Research shows moves to ban pay-to-delay deals are justified

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Controversial deals that delay generic versions of drugs coming onto the market can lead to consumers paying significantly more for some treatments, according to new research by an academic from the University of East Anglia (UEA).

Dr Farasat Bokhari's study shows that moves to investigate and ban pay-to-delay deals – which typically involve a branded manufacturer holding a drug patent paying a rival generic firm to delay the release of its cheaper version – are justified.

The deals are on the rise in the United States and Europe and the practice has prompted concerns from regulators on both sides of the Atlantic that they are anti-competitive, infringe competition laws, and allow branded manufacturers to charge higher, monopoly prices – ultimately costing health services and taxpayers millions more.

Dr Bokhari, a health economist in the School of Economics and ESRC Centre for Competition Policy at UEA, analysed the impact of such agreements on US market prices for drugs used to treat attention deficit hyperactivity disorder (ADHD). He applied economic models to five years of sales data to estimate the price increases resulting from the delayed entry of a generic version of Adderall XR. The branded version was introduced by Shire in 2001 and is an extended release form of the company's older product Adderall. By 2003 Adderall XR had almost 25 per cent of the market share for ADHD drugs in the US, while sales of all ADHD drugs totalled more than $2.2billion. A generic version of

Adderall XR was introduced in 2009.

Published in the *Journal of Competition Law and Economics*, the study shows that, on average, the percentage increase in prices is 4-4.5 times higher when entry-limiting deals are made and a generic is not available in the market, compared to when the generic is available but the branded and generic firms jointly set their profit-maximizing price.

For example, in the absence of Adderall XR, the price of the drug Concerta would be 4.97% higher ($101.23 per month instead of $96.45), Ritalin SR/LA would be 4.34% more ($61.75 instead of $59.20), while the generic version of Adderall would be 2.45% higher ($27.16 instead of $26.52). Similarly, prices of most other ADHD drugs would be higher - with an average increase of almost 4.6% - with some, such as Dexedrine SR and its generic, increasing by as much as 8.69% ($43.75 instead of $40.25) and 9.38% ($38.42 instead of $35.14) respectively.

"Pay-to-delay is a problem in the immediate future for health services in the US and Europe, and in the long run for taxpayers," said Dr Bokhari. "While the monthly price increases may not seem huge, when you take into account the number of people using these treatments even modest increases have a significant impact on consumer welfare and add millions a year to their overall cost.

"The pay-to-delay deals in this segment of the market highlight the tension between patent laws and antitrust law in an economically significant area. These are blockbuster drugs and pay-to-delay agreements made by the patent holder may ward off the entry threat by other potential challengers. If they are on the market without generic versions to challenge them then companies can maintain monopoly prices, and in doing so harm consumers by preventing or delaying access to cheaper drugs."

In the US, the Federal Trade Commission (FTC) is challenging the agreements, suing several pharmaceutical firms in the courts. Until recently the payments had been upheld under the 'scope of the patent test' since under the terms of settlement, the delayed generic entry still took place before the branded patent expired. However, one such case is now before the US Supreme Court, which is considering whether the deal is illegal and is due to give its decision this month. The FTC has also supported legislation introduced in the US Congress aimed at banning the agreements.

In April the UK's Office of Fair Trading (OFT) issued a 'Statement of Objections' to GlaxoSmithKline (GSK) for agreements with three generic makers in relation to its drug Seroxat, commonly used to treat depression. The OFT alleges that these involved substantial payments from GSK to keep the generic versions off the market, and that GSK's conduct amounted to an abuse of its dominant position in the market. The European Commission has also issued a Statement of Objections in three similar pay-to-delay cases in recent months.

Dr Bokhari said: "The drug companies argue that they have a right to protect their intellectual property and that these agreements benefit consumers by enabling generic versions to come onto the market sooner than they would normally have, for example if licensed entry has been allowed at a later date but before the patent expires. But while the deals may be beneficial to some extent, in that they might save courts and administrative bodies, such as patent offices, time and effort, they allow branded drug firms to charge monopoly prices and in a typical deal there may be a two to three year delay in a cheaper version becoming available.

"My research shows that in this respect, the challenges by the FTC, attempts to introduce legislation in the US Congress to ban such deals, and the investigations by the OFT and EU Commission are justified."

In the US, while there were three agreements in 2005, there were 19 in 2009, 31 in 2010 and 40 in 2012. Similarly, in 2011 in the EU there were 13 settlements limiting generic entry and involving payment to a generic drug maker. According to the FTC, pay-to-delay deals have cost US consumers $3.5 billion a year.

More information: The paper 'What is the price of pay-to-delay deals?' by Dr Farasat Bokhari is published online in the *Journal of Competition Law and Economics*.

Provided by University of East Anglia