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Key words: pay-to-delay, reverse payment, price simulations, ADHD drugs

JEL Classification: I11, K21, L41

# What is the price of pay-to-delay deals? <sup>†</sup>

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## Abstract

When a branded drug manufacturer makes a payment to a potential entrant to delay generic entry it raises anticompetitive concerns. In this paper I highlight one such deal in a subsegment of drugs used to treat attention deficit hyperactivity disorder (ADHD) – mixed amphetamine salts (MAS) – and compute market equilibrium prices under three counterfactuals. In the first case, equilibrium prices are computed if all MAS drugs were produced by a single profit maximizing firm, while in the latter two counterfactuals, I compute equilibrium prices when either an immediate release generic or an extended release branded drug are not available in the market. The simulations show that the average percentage increase in drug prices is 4-4.5 times larger in the latter two cases (when a drug is not available in the market) compared to a simple joint profit maximization of the same products. In this respect, the challenges by the Federal Trade Commission to the so called, ‘pay-to-delay’ deals and the recent legislations introduced into the Congress to ban such deals are justified.

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## 1. INTRODUCTION

A pay-to-delay deal (or ‘reverse payment’) involves a payment from a branded drug manufacturer to a generic maker to delay market entry. Under the terms of a typical pay-to-delay deal, a pharmaceutical company holding a patent on a drug enters into an agreement with a generic challenger where, in return for withdrawing the challenge, the generic firm receives a payment and/or an authorized licensed entry at a later date, but before the expiration of the patent itself. Such a move by the patent holder may ward off entry threat by other potential challengers and delay generic entry, causing a welfare loss for the consumers, and violate both the Antitrust Sherman Act in the US as well as Article 101 of the EU treaty. Nonetheless, pay-to-delay deals are on the rise on both sides

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<sup>†</sup>I greatly appreciate the comments and feedback provided by .... The usual caveats apply.  
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of the Atlantic. For instance, in the U.S., while there were three agreements involving a restriction on generic entry and a payment to the generic maker in 2005, there were 19 such agreements in 2009 and 31 in 2010 (EU, 2012; FTC, 2011a,b). According to the Federal Trade Commission (FTC), pay-to-delay deals stifle competition from lower-cost generic medicines and have cost U.S. consumers on average \$3.5 billion per year (FTC, 2010).

Precisely because of these concerns, the FTC is challenging these settlements as a top priority and has sued several pharmaceutical firms in different district courts (Leibowitz, 2009). Until recently the courts generally upheld these settlements under the ‘scope of the patent test’ since under the terms of settlement, the delayed generic entry still took place prior to the expiration of the patent (FTC, 2011c, 2010; Hemphill, 2009, 2007; Frank, 2007). However, in a recent decision by the Third Circuit Appellate Court of the U.S., the court found such a pay-to-delay deal to be ‘prima facie evidence of an unreasonable restraint of trade,’ and expressed the view that ‘scope of the patent test’ restricts the application of antitrust law and is contrary to precedent on patent litigation and competition. It further instructed the courts in its circuit to apply a ‘quick look rule of reason analysis’ based on the economic realities of the reverse payment settlement (3rd Circuit, 2012).

The Hatch-Waxman Act of 1984 seeks to preserve incentives of undertaking R&D by innovators but at the same time offers rewards for generic entry. Nonetheless, as noted in Bulow (2004), several features of the Act provide incentives to game the system. The pay-to-delay deals are one such example. Under section IV of the Hatch-Waxman Act, a generic maker can submit an abbreviated new drug application (ANDA) with the Food and Drug Administration (FDA) to launch a generic version of a patented drug when all the relevant patents expire, or certify that the patents are invalid and/or are not infringed by the generic product. The manufacturer of the branded drug can sue the generic maker, which automatically delays the ANDA approval for 30 months to permit litigation. If, however, the generic maker wins the litigation, it is granted a six-month market exclusivity period. The litigating parties may reach an agreement in which the branded manufacturer may convince the generic filer to drop the challenge to the patent. In return, it can offer a *licensed* exclusive six-month entry at a later date, but before the expiration of the registered patent date. This can be achieved by first reaching a non-exclusive licensing agreement with a *second* ANDA filer, who does not have automatic six month market exclusivity under the section IV clause, and then offering an exclusivity deal to the first filer, prior to the entry of the second licensed entry. The branded manufacturer can further sweeten the deal by offering a ‘reverse payment’ to the first filer (Kesselheim et al., 2011; Frank, 2007).

A common concern about these settlements is that while they may be beneficial to some extent, they prevent generic entry by allowing branded drugs to charge monopoly prices. For instance, the litigating parties may prefer to discontinue the dispute because it is too costly, time-consuming and/or

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risky with regard to the court outcome. They may save courts and/or administrative bodies, such as patent offices, time and effort. However, they may also harm consumers by preventing/delaying generic entry, thus allowing higher maintained prices of the branded drugs. A closely related literature looks at the impact of authorized generic entry (as may happen under a pay-to-delay deal as well) on subsequent independent generic entry and prices. [Hollis \(2003\)](#) argues that authorized generics deter independent generic entry in intermediate sized markets (and “probably” in other markets as well) while [Reiffen and Ward \(2007\)](#) show that authorized generic entry may deter independent generic entry in small and intermediate sized markets only and raise the long run prices by 1-2%. By contrast [Berndt et al. \(2007\)](#) argue that the effect of authorized entry on independent generic entry – and ultimately on consumer welfare – is likely to be small but positive.

In this paper I consider entry limiting agreements reached in one pharmaceutical segment – psychostimulant drugs used for the treatment of attention deficit hyperactivity disorder (ADHD) – and compute the simulated market equilibrium prices under hypothetical situations where either a generic is not available due to delayed entry, or the branded and generic prices are jointly set as they might be under an authorized generic entry. In August 2006, Shire PLC and Barr Laboratories reached an agreement where Barr would not market a generic version of Shire’s blockbuster drug Adderall XR until April 2009, at which point Barr would enter as a generic maker under license from Shire. This paper provides results of simulations that compute price changes from their baseline observed values to those under alternative counterfactuals constructed to mimic delays in generic drug entry in this market. The simulations in turn require estimates of demand system parameters of these drugs. As my point of entry, I use the estimated demand elasticities given in [Bokhari and Fournier \(forthcoming\)](#) and instead focus on computing *ex ante* price changes in order to gauge the likely impact of delayed generic entry.<sup>1</sup>

The market for psychostimulant drugs provides an important case study for two reasons. First, ADHD is a psychiatric condition which has an estimated prevalence of nearly 8% in school aged children in the U.S., of which 60% are prescribed medication for the disorder ([Centers for Disease Control and Prevention, 2005](#)). Between 1999 and 2003, the average consumption rate across states grew from approximately 14,321 gms/100K Children (age  $\leq 20$ ) to about 25,512 gms/100K Children ([Bokhari and Schneider, 2011](#)). In terms of total consumption, sales of ADHD drugs increased 1.8 fold between 1999 and 2003 surpassing \$2.2 billion (in constant 2000 dollars) by 2003. The pay-to-delay deals in this segment highlight the tension between patent laws and antitrust laws in an economically significant area.

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<sup>1</sup>Conditional demand estimation and welfare calculations when relevant drugs are not available in the market are given in [Bokhari and Fournier \(forthcoming\)](#).

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Second, the case of delayed entry by generic Adderall XR is similar in many respects to the K-DUR 20 case – now likely to go to the Supreme Court given that it has created a split in the 3rd and 11th Circuits – and can be quite informative. K-DUR 20 is an extended release form of potassium chloride used to treat high blood pressure. On August 6, 1995, Upsher-Smith filed an ANDA application with the FDA to market Klor Con M20, a generic version of K-DUR 20. At the time, Schering-Plough held a key patent on this branded drug which was set to expire in September 2006. Schering-Plough sued for patent infringement and in June 1997 the two companies reached an agreement in which Schering-Plough paid Upsher-Smith \$60 million and received licenses for 5 of Upsher’s products while Upsher-Smith agreed to wait until September 2001 to market the generic version.<sup>2</sup>

The next section describes the psychostimulant drugs market and the particulars of a deal in this segment that delayed the entry of a generic by several years and is similar to the K-DUR 20 case described above. Section three describes the data and the estimated demand parameters. Section four outlines the simulation algorithm and provides the results. The last section concludes.

## 2. BACKGROUND: ADHD DRUGS AND A PAY-TO-DELAY DEAL

Ritalin, which consists of active ingredient Methylphenidate-HCL (MPH), has historically been the choice of drug for treating ADHD. It was patented in 1954 by Ciba Pharmaceutical for the treatment of chronic fatigue, depression, and narcolepsy, as well as to offset the sedating effects of other medications. Ciba Pharmaceutical merged with J. R. Geigy Ltd to form Ciba-Geigy in 1970, which merged in 1996 with Sandoz Laboratories to form Novartis, the current producer of Ritalin. Since then several branded products – which differ by active ingredient or delivery mechanism – have entered the market such that by 2003 there were 16 branded products available in the market along with generics for many expired patents.

Both the active ingredient and the formulation play a significant role in product differentiation. Some molecules may be more effective in treating symptoms for one patient while others may be more suitable for another patient. Within each molecule, drugs are available in immediate-release (IR) tablets or liquid form as well as in extended-release (ER) tablets or capsules. The primary differences are in the absorption rate into the bloodstream, time to peak effect, and how many times a day they need to be administered. These differences provide important choices as IR tablets provide more tightly controlled regimens while the extended release forms reduce the peaks

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<sup>2</sup>The FTC challenged the pay-to-delay agreement between the parties and in 2003 concluded that the defendants had violated antitrust law. Their decision was set aside by the Eleventh Circuit in 2005, and the Supreme Court denied FTC’s petition for certiorari. However a group of private purchasers (wholesalers and retailers) brought a series of lawsuits against Schering-Plough which were consolidated in the District of New Jersey by the Judicial Panel on Multi-district Litigation. The Special Master appointed by the court recommended that the lawsuits be dismissed under the scope of the patent test but the Third Circuit rejected the precedent (July 2012) finding reverse payments to be presumptively illegal.

TABLE 1. Groups of Bio-equivalent Drugs

MPH - Methylphenidates			MAS - Mixed Amphetamine Salts		DEX - Dextroamphetamines		Other Molecules
IR (4hr)	ER-TAB (8hr)	XR (12hr)	IR (4hr)	XR (12hr)	IR (4hr)	ER (8hr)	
Ritalin	Ritalin SR	Concerta	Adderall	Adderall XR	Dexedrine	Dexedrine SR	Strattera
Methylin	Methylin ER	(OROS)	Generics		Dextrostat	Generics	Provigil
Generics	Metadate ER				Generics		Cylert
	Generics						Generics
	ER-CAP (8hr)						
	Ritalin LA						
	Metadate CD						

Note: The ‘Other Molecules’ group consists of three molecules: atomoxetine (Strattera), modafinil (Provigil) and pemoline (Cylert). Only pemoline is available as a generic.

and troughs over the day and eliminate the need for additional doses during school hours – a major consideration for many parents. Table 1 lists ADHD drugs on the market during the 1999-2003 period grouped by molecule and formulation with an approximate indication of how long the effect of the drug lasts (Barkley, 2006; Conner, 2006). As Table 1 shows, some of the subsegments consist of both branded drugs and generics, while others include only branded drugs.<sup>3</sup>

An important subsegment – and the focus of this paper – consists of drugs with mixed amphetamine salts (MAS) as the active ingredient and includes Adderall, its generic versions, and Adderall XR. Adderall is a reformulation of Obetrol, a drug originally approved in the 1960s for the treatment of obesity. In 1994, the rights to the Obetrol formulation were sold to Rexar, which was subsequently acquired by Shire. In turn, Shire received approval from the FDA in 1996 to market the mixed amphetamine salts (MAS) formulation to treat ADHD, selling it under the brand name Adderall. In 1999, Adderall had 21.6% share of all ADHD drugs. The generic version of Adderall (i.e., MAS-IR generic) entered in 2002 and by the end of 2003 there were three generic makers of this formulation. In order to protect its shares, Shire introduced a 12-hr version of Adderall, Adderall XR, in 2001.

In 2003, Shire’s Adderall XR was a blockbuster drug with nearly 25% of share of the ADHD drugs market when Barr Laboratories and Impax Laboratories filed ANDA applications (in November of 2002 and 2003 respectively) with the FDA to market generic versions of Adderall XR (Barr Laboratories, Inc., 2003c; Impax Laboratories, Inc, 2003). Under the terms of the Hatch-Waxman Act, Shire had a market exclusivity period until April 2005 but two key patents on the XR formulation further prevent entry in the MAS-XR segment until 2018. Consequently, Shire sued both firms for

<sup>3</sup>For instance, the MPH-ER tablets segment consists of Novartis’s Ritalin SR, Mallinckrodt’s Methylin ER, Celltech’s Metadate ER and generics by 19 other firms, while the MPH-ER capsule segment consists of only two branded drugs, Ritalin LA (Novartis) and Metadate CD (Celltech). The branded drugs within a segment carry a patent that differentiates them from other drugs in the same segment. In the case of Ritalin LA and Metadate CD (in MPH-ER caps), both use a bead-delivery system where the active molecule is packed into two types of beads, rapid-release which reaches the bloodstream quickly and extended-release beads which dissolve slowly. The primary difference is that Metadate CD uses 30% rapid-release beads while Ritalin LA uses 50% rapid-release beads – leading to a difference in the absorption profile across the two drugs. Similarly, Concerta, also an ER formulation of MPH and produced by Ortho-McNeil, uses a membrane based technology called Osmotic Release Oral System (OROS) which is not used by another drug. The OROS technology releases the active ingredient slowly throughout the day and this 12-hr MPH segment does not contain any other branded or generic drug.

- **A (1996)** – FDA approves Shire’s Adderall for ADHD (MAS-IR)
- **B (Oct/01)** – FDA approves Shires Adderall XR (MAS-XR) (protected by two patents till 2018)
- **C (Feb/02)** – FDA approves Barr’s ANDA for generic Adderall (MAS-IR). Generic Adderall launched.
- **D (Nov/02)** – Barr files ANDA for generic Adderall XR (MAS-XR) Shire sues Barr for patent infringement (Feb/03)
- **E (Nov/03)** – IMPAX files ANDA for generic Adderall XR (MAS-XR) Shire sues IMPAX for patent infringement
- **F (Oct/04)** – Shire’s initial market exclusivity for Adderall XR extend by 6 months
- **G (Apr/05)** – Shire’s exclusivity for Adderall XR ends
- **H (Jan/06)** – Shire settles with IMAPX – Impax to market MAS-XR no later than Dec/10 with non-exclusivity license from Shire
- **I (Aug/06)** – Shire settles with BARR – Barr to market MAS-XR by April/09 with exclusive license for 6 months from Shire
- **J (Oct/06)** – FTC probes settlements
- **K (Apr/09)** – Barr/Teva launch generic MAS-XR
- **L (Oct/09)** – Impax launches generic MAS-XR

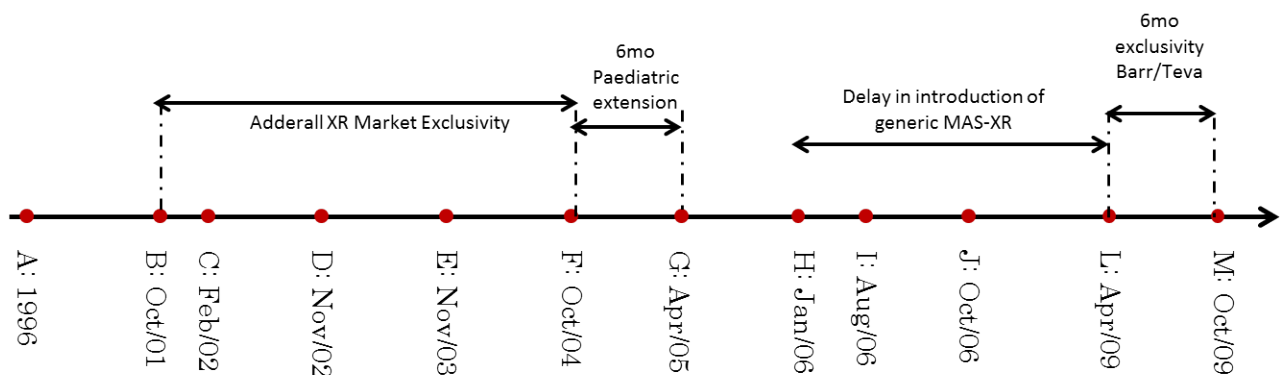


FIGURE 1. timeline

infringement of patents and the case between Shire and Barr was scheduled for trial for January 2006 ([Barr Laboratories, Inc., 2003b,a](#)). Shire settled with Impax – the second ANDA filer – in January 2006 and allowed it to market the generic version of Adderall XR under its own license prior to January 2010 ([FDAnews Drug Daily Bulletin, 2006](#)). Since Impax was the second filer of the ANDA application, and not entitled to six month exclusivity under paragraph IV of the Act, Shire did not offer an exclusive licence to Impax. Following this deal, Shire and Barr also reached a settlement in August 2006 where Shire agreed to grant Barr Laboratories a 180-day *exclusive* license to market generic Adderall XR in exchange for delaying entry until April 2009 ([Barr Laboratories, Inc., 2006](#)).

True to the terms of the deal, Teva Pharmaceuticals (which now owns Barr Laboratories) introduced generic Adderall XR on April 2, 2009 and Impax started shipping the generic version on October 2, 2009 ([Teva Pharmaceutical Industries Ltd., 2009](#); [Impax Laboratories, Inc., 2009](#)). According to the press release by Shire, no payments were made by Shire as part of the settlement of the Adderall XR dispute. Nonetheless, there were a series of complex side deals between the parties involving value transfers and product acquisitions: As noted in [Hemphill \(2007\)](#), Shire agreed to pay Barr Laboratories a net amount of \$102 million. Shire agreed to compensate Duramed – a subsidiary

of Barr Laboratories – up to \$165 million for product development for five products related to transvaginal ring technology which Shire planned to apply to women’s health products, as well as to seek regulatory approval to market Duramed’s Seasonique (an oral contraceptive). Further, Shire sold the rights to its older Adderall immediate release (IR) product to Duramed for \$63 million (see also [Patel \(2006\)](#) and [Barr Laboratories, Inc. \(2006\)](#)).

### 3. DATA AND DEMAND ESTIMATES

[Table 2](#) summarizes the average price in defined monthly dosage and market shares of drugs in urban counties in the U.S. in 1999 and 2003. Yearly data were obtained from the NDCHealth’s proprietary Source Territory Manager<sup>®</sup> files which provides sales by value (in dollars) and volume (in weight) for individual drugs by strength, period and geographic locations. Price per unit of weight was derived as sales divided by volume and deflated to constant 2000 dollars using the consumer price index. The units were then changed to defined monthly dosage (DMD) using the World Health Organization’s (WHO) definition for defined daily dosage (DDD) and a dosage equivalence between MPH-IR and other drugs.<sup>4</sup>

Simulations are based on conditional demand estimates given in [Bokhari and Fournier \(forthcoming\)](#). Here I only briefly describe the estimation procedure and the interested reader can find more details therein.<sup>5</sup> Following [Ellison et al. \(1997\)](#) and [Hausman and Leonard \(2005\)](#), a series of conditional demand systems were estimated by assuming weak separability of preferences and multistage budgeting by a representative consumer. This strategy allows the segmentation of the ADHD drugs into smaller multi-level subsegments. The lowest segment consists of all drugs in the same molecule and form. Thus, for example, one of the segments is MPH-IR which consists of all 4-hr drugs within the MPH molecule (drugs 1-3 in [Table 2](#)). Conditional demand equations for this segment were estimated using the almost ideal demand system (AIDS) specification where relative shares of revenues are a function of log prices, a log price index, and segment revenue plus county level exogenous variables, state fixed effects and time trends ([Deaton and Muellbauer, 1980a,b](#)). Homogeneity and symmetry restrictions were imposed and the system was estimated as SUR and 3SLS, where in the latter case, following [Hausman \(1997\)](#), the instruments used for prices were prices from other geographic markets. Such instruments are relevant if prices in different cities are correlated via common marginal cost shocks, and valid if there are no common demand side shocks across cities (see [Bresnahan \(1997\)](#)). To minimize the possibility of common regional demand side

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<sup>4</sup>WHO defines 30mg of MPH-IR as DDD or 0.9 grams per month and hence the price per monthly dosage of Ritalin is set to  $0.9 * p_r$  where  $p_r$  is the price per gram. Since not all drugs are listed in the WHO database, other drugs were converted to DDD using a dosage equivalence between them and MPH-IR. For example, the price of Concerta per gram in 2003 is \$73.94, but 1mg of Concerta is equivalent to 0.69mg of Ritalin and hence the price per month of Concerta is set to  $\$73.94 * 0.9 / 0.69 = \$96.45$ . Such a conversion assumes that a typical patient consumes 0.9 grams of Ritalin per month and if they are on another drug, appropriate dosage conversion is used for grams per month.

<sup>5</sup>An appendix with estimation details is attached for the referees.

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TABLE 2. Average Prices and Shares

Product	Firm	1999		2003	
		Price	Share	Price	Share
1-Ritalin (1.0)	Novartis	48.6	0.117	52.41	0.009
2-Methylin (1.0)	Mallinckrodt	40.74	0.045	31.81	0.013
3-Generic MPH-IR (1.0)	19 firms	39.32	0.289	33.06	0.026
4a-Ritalin SR (0.83)	Novartis	66.43	0.047	76.44	0.003
4b-Ritalin LA (1.25)	Novartis	.	.	57.25	0.024
5a-Metadate CD (1.25)	Celltech	.	.	56.22	0.024
5b-Metadate ER (0.83)	Celltech	NA	NA	66.11	0.002
6-Methylin ER (0.83)	Mallinckrodt	.	.	52.29	0.006
7-Generic MPH-ER (0.83)	15 firms	54.21	0.105	48.12	0.008
8-Concerta (0.69)	Ortho-McNeil	.	.	96.45	0.261
9-Adderall (2.86)	Shire	17.79	0.216	31.87	0.029
10-Generic MAS-IR (2.86)	3 firms	.	.	26.52	0.076
11-Adderall XR (2.14)	Shire	.	.	52.58	0.238
12-Dexedrine (1.75)	Glaxo Smith Kline	25.55	0.013	34.94	0.002
13-Dextrostat (1.75)	Shire	21.63	0.016	23.25	0.002
14-Generic DEX-IR (1.75)	4 firms	.	.	24.62	0.004
15-Dexedrine SR (2.14)	Glaxo Smith Kline	28.45	0.062	40.25	0.007
16-Generic DEX-ER (2.14)	2 firms	.	.	35.14	0.011
17a-Cylert (0.44)	Abbott Laboratories	81.05	0.061	90.06	0.002
17b-Provigil(0.28)	Cephalon, Inc	80.04	0.022	89.85	0.094
17c-Generic Pemoline (0.44)	8 firms	66.41	0.005	60.49	0.004
17d-Strattera (0.83)	Eli Lilly	.	.	83.59	0.156

**Notes** Prices are per unit of defined monthly dosage (DMD). The number in parenthesis in front of the name of the drugs is the conversion factor used for converting to generic MPH-IR equivalent dosage.

shocks, I used the average price from 20 randomly selected counties from the other three census regions that do not include the initial county. Other lower level segments were estimated the same way.<sup>6</sup> The next level up aggregates drugs by forms and estimates conditional demand for forms within the same molecule using an AIDS specification. For example, within the MAS molecules, revenue shares of MAS-IR and MAS-XR are functions of log prices of the forms (IR and XR), a log price index of the molecule (MAS, i.e., drugs 9-11) and total expenditures on the form and the rest of the estimation proceeded as in the lower levels. The third level up differentiates between molecules and was specified as a Cobb-Douglas system, where log quantity of each molecule was a function of log prices of the molecules, total expenditure and exogenous variables. Finally, at the top is a single equation consisting of all ADHD drugs. Based on conditional demand parameters

<sup>6</sup>Due to data limitations, some drugs were treated as one product. Specifically, in the MPH-ER segment drugs 4a and 4b were combined into one product 'Ritalin SR/LA' and drugs 5a and 5b were treated as a single product 'Metadate ER/CD'. Similarly, products 17a-17d were combined into one aggregate product 'Other'.

and average market shares, unconditional elasticities of the full system were computed as described in [Ellison et al. \(1997\)](#) and standard errors were obtained using bootstrap methods.

#### 4. PRICE SIMULATIONS

The objective of this exercise is to gauge the effect of entry by generic Adderall XR on other prices. However, the generic was not introduced until 2009 while the litigation among the parties and the FTC challenge was in the ex ante period. Thus, I use the unconditional demand parameters to compare the 2003 actual prices with the 2003 predicted prices under three counterfactuals. In the first case, prices are predicted when Shire and the generic makers of MAS-IR (i.e., the generic version of Shire’s 4-hr MAS tablet) set prices so as to maximize their joint profits. The idea is that if generic MAS-IR had entered under a license from Shire – i.e., an authorized generic entry as is sometimes done under the terms of a delayed entry deal – prices would be mutually agreed upon to maximize the joint profits. In the second and third scenarios, I consider out of sample projections to simulate the cases when either generic Adderall is not available in the market, or Shire’s branded Adderall XR is not available in the market. The latter two scenarios are relevant because, though generic Adderall XR entry did not take place till much later, this drug shares characteristics with other drugs in the market: (a) it is a MAS-XR drug and hence similar to Adderall XR, but is not branded, and (b) it is a generic MAS drug like MAS-IR generic, but is instead an XR formulation rather than an IR formulation. Nonetheless, these two simulations are based on out of sample projections as they require first computing the price that would set demand of the  $N$ th product to zero (i.e., a projection on the vertical price axis) and then computing the equilibrium prices of the remaining products  $N - 1$  products (see [Hausman \(1997\)](#)).

**Algorithm** Price simulations are based on a Nash-Bertrand price competition model with multi-product firms ([Nevo, 1998](#)). Let there be  $I$  related products and demand for product  $i$  be given by

$$Q_i = D_i(p_1, \dots, p_I, Z_i) \quad (1)$$

where  $Z_i$  is the vector of exogenous demand shifters. If there are  $L$  firms, and the  $l$ th firm produces a subset  $\mathfrak{L}_l$  of the products, then it maximizes its joint profit over these products as

$$\Pi_l = \sum_{r \in \mathfrak{L}_l} (p_r - c_r) D_r(p_1, \dots, p_I, Z_i)$$

where  $c_r$  is the constant marginal cost. Under Nash-Bertrand price competition, price  $p_i$  of any product  $i$  produced by firm  $l$  satisfies the first order conditions

$$Q_i + \sum_{r \in \mathfrak{L}_l} (p_r - c_r) \frac{\partial D_r(p_1, \dots, p_I, Z_i)}{\partial p_i} = 0. \quad (2)$$

Let  $\Theta$  be a 1/0 matrix with ones in the leading diagonal and in locations where a firm jointly produces products  $r$  and  $i$  and define  $\Omega$  such that  $\Omega_{ri} = -\Theta_{ri} \frac{\partial D_r(p_1, \dots, p_I, Z_i)}{\partial p_i}$ . Then the first order conditions imply a price equation (in matrix notation) of the form

$$p = c + \Omega^{-1}Q(p_1, \dots, p_I, Z_i). \quad (3)$$

Step 0 is to obtain the parameter values of the demand system. To this end, I assume a linear demand system and use the unconditional elasticity estimates in [Bokhari and Fournier \(forthcoming\)](#) to calculate the relevant demand parameters.<sup>7</sup> As a first step, the marginal cost  $c_i$  of each product (and for each market separately) is backed-out using [Equation 3](#) and the actual joint ownership matrix  $\Theta$ . For the first scenario, the next step is to change the values of  $\Theta_{ri}$  matrix from zero to one in relevant locations to allow for joint profit maximization of generic MAS-IR with other products by Shire (Adderall, Adderall XR and Dextrostat). Using this new joint profit maximization matrix, the derived marginal costs, and the estimated demand parameters, [Equation 3](#) is resolved for new equilibrium prices. For the second (and third) scenario, the first step is the same as in the earlier scenario (i.e., compute the marginal costs) but the second step is different. The second step is to compute a virtual price that sets the demand of the product in question to zero. As an example, let generic MAS-IR be the  $N$ th drug. Then, based on the  $N$ th demand function, compute  $p_N$  that sets  $q_N = 0$  by a projection to the vertical axis. Step three is to substitute this value of  $p_N$  into the remaining  $N - 1$  demand equations and the final step is to resolve [Equation 3](#) for the remaining  $N - 1$  prices. [Table 3](#) summarizes the results from the three scenarios.<sup>8</sup>

In the first counterfactual where Shire and the producers of generic MAS-IR engage in a joint profit maximization, there is a 3.76% increase in the price of generic MAS-IR and 1.10% increase in the price of Adderall XR. Given that these two drugs alone had about 31.4% of the market share in 2003, even these modest price increases translate into large negative welfare effects. The largest price increase is that for Dextrostat (11.78%), another Shire product, but the market share of this drug is very small. The price increase for Dextrostat is large because of the large positive cross-elasticities between this product and other MAS drugs (e.g. a 1% increase in price of generic MAS-IR implies a .36% increase in the demand of Dextrostat). The share weighted average price increase of the main ADHD drugs is about 1% and is comparable to the 1-2% higher (long run) equilibrium prices due to authorized generic entry in [Reiffen and Ward \(2007\)](#).

<sup>7</sup>B&F provide unconditional elasticity matrix at the sample mean (not the parameters of an unconditional demand system) but the relevant parameters can be obtained by assuming a functional form: if the demand system is linear, then given an elasticity matrix  $E$  and a matrix  $B$  with entries  $b_{ij} = q_i/p_j$ , an  $I \times I$  matrix  $A$  of slopes can be obtained as  $A = E\#B$  (where  $\#$  is the element by element multiplication) and a  $I \times 1$  vector of intercepts is then obtained as  $q - Ap$ . In the current exercise, I construct the matrix  $B$  using the sample average values of quantities and prices to obtain the slopes and intercepts. Further, I also set the terms in the cross-elasticity matrix  $E$  to zero if they were not statistically significant.

<sup>8</sup>Drug 17 is an aggregate product ‘Other ADHD drugs’ (see [Table 2](#)) and consists of individual products from 11 firms (3 brand names and eight generics). The demand estimates for this aggregate product were not robust to small changes in the demand specification. To overcome this difficulty, I set its cross-price elasticity with the other 16 drugs equal to zero. Thus its price does not change in these simulations and hence is removed from the table.

TABLE 3. Simulated Percentage Price Changes

Product (Firm)	Counterfactuals		
	1. Generic MAS-IR by Shire	2. Generic MAS-IR Not available	3. Adderall-XR Not available
	Mean (std)	Mean (std)	Mean (std)
1-Ritalin (Novartis)	0.33 (0.07)	3.61 ( 1.08)	4.65 (0.75)
2-Methylin (Mallinckrodt)	0.38 (0.14)	4.16 ( 1.84)	5.29 (1.56)
3-Generic MPH-IR (19 firms)	0.51 (0.12)	5.53 ( 1.83)	7.08 (1.22)
4-Ritalin SR/LA (Novartis)	0.31 (0.06)	3.36 ( 0.98)	4.34 (0.66)
5-Metadate CD/ER (Celltech)	0.42 (0.08)	4.56 ( 1.29)	5.89 (0.81)
6-Methylin ER (Mallinckrodt)	0.36 (0.10)	3.91 ( 1.38)	5.02 (1.08)
7-Generic MPH-ER (15 firms)	0.39 (0.10)	4.20 ( 1.47)	5.37 (1.06)
8-Concerta (Ortho-McNeil)	0.36 (0.07)	3.85 ( 1.11)	4.97 (0.70)
9-Adderall (Shire)	0.52 (0.17)	2.14 ( 0.77)	1.59 (0.34)
10-Generic MAS-IR (3 firms)	3.76 (1.08)	-	2.45 (0.51)
11-Adderall XR (Shire)	1.10 (0.28)	4.33 (1.30)	-
12-Dexedrine (GSK)	0.23 (0.04)	2.50 (0.69)	3.24 (0.44)
13-Dextrostat (Shire)	11.78 (3.20)	9.52 (2.74)	-26.70 (4.23)
14-Generic DEX-IR (4 firms)	0.60 (0.13)	6.52 (1.98)	8.42 (1.40)
15-Dexedrine SR (GSK)	0.62 (0.12)	6.73 (1.86)	8.69 (0.92)
16-Generic DEX-ER (2 firms)	0.67 (0.14)	7.28 (2.14)	9.38 (1.29)
Average	1.00 (0.33)	4.15 (1.22)	4.58 (0.65)

**Note:** The means and standard deviations are over 778 markets. The last row is the average percent change over the products weighted by original relative shares.

In the second counterfactual, the quantity sold of generic MAS-IR is set to zero by increasing its price by 55.46% (on average). Demand is now distributed over the remaining products based on the estimated substitution patterns. Patients switch to drugs not just in the same molecule and form but more widely, such that the prices of all the other drugs – and not just MAS drugs – increase quite significantly. The average price increase, or equivalently an increase in average profit margin (if costs do not change), is 4.15%.<sup>9</sup> Finally, in the third case, the price of Adderall XR is increased by 55.84% (on average) to set demand for this drug equal to zero. No other drug is available in the molecule-form combination of Adderall XR. Compared to the second counterfactual, the percentage increase in price of each product is higher – on a product-by-product basis – with the exception of the Shire’s products. This is because while the role of the molecule is important, so is the form. Since under this counterfactual there is no 12-hr drug in MAS (and there is already no 8-hr drug in MAS either), some consumers switch to the 4-hr versions of the same molecule (Adderall and Generic Adderall) while others who prefer a daylong coverage switch to other molecules: Concerta

<sup>9</sup>This is the average percentage change in the price of the remaining N-1 products, i.e., excluding generic MAS-IR and is weighted by the relative shares of these drugs.

(12-hr) or a combination therapy of MPH 8-hr and 4-hr, so no drug administration is needed during school hours. Whatever the reasons for switching so widely to other molecules, it is clear that non-availability of MAS-XR, on average, allows for higher equilibrium prices of all other drugs.

## 5. DISCUSSION

The U.S. Congress has made several attempts in recent years to limit the ability of pharmaceutical firms to delay generic entry vis-a-vis the ‘pay-to-delay’ deals. For instance, the “Preserve Access to Affordable Generics Act” (S.27–112th Congress, S.369 – 111th Congress, and S. 316 – 110 Congress) and the “Protecting Consumer Access to Generic Drugs Act” (H.R. 3995 – 112th Congress) seek to establish the *presumption* that reverse payments with limitations on entry are anticompetitive (unless otherwise demonstrated to be procompetitive) and are in line with the recent decision by the 3rd Circuit ([3rd Circuit, 2012](#)). Similarly, the “Fair and Immediate Release Generic Drugs Act” (S. 1882 – 112th Congress) aims to abolish the 180 days exclusivity for the first ANDA filer in order to remove the incentives for the pay-to-delay deals.<sup>10</sup> While no such law has as yet passed, it maybe up to the Supreme Court to decide the fate of pay-to-delay deals if it approves the certiorari petition for K-DUR 20.

In all three counterfactuals, there is a significant increase in the price of ADHD drugs, but the percentage increase is 4-4.5 times larger in the case of a missing drug compared to when Adderall and its generic versions jointly set profit maximizing prices. In a typical pay-to-delay deal, both features may be present: a two to three year delay in any generic entry – authorized or independent – followed by a term of licensed entry and joint profit maximization. To the extent that these counterfactuals mimic the delayed entry of generic Adderall XR, the price simulations shown above support reforms that establish the presumption of anticompetitiveness of pay-to-delay deals.

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<sup>10</sup>Interestingly, a provision that would have allowed the FTC to initiate proceedings in the case of pay-to-delay deals was also added to an appropriations bill (the “2010 Supplemental Appropriations Act”, H.R. 4899 – 111th Congress) but was eventually stripped by the Senate prior to its passage into law.

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