percent of new drug approvals at the FDA. The technologies underlying these new drugs often originate in academic research labs and are then out-licensed to small companies that develop them further, with funding from venture capital, private equity, licensing deals with larger companies, IPOs and follow-on public funding. Once these small companies have established proof of concept of the new drug or technology, they are usually acquired by mid-size or larger companies. The largest companies thus maintain their dominance by success in acquisition.

The evidence suggests that most companies tend to grow initially around one or two "blockbuster" drugs, but then have great difficulty maintaining innovation from their own inhouse labs. Those that continue to survive and grow do so primarily through in-licensing and acquisitions. More research is needed to understand why the same firms persist as market leaders in terms of acquisitions and sales, despite the declining share of new drugs that originate in their labs.

Efficiencies: It has been reported that drug development has become slower and much more costly in the last couple of decades. There might sometimes be a concern that a merger of firms that are competitors in R&D could have adverse effects on the development of new drugs by limiting firms' incentives to innovate, but a merger might also have procompetitive effects by reducing the cost of R&D. What has research shown about the effects of mergers on R&D productivity?

Is there any research that would help us identify mergers that are most likely to lead to benefits? How should we think about mergers between new startups focused on new research technologies (biotechnology, gene sequencing, gene editing) with larger, established firms with complementary skills and assets related to the "D" side of R&D, i.e. regulatory process and marketing?

The evidence that R&D has become more costly over the last decade is based on limited, biased data that draws solely on the experience of large firms, whose share of new drugs originated has declined to about 25% in 2018. Although we lack representative data on R&D costs, including the growing role of smaller companies, available data do show a decline in the average number of patient-years required for drug approval, which implies a decline in a major component of R&D cost. This decline is unsurprising, given the shift to orphan and other specialty drugs, as well as significant changes in FDA requirements.

Empirical studies of biopharma mergers do not show evidence of consistent effects of mergers on R&D, positive or negative. Although large-scale mergers are often rationalized in part by the potential for cost savings, those savings derive mostly from overhead functions, marketing and sales, rather than R&D. Difficulties in post-merger integration and loss of top talent are often cited as offsets to any potential efficiency gains in R&D from economies of scale or scope.

One possible exception is mergers where a larger firm acquires a smaller firm with which it already has a licensing agreement on a lead product. In such cases, the merger can reduce costs of coordination, monitoring and effort duplication, and reduce financing costs for developing the shared product, because the large firm has access to retained earnings. The small firm also has few other potential suitors, if its lead product is already partnered with its would-be acquiror.

Although there is clearly some potential efficiency gain from putting together complementary skills and assets of small and larger firms, there may be other ways to achieve such gains e.g. small firms can and do hire personnel who bring experience from larger firms and use outside consultants to fill their skill gaps. To the extent that the main force driving outright acquisitions is the lower cost of capital enjoyed by larger firms with retained earnings, it may be worth considering whether there are social costs to allowing such advantages to drive the persistent pattern of acquisition of smaller firms by larger firms in this industry.

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