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Product competition, managerial discretion, and manufacturing recalls in the U.S. pharmaceutical industry

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ABSTRACT

Empirical research examining whether and how competition influences product recalls is limited. We address this important research gap by creating a novel measure of product competition using data from the Food and Drug Administration's Orange Book, and combining it with product recall data across a 12-year period. Our results show that product competition is positively associated with manufacturing-related recalls, providing evidence of a possible downside to competition in the pharmaceutical industry. Although competition is fostered by numerous federal regulations, we find that it may encourage companies to relax quality standards during the manufacturing process, which may result in lower quality products. We also find that this relationship is contingent on managerial discretion surrounding the recall decision. While product competition is associated with an *increase* in high severity, low discretion recalls, it is associated with a *decrease* in low severity, high discretion recalls. Findings from this study have critical implications for policy-makers who regulate product competition in the pharmaceutical industry.

1. Introduction

A fundamental principle of capitalism rests on the widely held notion that competition is predominately good, resulting in lower prices and higher quality (Friedman, 2009; Mazzeo, 2003). Economic theory, however, suggests a more nuanced view. While competition typically leads to lower prices, the relationship between competition and quality often depends on whether the price is regulated or set by firms (Gaynor, 2006). When the price is regulated, the competition-quality relationship is clear: competition improves quality (Gaynor and Town, 2011; Gaynor, 2006). However, in settings where prices are set by firms, the impact on quality is not as clear (Matsa, 2011; Gaynor, 2006; Jin, 2005). Kamien and Vincent (1991) as well as Ma and Burgess (1993), for instance, showed that if prices are set by firms, increased competition results in lower quality while Allard et al. (2005) and Dranove and Satterthwaite (1992) found the opposite result. Additionally, policy-makers in certain industries have leveraged regulations to increase competition with the goal of lowering prices for consumers, but the effect of such regulations on product quality remains uncertain.

The Drug Price Competition and Patent Term Restoration Act of 1984 is a prime example of such competition-inducing regulation. Commonly called the Hatch-Waxman Act, this legislation was intended to increase product competition in the pharmaceutical industry and lower drug prices by creating an expedited approval process for generic drugs. Before this Act, every drug went through a long and an expensive New Drug Application (NDA) process that required extensive clinical tests and trials. This Act introduced a second, expedited drug approval process: the Abbreviated New Drug Application (ANDA) process. The ANDA process only requires firms to demonstrate evidence of a drug's bioequivalence (comparable in “dosage form, strength, route of administration, quality, performance characteristics, and intended use” - FDA, 2017a) to an original, pioneer drug rather than conduct lengthy clinical tests and trials themselves. In other words, a drug is eligible for ANDA approval if there is an original version of the drug already on the market to which it can be compared.

The ANDA process was designed to spur product competition in the pharmaceutical industry by making lower priced drugs available to consumers, while still maintaining high product quality standards. As intended, the ANDA process has led to a considerable increase of bioequivalent drugs entering the market and in reduced drug prices (FDA, 2015). Because drugs approved via the ANDA process need to be bioequivalent to pioneer drugs, firms are not allowed to change the

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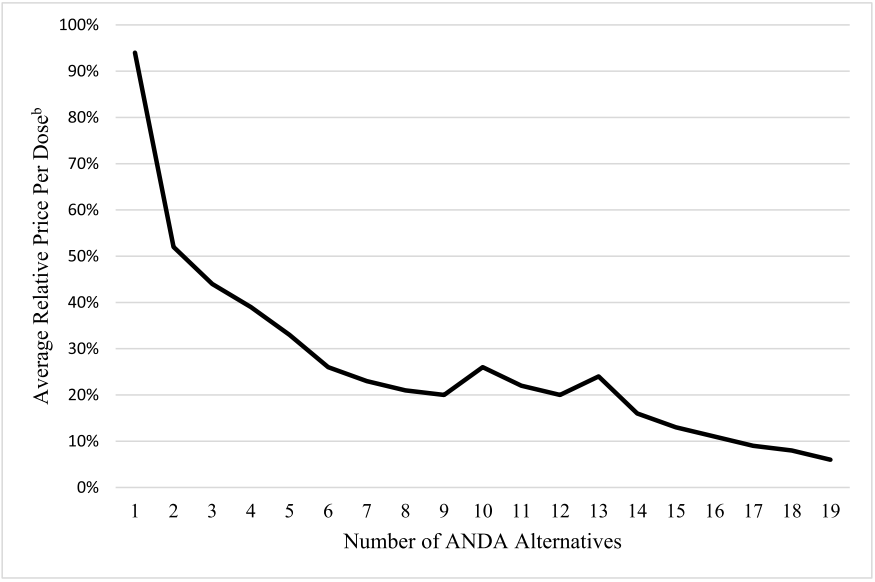

Fig. 1. Product Competition and Drug Prices.[a]

[a] Figure reproduced using data from FDA (2015).

[b] Average Relative Price Per Dose is the ratio of the average generic price to the corresponding branded price for pharmaceuticals sold in the U.S. (FDA, 2015).

design of the product (FDA, 2017a). However, firms do have considerable leeway concerning manufacturing decisions as long as they abide by Current Good Manufacturing Practices (CGMP), which are broad guidelines dictating *how* work is done, not necessarily *what* work is done (AAM, 2013). According to the Food and Drug Administration (FDA), CGMP regulations provide "minimum requirements for the methods, facilities and controls used in manufacturing, processing and packaging of a product" (FDA, 2014). For example, CGMP dictates that suppliers are to be audited regularly, but not which suppliers to use, where they are located, or how many suppliers are included in the supply chain. Additionally, CGMP requires firms document that they have trained their employees, but not what training techniques to use. Decisions such as these are left to the purview of firm management, may be influenced by the level of product competition a firm faces, and may have product quality implications.

In fact, evidence suggests that the Hatch-Waxman Act has fulfilled its intent to increase product competition through an increase in bioequivalent drugs, resulting in lower drug prices for consumers (Fig. 1). However, the impact of this increased product competition on product quality, specifically product recalls, has to the best of our knowledge not been examined. While lower drug prices are critical to consumer welfare, lower product quality can be very harmful. Thus, one of the primary objectives of this study is to examine whether product competition influences product quality. Because the ANDA process was created to increase product competition, we investigate how an increase in ANDA drugs as a proportion of all NDA and ANDA drugs marketed by the firm, influences future manufacturing-related product recalls.

Our second objective is to examine if the product competition-quality relationship is contingent on contextual factors, as suggested in past research (Yayla-Küllü et al., 2013; Banker et al., 1998; Karmarkar and Pitbladdo, 1997). Specifically, we examine if the relationship between product competition and manufacturing-related recalls is affected by managerial discretion (Hambrick and Finkelstein, 1987). Managerial discretion surrounding pharmaceutical recalls varies greatly and is inversely related to the severity of the recall – that is, high severity recalls have less managerial discretion as consumer lives are often at stake and the need for a recall is more apparent, while low severity recalls have more managerial discretion, as there is, by definition, no health risk to consumers (Ball et al., 2017).[1] We argue that high severity, low discretion recalls represent more objective product quality issues whereas low severity, high discretion recalls represent more subjective product quality issues and thus provides an ideal means to determine if the relationship between product competition and product recalls changes with managerial discretion.

We test these relationships with 939 pharmaceutical recalls across 64 firms from 2002 to 2014, using fixed effects and random effects negative binomial panel models. Our results show that firms that face more product competition have significantly more manufacturing-related recalls. In other words, high product competition is associated with lower quality manufactured products. Our results also suggest that the product competition-recalls relationship is contingent on managerial discretion. Specifically, product competition is positively associated with high severity, low discretion manufacturing-related recalls while it is negatively associated with low severity, high discretion manufacturing-related recalls. We also conduct robustness checks to substantiate these results, and to explore the mechanism underlying the relationship between product competition and manufacturing-related recalls. In doing so, we find that compliance with CGMP guidelines acts as a mediator in our model, which indicates that high product competition may encourage firms to relax their attentiveness to manufacturing quality standards, which in turn may lead to an increase in manufacturing-related recalls.

2. Literature and hypotheses

2.1. Competition and quality literature review

A significant amount of research has found that when competition intensifies, firms modify their actions to improve performance (Lumpkin and Dess, 1995; Vilcassim et al., 1999). Most of the research on how competition changes a firm's actions has been analytical in nature (Banker et al., 1998; Kranton, 2003; Lenox et al., 2006), has focused on industry rather than product competition at the firm-level (Ferrier, 2001; Dranove et al., 1992), or has been conducted in service

[1] An example of a high severity recall would be a drug that leads to consumer deaths or injuries, while a low severity recall would be a packaging problem on a drug that could not harm consumers (FDA, 2009).