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ABSTRACT

The tradeoff between incentives to invest in R&D and efficient pricing takes a special form in the pharmaceutical sector. Brand drugs command high prices until generic competition begins, the timing of which usually depends on the outcome of patent infringement litigation. One potential outcome is a collusive agreement between the brand and a potential generic competitor that delays competition, with the brand sharing the profits from the delay by paying the generic challenger. Collusive patent settlements have plagued competition in pharmaceutical markets globally and especially in the U.S., the world's largest market. This paper estimates the cost of these collusive settlements to U.S. drug purchasers using stock price movements. If the brand firm's increase in profits from collusion is capitalized into stock prices, the change in value upon a settlement announcement can be used to estimate the new profit flows from higher prices to purchasers. We assembled data on 64 settlements reached during 2014-2023 and used the announcement descriptions and information that surfaced later to identify 17 potentially collusive settlements. We applied event study methods and found, consistent with prior research, that settlement announcements with no indication of collusion had no significant effect on the stock prices of brand firms implying that they tended to meet traders' expectations. Stock prices increased by approximately 3.5%, on average, after settlements with an indication of collusion, implying they increased brand profits by delaying generic entry. These increases correspond to a total increase in U.S. purchaser spending of $3.1-$3.2 billion per year during 2014-2023. Factoring up our estimate to the entire industry implies the increase in spending may be closer to $12 billion per year.

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A data appendix is available at http://www.nber.org/data-appendix/w33196

1. Introduction

High-income countries rely on time-limited patent protection to mediate the tradeoff between long-term incentives to invest in new products and short-term efficient pricing. Nowhere does this tradeoff attract more attention than the R&D-intensive pharmaceutical sector. On one side of the tradeoff, in the U.S. pharmaceutical market (the largest in the world), brand drug companies spent 25% of net revenues on R&D in 2019, a higher share even than other research-intensive sectors like software and semiconductors (Congressional Budget Office, 2021). And these investments have improved public health. Of the 3.3 years in increased life expectancy gained in the U.S. between 1990 and 2015, pharmaceuticals (about 10% of health care costs) were responsible for 35%, compared to 13% attributable to all other medical care.[1] Yet on the other side of the tradeoff, patent and other regulatory exclusivities shelter monopoly prices that put drugs with benefits far exceeding short-run costs out of reach even of insured patients. In many countries, very expensive drugs are simply kept off national drug lists altogether (Kyle, 2025).

Within a regulatory structure set at the national level, brand and generic manufacturers act to determine when monopoly prices end and competition begins. In ways we describe below, the U.S. leverages the competing interests of brand and generic manufacturers to encourage legal challenges to patents that may not be legitimate barriers to competition. The legal system can, however, be misused. Patent disputes, including those in the drug industry, are usually between potential competitors, raising the immediate antitrust concern that when parties privately negotiate a settlement, they collude to maximize joint profits (Shapiro, 2003). As Lemley and Shapiro (2005) put it twenty years ago:

[1] The balance was attributed to factors other than medical care (Buxbaum et al., 2022).

> "… The monopolist and the entrant will have an incentive to negotiate in a way that leads to the monopoly level of output and the monopoly price. … an easy way for the parties to settle and achieve full monopoly profits: the incumbent can pay the potential entrant not to enter the market."

This is exactly what has happened in the drug industry in the U.S., where "pay-for-delay" settlements have increased costs for drug purchasers and subvert the socially chosen tradeoff between dynamic and static efficiency (Edlin et al., 2013; Elhauge and Krueger, 2012).[2] They have also been called "reverse-payment" settlements because the plaintiff brand drug seller pays the defendant generic entrant to settle, the reverse of the typical direction.

The U.S. is particularly vulnerable to delayed generic entry because of the high prices paid for brand drugs. Unlike other high-income countries that regulate or negotiate drug prices, the U.S. relies almost exclusively on competition from generic suppliers to moderate drug costs (Kyle, 2025). On average, buyers in the U.S. pay three times the price for brand drugs compared to buyers in the U.K. and E.U. (Mulcahy et al., 2024). Once competition begins, however, public and private policies in the U.S. are very successful at substituting lower-cost generics. In recent years, generics are prescribed 97% of the time when they are available (IQVIA Institute, 2021). Generic prices tend to be lower in the U.S. compared to Europe (Mulcahy et al. 2024). With high brand and low generic prices, a delay in generic entry can cost purchasers of a blockbuster drug billions of dollars per year. The main purpose of this paper is to provide an industry-wide estimate of the magnitude of the higher prices collusive settlements delaying competition imposed on drug buyers.

One reason estimating the impact of reverse-payment settlements is useful is that the extent to which they continue to interfere with competition in the U.S. drug industry is unclear. The

[2] Competition authorities in the E.U. have adopted the "pay-for-delay" terminology to describe patent settlements in which a brand company transfers value to a generic in connection with an agreement about a date of generic entry (European Commission, 2024).

Federal Trade Commission (FTC) has led efforts to challenge the legality of specific reverse-payment settlements under antitrust law. The resulting court rulings and consent decrees may have curtailed their frequency (Federal Trade Commission, 2019). FTC tracking indicates that settlements with "explicit compensation beyond solely litigation fees" to the generic firm have petered out (Federal Trade Commission, 2025). On the other hand, a competing hypothesis is that efforts to limit reverse payments may have simply driven brand and generic firms to use more complex and harder-to-detect forms of payment (Drake and McGuire, 2024; Drake et al., 2025).

Incentives to brand and generic firms to maximize joint profits by delaying generic competition and dividing profits with a reverse payment are present in other countries. In the E.U., 11% of the drug patent litigation settlements reached in 2016 included a "limitation on generic entry" and a "value transfer … to the generic company" (European Commission, 2018). The European Commission has attempted to deter such deals by levying fines against the involved parties (Chee, 2024; European Commission, 2024). Reverse-payment settlements have attracted attention from competition authorities in Canada, India, Japan, Korea, and the U.K. as well (Carrier, 2017; Gallasch and Mariyama, 2020).

Assessing the harm from a reverse-payment settlement involves comparing (1) spending on brand and generic versions of the drug based on the observed actual generic entry date that was potentially influenced by the payment with (2) spending associated with the generic entry date in an unobserved counterfactual settlement without the reverse payment.[3] In private antitrust litigation, alternative dates and financial harms are estimated by economists on behalf of

[3] Another possible counterfactual is that the parties do not settle and pursue litigation, in which case spending by purchasers is based on the likelihood of various litigation outcomes (Ghili and Schmitt, 2017).

plaintiffs and defendants with the aid of confidential business documents obtained in discovery. An industry-wide estimate of the prevalence of and harm from reverse-payment settlements must be made without access to firms' internal communications and projections.

After reviewing related literature and providing some institutional background, this paper quantifies the magnitude of the problem using publicly available data. As we explain below, harms to purchasers are approximately equal to the additional profits to the brand and generic sellers after a reverse-payment settlement in relation to a competitive settlement. Industry experience indicates that the lion's share of these incremental profits accrues to the brand seller (Ghili and Schmitt, 2017; Drake and McGuire, 2016), so estimating the incremental brand profits will capture most of the harm.

We use financial market event study methods to estimate the brand firms' incremental profits from settling patent litigation (MacKinlay, 1997). Stock traders are attuned to profit prospects for drug companies and react quickly to announcements changing those prospects, capitalizing anticipated new profit flows into stock prices. Following event-study methods, after excluding observations with potentially confounding events, we assume the immediate change in stock price value over trends identifies the effect of a settlement announcement. We then assume the difference in the stock-price effect between settlements with and without an indication of collusion estimates the capitalized additional profits anticipated from collusion. As we discuss in more detail later, to the degree our assumptions don't fully hold, for example, if financial markets anticipate a collusive settlement to some degree, our methods will underestimate the cost of collusion.

For this paper, we assembled data on 64 U.S. patent litigation settlements over the ten-year period 2014-2023 that were publicly announced and met criteria for inclusion in an event study

analysis. The actual contracts were not publicly available, so we used descriptions of the terms in the announcements and information that surfaced later to categorize 17 of the settlements as potentially containing a reverse payment. Two settlements appeared to include explicit compensation to the generic firm in the form of the brand's promise that it would not sell a competing "authorized generic" (AG). (An AG launch upon the traditional generic's entry is historically common, especially for top-selling drugs.) Ten settlements included terms that could convey value to the generic firm by deterring the brand from selling its AG. We classified an additional five settlements as including an indication of reverse payment because the brand did not in fact sell an AG after the traditional generic's launch.

Brand firms' stock prices increased significantly (by about 3.5%) after settlements with indication of reverse payment, but not in response to other settlements, on average. Brand firms' market capitalization (the total value of a firm's shares) increased by approximately $16.1-$16.5 billion in response to announcements of settlements with indication of reverse payment. This translates to approximately $3.1-$3.2 billion per year in pre-tax 2024-dollar sales, corresponding to additional spending by drug purchasers during 2014-2023. There are multiple reasons our estimates provide a conservative lower bound of the harm from reverse-payment settlements. Factoring up the harm based on the percentage of reverse-payment settlements not included in our data, we estimate that the industry-wide harm could be about $12 billion per year.

2. Related Literature

2.1. Collusion in the drug industry

Federal and state antitrust authorities as well as private plaintiffs have alleged price fixing, market allocation, and other forms of collusion among brand manufacturers, among generic

manufacturers, and between brand and generic manufacturers. As an example of brand collusion, in *Insulin Pricing Litigation*, currently at the United State District Court for the District of New Jersey, three large brand insulin manufacturers are alleged to have coordinated prices for insulin products.[4]

The U.S. Department of Justice and a group of State Attorneys General have alleged that generic drug manufacturers colluded to fix prices on a wide range of generic drugs.[5] Economic research has tested for and found an effect of the alleged collusion. Clark, Fabiilli, and Lasio (2022) studied the causal effects of collusion on the prices of six drugs included in the Connecticut Attorney General's complaint. These six drugs were selected because they were produced by Heritage, whose CEO acknowledged colluding with representatives from other manufacturers. In relation to a set of control drugs, collusion significantly increased the prices of four of the six drugs in the range of 13% to 166%.

Starc and Wollman (2025) compared the price path of generics sold by the large generic firm Teva that were and were not alleged to be part of the collusion. Starc and Wollman dated the start of Teva's participation in the conspiracy as when Teva hired an industry insider charged by upper management with increasing revenues from generic products. The authors analyzed the price path of 416 of Teva's oral-solid drugs over 12 years, of which 113 were classified as involved in the conspiracy. Collusion with other generic sellers led to abrupt price increases averaging 40-50%.

[4] This case is brought by a class of private payers. Civil Action No. 3:17-cv-00699(BRM)(LHG). For a detailed description of pricing for long-acting insulin products, see Senate Finance Committee (2021).

[5] Starc and Wollman (2025) describe the working of the generic drug cartel and some of the lawsuits filed by public authorities.

A large economic literature has addressed collusion in patent settlements between a brand firm and a potential generic challenger. Early economic research on reverse-payment settlements focused on understanding why the brand drug seller (the plaintiff in a patent infringement lawsuit) would pay the generic firm (the defendant) and whether such a payment could be harmful to competition. Shapiro (2003) concluded that a brand firm, acting rationally, would not include an otherwise unexplained reverse payment in a settlement unless it was getting a delay in generic entry in return. The "unexplained" portion of a reverse payment is the amount that exceeds the brand firm's avoided litigation expenses and the fair value of any services provided by generic. Shapiro's straightforward economic inference was proven mathematically in several papers (Elhauge and Kreuger, 2012; Eldin et al., 2013).

2.2. Event studies of patent litigation outcomes in the drug industry

Financial market-event study methods have been used to examine the impact of patent litigation outcomes on stock prices. Panattoni (2011) studied the effect of 37 district court decisions and found that brand firms' stock prices significantly increased after a win and significantly decreased after a loss. Jacobo-Rubio, Turner, and Williams (2020) reported similar results. These findings imply that investors account for how potential litigation outcomes affect the likely timing of generic entry for important brand products.

In previous research that used event study methods to examine U.S. patent litigation settlements over the period 1993 to 2013, settlement announcements with no indication of a reverse payment had no significant effect on the stock prices of brand firms, implying that they tended to meet investors' expectations about the likely timing of the generic entry (Drake et al., 2015). On the other hand, stock prices tended to increase significantly upon announcement of

settlements with indication of reverse payment (by 6% on average), implying that they delayed generic competition longer than investors expected.

2.3. Prior estimates of the industry-wide harm from reverse-payment settlements

Since 2010, several efforts have been made to quantify the magnitude of harm to U.S. drug purchasers from reverse-payments settlements. Although antitrust authorities have recognized that collusive settlements may delay competition in other countries, we were not able to identify any efforts to quantify the extent of the problem elsewhere.

Spurred by concerns about the harmful effects of reverse payments in the U.S., the Medicare Modernization Act of 2003 required brand and generic drug companies to provide a copy of their confidential settlement agreements to the FTC for review. The FTC is required to report summaries of the terms of the agreements. In 2010, the FTC estimated the industry-wide frequency and harm from reverse-payment settlements by analyzing the outcome of 218 drug patent litigation settlements executed during fiscal years (FY) 2004-2009. The FTC found that 66 settlements included compensation to the generic firm and 152 did not. Agreements with compensation prohibited generic entry for 17 months longer, on average, compared to agreements without compensation. The FTC interpreted this difference as the delay in generic entry due to the brand-to-generic payment. Applying the 17-month average delay period to an estimate of the brand drug dollar sales that were potentially affected by reverse-payment settlements, the FTC estimated that the harm from pay-for-delay settlements was $3.5 billion in 2010 (Federal Trade Commission, 2010).

Feldman analyzed Medicare expenditures for twelve drugs potentially affected by reverse-payment settlements reached between 2005 and 2013 to update, in her words, “The Price Tag of ‘Pay for Delay’” (Feldman, 2022). She defined a settlement as including a pay-for-delay if it

"contained either explicit or potential compensation from a brand manufacturer to a generic manufacturer, and a restriction on the generic manufacturer's ability to market its product in competition with the branded product." She then assumed the length of the delay was the time between the actual settlement entry date and either (1) the expiration of the automatic 30-month stay specified by regulation or (2) the expiration of the primary (i.e., composition) patent. Alternatively, following the FTC, she also calculated harm by assuming that each reverse payment delayed generic entry by an additional 17 months.[6] Feldman estimated that the cost to Medicare Part D plans alone from the delays in generic entry for the period 2006-2017 was between $2.3 billion and $13.5 billion per year in terms of nominal dollars, depending on the counterfactual used. Scaling up to the entire market, Feldman estimated that the harm from pay for delay in the U.S. was between $6.2 billion and $37.1 billion per year in terms of nominal dollars.

In August 2022, the Congressional Budget Office (CBO) released a preliminary cost estimate of potential savings to the federal government from the effects of a proposed bill intended to prevent reverse-payment settlements (Congressional Budget Office, 2022). CBO estimated that the federal government would save $519 million over the ten-year period 2022-2032 ($51.9 million per year). In March 2024, CBO updated its estimate of savings to $1,280 billion over the ten-year period 2024-2034 ($128.0 million per year), still a fraction of previous estimates (Congressional Budget Office, 2024). CBO determined that drugs and biologicals with $4-$5 billion in annual sales would be affected by the bill and that companies would "generally comply

[6] Ghili and Schmitt (2017) proposed a different method for estimating the date of entry in the absence of a reverse payment. They described how a Nash-bargaining model could be used to infer the strength of the patents at issue in the litigation and then what date compromise would likely emerge in negotiation in the absence of reverse payments. The method involves first calculating each party's payoffs from winning or losing the litigation and from the reverse-payment settlement. The chance that the patent would be upheld in court can then be estimated by assuming that the parties split the gains evenly from settling (over litigation).

with the new requirements." CBO also used the FTC's estimate and assumed the bill would accelerate generic entry by approximately 17 months for affected drugs.

CBO provides little information about how its estimates are generated and it is unclear why Feldman's were so much higher. The proposed bill would only affect future settlements, which explains why CBO's estimate of savings ramps up slowly. CBO acknowledged that much of the uncertainty in its cost estimate is due to uncertainty in the estimated dollar sales that would be affected by the bill (Congressional Budget Office, 2024).

At the time CBO issued its estimate, the FTC had only summarized the terms of settlements executed through FY2017. However, the FTC recently released reports summarizing the terms of settlements reached between FY2018 and FY2021 (Federal Trade Commission, 2025). The FTC found that the number of agreements with a restriction on generic entry and explicit compensation (not including cash payments less than $7 million) decreased from a peak of 33 in FY2012 to just one in FY2020 and none in FY2021 (Federal Trade Commission, 2025). As we noted earlier, the drop in the FTC count of settlements with explicit compensation could simply reflect brand and generic firms' transition to more complex forms of reverse payments. The FTC was aware of this possibility, noting in its latest report that 17 settlements in FY2021 included "possible compensation." Whether any "possible compensation" affects generic entry and the prevalence of settlements with reverse payments beyond FY2021 are both unknown.

3. Institutional Background

3.1. Regulation of entry in the pharmaceutical industry in the U.S.

A brand drug manufacturer must submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) and receive the FDA's approval before the drug can be sold (Food

and Drug Administration, 2022). An NDA includes a summary of required clinical studies regarding the drug's safety and efficacy. The NDA must also include information about any patents that could reasonably be asserted against firms selling generic copies of the drug, information made public in an FDA publication called the *Orange Book*.

The Hatch-Waxman Act of 1984 created an alternative pathway to FDA approval for generic drug manufacturers. Instead of submitting an NDA, a generic firm can submit an abbreviated NDA (ANDA) (Food and Drug Administration, 2025b). An ANDA submission relies on clinical research described in the NDA of a reference product, which greatly reduces the submission costs for a generic firm. The proposed generic must have the same active ingredient(s), form, route of administration, and strength as the reference product and must be similarly absorbed by the body (Food and Drug Administration, 2025b).

The Hatch-Waxman Act also structured a process for patent litigation between generic and brand drug manufacturers (Hemphill and Sampat, 2025). An ANDA filer that intends to sell its product before the expiration of any of the reference drug's patents must include a "Paragraph IV certification" in its ANDA. A Paragraph IV certification asserts that a patent is invalid or will not be uninfringed by the proposed generic product and is treated as a technical act of patent infringement. A Paragraph IV ANDA filer must also notify the brand drug seller of its submission, allowing the brand firm to initiate patent infringement litigation against the generic applicant. The Hatch-Waxman Act prohibits the FDA from granting approval of the generic's ANDA until 30 months after the brand firm received the notice. The "30-month stay" gives the parties a chance to resolve the litigation before the generic product is sold. Reverse-payment agreements delaying generic entry sometimes emerge from these negotiations.

To encourage generic firms to challenge patents, the Hatch-Waxman Act provides eligibility for a 180-day generic exclusivity period to the first generic firm to submit a substantially complete ANDA with a Paragraph IV certification (Hemphill and Sampat, 2025). The FDA cannot approve an ANDA submitted by later filers until the generic exclusivity period has expired. The 180-day exclusivity period facilitates reverse-payment settlements because, by paying off the first ANDA filer to delay its entry, the brand firm essentially delays the entry of all ANDA filers (Hemphill, 2006).[7]

3.2. Antitrust scrutiny of reverse-payment settlements in the U.S.

After split decisions at the appeals court level, in 2013, in *FTC v. Actavis*, the U.S. Supreme Court concluded that reverse-payment settlements could violate antitrust laws.[8] The Court recommended a rule-of-reason approach using the existence and size of any reverse payment to infer collusion (Edlin et al., 2013; Edlin et al., 2015).

Since *Actavis*, dozens of antitrust cases alleging that reverse-payment settlements resulted in delayed generic have been pursued by the FTC and private plaintiffs. A recent survey found that 29 had been settled, eight had been resolved, and three were ongoing (Carrier and Bank, 2024). Several of the settlements obliged defendants to pay hundreds of millions of dollars in compensation to purchasers of specific drugs. For example, in 2015, in the FTC's case related to the drug Provigil, the defendant agreed to pay $1.2 billion to compensate drug purchasers. Of

[7] Later filers can technically force the first filer to use or lose its exclusivity period by winning the patent litigation through the appeals process, but this rarely happens in practice because later filers have relatively little to gain by winning the litigation which may open entry to other generic sellers (Hemphill and Lemley, 2011; Drake and McGuire, 2020).

[8] Elhauge and Kruger (2012) contains a discussion of the conflicting judicial decisions at the Courts of Appeals level prior to *Actavis*.

the eight cases that have been resolved, the FTC won an administrative decision that was affirmed by the Fifth Circuit and private plaintiffs lost the other seven.[9]

3.3. Old and new forms of reverse payment

The forms of payment brand firms make to first-to-file generic firms have evolved over time (Hemphill, 2009). In several settlements executed in the 1990s, the brand firm simply wired the generic firm a large sum of money. Since then, some settlements have included "side deals" with favorable terms for the generic firm. Other settlements have included a promise by the brand firm not to sell an authorized generic (AG), *i.e.*, its product labeled as a generic, during the first filer's 180-day exclusivity period.

A no-AG agreement works like this. Usually only one ANDA filer can sell its generic product during the 180-day generic exclusivity period. However, the brand firm can sell a second generic product under the brand drug's regulatory approval. By barring the brand firm from selling its AG, a no-AG agreement reduces the number of initial generic products to one (just the ANDA filer's).

The reduction in generic competition from a no-AG agreement conveys substantial value to the generic firm. The generic firm's profits are more than doubled because it can sell at a higher price without competition from an AG and can capture all the generic unit sales (instead of about half). For a blockbuster brand drug, a no-AG agreement can be worth hundreds of millions of dollars to the generic firm. No-AG agreements are an especially harmful form of payment for drug purchasers because, on top of delaying generic entry, they also increase the initial generic price by reducing the number of generic drug sellers (Edlin et al., 2015).

[9] Three of the losses were unfavorable jury verdicts and four were dismissed by judges at the motion-to-dismiss stage. Unlike the FTC, private plaintiffs must prove that a reverse payment resulted in an actual delay in generic competition. Carrier and Bank (2024) observed that "the facts in the cases that settle before trial tend to threaten greater liability as compared to the more nuanced cases that proceed to judgment."

No-AG agreements have themselves evolved in response to antitrust scrutiny. The presence of *explicit* no-AG terms in patent litigation settlements seems to have ended after antitrust challenges which, in at least one case, resulted in a consent decree by a major generic seller to not execute settlements with explicit no-AG terms (Federal Trade Commission, 2019). However, some recent settlements have included so-called *implicit* no-AG agreements. These agreements technically allow the brand to sell an AG but provide incentives for it not to do so. Three forms of implicit no-AG agreements have been observed:

(1) *Tiered royalty provisions* provide the brand a share of the generic firm's profits that is reduced (or eliminated) if the brand introduces its AG. The royalties incentivize the brand not to compete. The brand can earn more from receiving a share of the profits in a generic monopoly than it can from selling a second generic product at a lower price in a generic duopoly (Drake and McGuire, 2024; Federal Trade Commission, 2025). For example, consider a generic-to-brand royalty rate that is set to 50% in a generic monopoly and 0% in a generic duopoly. The brand firm could capture about half the generic market and retain all the profits from selling an AG in a generic duopoly (Federal Trade Commission, 2011), but it would lose its 50% share of the ANDA generic's profits by doing so. Because the monopoly price is higher than the duopoly price, the brand firm rationally does not introduce its AG.

(2) *Volume limits* cap the number of units (e.g., pills) the generic firm is allowed to sell. Volume limits also incentivize the brand not to compete (Drake and McGuire, 2024; Federal Trade Commission, 2025). For example, consider a volume limit set to equal 50% of what the total generic units would be if it were not for the limit. The brand firm's AG would usually capture the remaining 50% of generic units (Federal Trade Commission, 2011). However, because of the volume limit for the ANDA generic, the brand firm's AG sales would only

cannibalize its brand drug sales, not take market share from the ANDA filer. Because the brand drug is sold at a higher price than the AG, the volume limit on the ANDA filer induces the brand to withhold its AG.

(3) *Third-party no-AG agreements* are a commitment by the brand manufacturer not to sell an AG through a third party (i.e., a different firm not involved in the settlement). Because marketing strategies are very different for brand and generic drugs, many brand firms without experience marketing generic products sell AGs through distribution agreements with a third party (Federal Trade Commission, 2011). Thus, a promise not to enter into such a distribution agreement may be enough to deter the brand firm from selling an AG (Federal Trade Commission, 2025).

Like explicit no-AG terms, implicit no-AG agreements also reduce the expected number of generic sellers. This reduction in competition provides a net benefit to the generic firm (despite the royalty payments or volume limit) by allowing it to sell at a higher price as the only generic seller during the exclusivity period.

While explicit no-AG terms seem to have disappeared from brand-generic patent settlements, implicit no-AG agreements may be taking their place (Drake and McGuire, 2024; Drake et al., 2025). We assess harm from agreements with an indication of including implicit as well as explicit no-AG agreements. Implicit no-AG agreements have fallen under the FTC's categorization of "possible compensation" whereas explicit no-AG terms are categorized as explicit compensation (Federal Trade Commission, 2025).

4. Data Collection and Event Study Methods

4.1. Identification of settlements

To assemble data on brand-generic patent litigation settlements, we started with the FDA's list of drugs for which a Paragraph IV certification had been filed (Food and Drug Administration, 2025a). We used Google and LexisNexis to search on the drug name and variations of the phrases "settle," "patent dispute," "patent challenge," and "patent litigation." We found 94 settlements that were publicly announced between 2014 and 2023 for which we could determine that the settling party was (or likely was) a first-to-file generic firm. For drugs with multiple first filers, we included the earliest settlement with a first filer in our data.

Of the 94 settlements we identified, 64 met the criteria for our event-study approach. Specifically, we included settlements if (1) the date the settlement was announced was clear, (2) the brand company was publicly traded, and (3) no confounding events occurred on the date of the announcement or the day after that might have affected the brand company's share price. These settlements are listed in Table 1.

Table 1. Drug patent litigation settlement announcements meeting event study criteria

Settlement announcement	Brand drug name	Licensed entry date	Possible reverse payment terms	ANDA filer initially sells alone	Pre-generic annual sales ($M)
3/19/2014	**Daytrana**	**9/1/2015**	**Profit Split**	**Unclear - No Entry**	**98**
4/15/2014	Generess	4/1/2015		No	115
4/17/2014	**Celebrex**	**12/2014**	**Profit Split**	**Unclear - Generic Exclusivity Lost**	**2,560**
5/15/2014	**Gleevec**	**2/1/2016**	**Explicit No AG**	**Yes**	**5,000**
6/2/2014	**Nuvigil (100 and 200mg)**	**6/1/2016**		**Yes**	**373**
6/20/2014	**ProAir HFA**	**12/19/2016**	**Volume Limit**	**Unclear - Late Entry**	**429**
10/10/2014	**Amitiza**	**1/1/2021**	**Profit Split**	**Yes**	**427**
11/26/2014	**Forfivo XL**	**1/15/2018**	**Explicit No AG**	**Unclear - Late Entry**	**44**
2/11/2015	**Rescula**	**Before July 2021**	**Profit Split**	**Unclear - No Entry**	**0**
4/13/2015	Gralise	1/1/2024		No	85
4/14/2015	Epiduo	Undisclosed		No	251
4/30/2015	Banzel	5/30/2022		Unclear - Multiple Generics	155
6/3/2015	Zipsor	3/24/2022		No	10
7/1/2015	Pristiq	Undisclosed		No	883
9/10/2015	Namenda XR	1/31/2020		Unclear - Early Entry	936
10/1/2015	**Remodulin**	**6/26/2018**		**Yes**	**599**
10/2/2015	Rayos	12/23/2022		No	52
10/5/2015	Absorica	12/27/2020		No	158
10/5/2015	Ampyra	2027		Unclear - Early Entry	543
10/27/2015	Abstral	6/1/2018		Unclear - No Entry	5
12/11/2015	**Tamiflu**	**Before 2/23/2017**		**Yes**	**400**
12/23/2015	**Revlimid**	**Mar-22**	**Volume Limit**	**Yes**	**8,695**
5/25/2016	Folotyn	12/1/2022		Unclear - No Entry	48
8/31/2016	**Namzaric**	**1/1/2025**		**Yes**	**89**
1/6/2017	Treanda	11/1/2019		Unclear - Late Entry	193
1/13/2017	Qudexy XR	3/19/2020		Unclear - Late Entry	121
1/17/2017	Livalo	5/2/2023		Unclear - Multiple Generics	298
3/7/2017	**Trokendi XR**	**1/1/2023**	**Profit Split**	**Yes**	**488**
4/6/2017	**Xyrem**	**1/1/2023**	**Profit Split**	**Yes**	**1,300**
4/13/2017	Kuvan	10/1/2020		No	489
10/5/2017	**Omidria**	**4/1/2032**	**Profit Split**	**Unclear - No Entry**	**74**
10/18/2017	Adzenys XR	9/1/2025		Unclear - No Entry	27
10/30/2017	Nexavar	Undisclosed		Unclear - Multiple Generics	70
1/29/2018	Zohydro ER	3/1/2029		Unclear - Early Entry	42
2/15/2018	Orenitram	6/15/2027		Unclear - No Entry	186
5/3/2018	Linzess (145mg, 290mg)	8/5/2030		Unclear - No Entry	1,002
5/24/2018	Vascepa	8/9/2029		Unclear - Early Entry	847
6/20/2018	Rytary	7/31/2025		Unclear - No Entry	92
8/9/2018	Tyvaso	1/1/2026		Unclear - No Entry	415
9/12/2018	**Xifaxan**	**1/1/2028**	**Volume Limit; Profit Split**	**Unclear - No Entry**	**1,810**
9/21/2018	Ravicti	7/1/2025		Unclear - No Entry	326
12/26/2018	Cotempla XR	7/1/2026		Unclear - No Entry	1
2/13/2019	Jublia	Undisclosed		Unclear - No Entry	274
3/18/2019	**Victoza**	**12/22/2023**		**Yes**	**1,650**
5/7/2019	Kyprolis (30mg)	Undisclosed		Unclear - No Entry	921
5/30/2019	Kyprolis (10 and 60mg)	2027		Unclear - No Entry	921
8/21/2019	Aggrastat (12.5mg)	3/1/2023		Unclear - No Entry	12
11/5/2019	Evomela	2026		Unclear - No Entry	28
1/2/2020	Gocovri	3/4/2030		Unclear - No Entry	120
5/8/2020	Myrbetriq	Undisclosed		Unclear - Multiple Generics	2,403
10/1/2020	Xtampza ER	9/2/2033		Unclear - No Entry	105
11/18/2020	Aggrastat (5mg)	11/1/2022		Unclear - Multiple Generics	12
5/26/2021	Linzess (72mg)	3/31/2029		Unclear - No Entry	1,073
7/22/2021	Movantik	10/1/2030		Unclear - No Entry	200
12/8/2021	Bijuva	5/25/2032		Unclear - No Entry	6
1/14/2022	Hetlioz	3/13/2035 or 7/27/2035		Unclear - Early Entry	174
6/9/2022	Austedo	4/1/2033		Unclear - No Entry	971
8/8/2022	Alecensa	Undisclosed		Unclear - No Entry	1,600
9/12/2022	Descovy, Velimidy, Odefsey	10/31/2031		Unclear - No Entry	2,000
2/27/2023	Ocaliva	Undisclosed		Unclear - No Entry	286
3/3/2023	Symbicort	Undisclosed		No	2,495
3/29/2023	Ingrezza	2040		Unclear - No Entry	1,430
8/30/2023	Vivitrol	1/15/2027		Unclear - No Entry	380
10/31/2023	Yupelri	4/23/2039		Unclear - No Entry	221

Notes: The settlement announcement column includes the first day the market could react to the settlement. Settlements classified as including indication of reverse payment are bolded. Profit Split refers to settlements that included generic-to-brand payments based on the generic firm's sales or profits. Explicit No AG refers to settlements that appeared to not allow the brand to sell a second generic product for some period. Volume Limit refers to settlements that limited the quantity of the generic firm's sales.

4.2. Classification of settlements with indication of reverse payment

To classify settlements with an indication of reverse payment, we examined the settlement announcements and other materials that were published later, such as company filings to the U.S. Securities and Exchange Commission, antitrust complaints, and news about generic entry. We also analyzed data regarding generic entry to determine whether the brand launched an AG. Of the 94 settlements that we identified, 23 were classified as having an indication of reverse payment, including 17 that met our event study criteria. The sources and specific language used for classification are provided in the Appendix.

We classified 15 settlements as including indication of reverse payment because they appeared to include explicit no-AG clauses or other terms that might function as an implicit no-AG agreement.[10] The following labels are used in Table 1:

- *Explicit No AG* refers to settlements that appeared to include terms that prohibited the brand from selling its own AG product for some period. For example, one settlement licensed the generic firm "to be the exclusive marketer and distributor of an authorized generic…"
- *Profit Split* refers to settlements that included generic-to-brand payments based on the generic firm's sales or profits. The announcements described the brand receiving royalties, a "share of the economics," or a "split" of the generic's gross profits.
- *Volume Limit* refers to settlements that limited the quantity of the generic firm's sales. The announcements described the generic receiving a "volume-limited license" or a

[10] As detailed in the Appendix, nine settlements provided the settling generic firm with a license to sell an AG under the brand drug's regulatory approval. This may signal that the parties intended to split the profits from a single product instead of competing with two separate products. Additionally, three settlements included an acceleration clause that allows the generic to enter earlier if the brand sales drop below a certain level. This form of acceleration clause may cost the brand and benefit the generic on expectation. We did not use these terms to classify settlements as having an indication of reverse payment, but doing so has a negligible effect on our results.

license for which "the volume … will be subject to manufacturing and supply quantities until patent expiry."

Eight additional settlements were classified as having an indication of reverse payment because the brand firm did not launch its own AG product upon entry by the ANDA filer. We determined this by examining the first marketing dates published in the FDA's National Drug Code Directory data, which we also checked against the first quarter of sales in the Medicaid State Drug Utilization Data (Centers for Medicare and Medicaid Services, 2022). We used other publicly available sources (e.g., news articles) when the entry dates in the National Drug Code Directory data and Medicaid data were inconsistent. This method of classification could not be used for drugs which had not yet experienced generic entry or for which the timing of generic entry differed from the date specified in the settlement announcement.

Table 2 compares the number of settlement agreements with an indication of reverse payment that we identified to the counts reported by the FTC. For the overlapping period, FY2015-2021, we identified 16 compared to 46 settlements (34.8%) reported by the FTC as having explicit compensation (other than cash payments below $7 million) or possible compensation. Four of the 16 settlements did not meet our event study criteria, so our data include 12 (26.1% of 46) potential reverse-payment settlements reported by the FTC. We identify a smaller share in more recent years and we were unable to identify any from public sources during FY2021-FY2023.

Table 2. Count of settlements with explicit or possible reverse payments to first-to-file generic firms as reported by the FTC versus identified by publicly available sources

		Identified with Publicly Available Sources:			% of FTC Total
Fiscal Year	Reported by FTC	Settlement Announcements	Generic Entry Experiences	Total	Identified by Public Sources
2015	5	3	0	3	60.0%
2016	9	2	3	5	55.6%
2017	8	2	1	3	37.5%
2018	10	2	0	2	20.0%
2019	5	0	2	2	40.0%
2020	3	1	0	1	33.3%
2021	6	0	0	0	0.0%
Total	46	10	6	16	34.8%

Notes: The fiscal year (FY) includes October through September (*e.g.*, FY2015 spans 10/1/2014 through 9/30/2015). Counts from the FTC reports include settlements with explicit or possible compensation other than for litigation costs that were reached with first-to-file generic firms. The Table does not include FY2014 because the FTC report did not contain the necessary information, and our data does not include settlements reached in the first quarter of FY2014.

4.3. Data on share prices and drug sales

Data listing daily stock prices (adjusted for dividends), trading volume, and market capitalization for the brand firms were downloaded from the S&P Capital IQ database, as well as each firm's global annual revenues from all products. We also collected data for each brand drug's annual U.S. sales prior to generic entry from publicly available sources. We calculated a ratio of the annual U.S. sales of the brand drug divided by each firm's global annual sales for all products, which is a measure of the drug's importance to the company that has been used in prior studies (Panattoni, 2011; Drake et al., 2015). Although some of the firms were listed on foreign exchanges, we used the Capital IQ option to download the financial data in terms of U.S. dollars. Multiple publicly listed firms partnered to sell ten of the drugs in our sample. We analyzed the stock price reaction of all firms so that the sample size in analyses below totals 75 "events" – including 19 with indication of reverse payment.

4.4. Event-study methods

Financial market event studies assess the impact of distinct events on the valuation of firms. Financial markets quickly incorporate new information that is reflected in firms' stock prices. Event studies have been used in a wide variety of investigations including those examining the effects of mergers and acquisitions, regulatory changes, and product announcements (Fama, 1991). We apply event study methods based on MacKinlay (1997).

We paired each stock with an index based on the exchange listing the stock. For example, the percentage change in the value of the Nasdaq Composite Index is used for stocks listed on the Nasdaq and the percentage change in the value of the Nikkei 225 is used for stocks listed on the Tokyo Stock Exchange.

Prior to conducting the event study analysis of stock prices, we first examined whether trading volume in shares of the brand firms' stock was elevated in the days around the settlement announcements to confirm that these announcements constituted meaningful news to investors. For each firm *i* and trading day *t*, actual trading volume was denoted as V_i^t. We calculated the expected volume, $E[V_i^t]$, as the average trading volume for each firm during the estimation window $\widehat{V}_i$ where the estimation window was defined as the 120 trading days ending 30 days prior to the settlement:

$$E[V_i^t] = \widehat{V}_i \quad (1)$$

We then calculated abnormal trading volume (AV_i^t) in each trading day *t* as the percentage difference between the actual trading volume and the expected trading volume:

$$AV_i^t = (V_i^t - E[V_i^t]) \,/\, E[V_i^t] \quad (2)$$

We used two models to analyze the daily percentage change in each firm's stock price, R_i^t, referred to as the actual return in event study terminology. For both models, data from the same 120-day estimation window was used to calculate the expected return, $E[R_i^t]$.

For the constant mean model, expected returns were calculated as the average return during the estimation window:

$$E[R_i^t] = \widehat{R}_i \quad (3)$$

For the market model, fitted values are from an ordinary least squares regression of the actual return on its paired market index MR_i^t estimated on data from the estimation window. The regression coefficients and the actual return from the market index were then used to calculate the expected return during the event window as:

$$E[R_i^t] = \widehat{\alpha}_i + \widehat{\beta}_i MR_i^t \quad (4)$$

For both models, the abnormal return, A_i^t, was calculated as the actual return minus the expected return: $A_i^t = R_i^t - E[R_i^t]$. The cumulative abnormal return (CAR) was calculated by summing the abnormal returns across the days in an event window. An event window ($-t_1$,t_2) begins t_1 days before the event and ends t_2 days after. For example, the window (0,1) defines a two-day event window that includes the event day and the day after. We compared CARs for settlements with and without indication of reverse payment using t-tests. Because the sample size was relatively small and the distribution of CARs was skewed, we used bootstrapping to calculate confidence intervals.

Other event study papers that have examined pharmaceutical litigation outcomes have used the two-day (0,1) event window (Panattoni, 2011; Jacobo-Rubio et al., 2020). A narrow window minimizes the risk of adding random noise to the measured effect. However, it is sometimes difficult to tell if the news became public before or after the close of trading, so including the day

after the settlement announcement better captures the full effect of the announcement. Following these other studies, we reported results based on the (0,1) two-day event window. Estimates determined with other event windows were similar.

4.5. Estimating spending by drug purchasers

Market capitalization is the total value of a firm's shares calculated as the number of shares multiplied by the price per share (Watson and Head, 2007). The adjusted change in market capitalization following an event is calculated as each firm's actual market capitalization the day before the event window multiplied by the CAR for that event. We converted the value of the brand firms' adjusted market capitalization increases after settlements with indication of reverse payment into estimates of additional spending by drug purchasers.

Discounted cash flow (DCF) valuation is frequently used to estimate the intrinsic value of a firm and its associated share price (Olbert, 2025). DCF valuation involves forecasting a firm's future cash flows and then discounting them to present value. Although cash flows are influenced by many factors, such as amortization and depreciation (Watson and Head, 2007), we assumed that the news of the generic entry date specified in a settlement announcement affects a firm's value by altering its expected profit flows with other factors held constant.

Cash flows in a DCF valuation are net of corporate taxes (Watson and Head, 2007). To convert each firms' capitalized change in expected profits into a capitalized pretax increase in profits (corresponding to what purchasers would pay), we divided it by (100% – the tax rate). We assumed that investors anticipated the tax rate on new U.S. sales to be equal to the federal corporate tax rate of 35% for settlements agreed to before November 2, 2017, the date the Tax Cuts and Jobs Act was passed, and 21% thereafter. Although firms' effective average tax rates are often lower than the corporate tax rate, we assumed that tax credits and deductions have

already been taken such that they would not affect the tax rate applied to new profits earned on the margin. We conservatively did not account for state taxes, which would increase our estimates of the magnitude of harm to purchasers.

Finally, we convert the pre-tax capitalized profit flows to 2024 dollars using the consumer price index for all urban consumers (CPI-U). Our conversion will tend to underestimate purchaser spending because discount rates for investors are typically higher than CPI-U. Technically, the increases in market capitalization (which are net present values) should be scaled up to increases in nominal value using investors' discount rates and then converted to 2024 dollars using CPI-U. However, our simplification is conservative and allows us to avoid the need to estimate the expected timing of the new profits from the settlement.

An increase in the brand firm's pre-tax profits approximates the increase in spending by drug purchasers from a delay in generic entry. Prices paid by drug purchasers reflect brand profits as well as costs, but costs do not represent new spending because, if generic entry had not been delayed, the drug would have otherwise been purchased from generic sellers at prices covering generic firms' costs. After multiple generic entry, generic drug prices may approach cost (Berndt, McGuire, and Newhouse, 2011). Generic costs can be expected to be less than brand costs because generic firms generally do not spend on promotion, making brand profits again conservative as a measure of extra spending by purchasers.

An important exception is that the generic price will often remain well above cost during the 180-day generic exclusivity period (Hemphill, 2006). Because of discounting, a delay in generic entry will tend to decrease the value of spending during the exclusivity period. However, for the generic to rationally agree to settle, the expected decrease in value must be outweighed by the higher profits the generic firm earns from the reduction in generic competition achieved by the

no-AG agreement. We conservatively ignore this component of the increase in purchaser spending. In any case, the event study methods we employ are unlikely to be sensitive enough to provide an accurate measure of the increase in generic profits from an implicit no-AG agreement (McGuire et al., 2016). Generic firms are often large firms that offer a broad bundle of products and have much less at stake in an individual legal case compared to brand firms.

Because of our reliance on publicly available materials and our event-study inclusion criteria, our sample does not include a full census of all patent litigation settlements. In the last step of our analysis, we consider how much higher our estimates of the overall harm from reverse payments might be if we had been able to estimate harm from all settlements with reverse payments. Specifically, we scale up our estimates by dividing them by the percentage of settlements with possible brand-to-generic compensation reported by the FTC that were included in our event study analysis (26.1%).

5. Results

5.1. Trading volume

Figure 1 shows the abnormal trading volume on trading days around the settlement announcements, where abnormal volume is defined as the percentage difference compared to the average trading volume during the estimation window (i.e., the pre-period). Trading volume was 72% higher than average on the announcement day for settlements with indication of reverse payment, and only 10% higher on the announcement day for settlements with no indication of reverse payment. (Announcement day is where the Days Relative to Settlement Announcement equals 0 in Figure 1 as indicated by the vertical line). The 72% elevation was significantly different than 0 ($p = 0.02$) and significantly different than the 10% ($p = 0.05$). Trading was not

significantly elevated on the announcement day for settlements with no indication of reverse payment (p = 0.33).

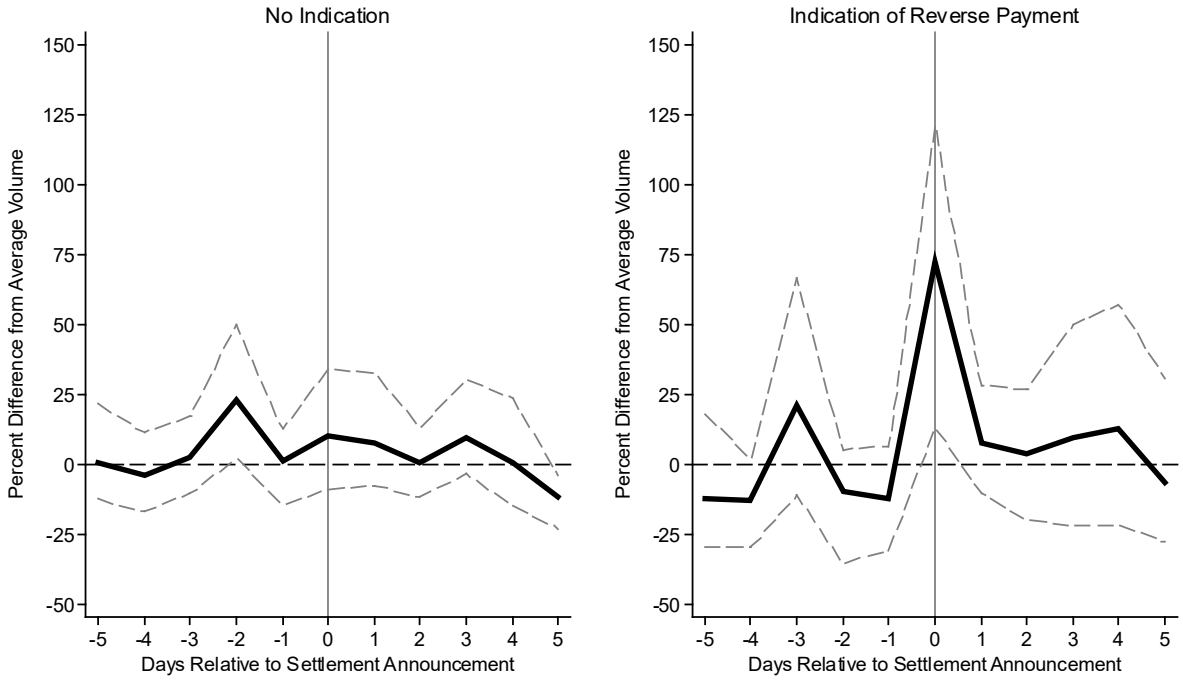

Fig. 1. Average abnormal trading volume in percentage terms compared to the pre-announcement estimation window in days surrounding settlement announcements with 95% confidence intervals

Notes: Four stocks with abnormal trading volume of 500% or higher on a trading day outside of the (0,1) event window due to an alternative event were excluded from this analysis.

Abnormal trading volume was subject to a few extreme outliers where trading volume was quite low during the estimation window, and then quite high during one of the days reported in Figure 1, so that the abnormal trading volume in percentage terms was relatively extreme (e.g., above 2,000%). We excluded four cases from our trading volume analysis that had abnormal trading volume greater than 500% because of the announcement of an event other than the settlement. (Similarly, smaller outliers that we did not exclude explain the smaller spikes on day

-2 for settlements with no indication of reverse payment and day -3 for the settlements with indication of reverse payment.) We did not exclude these outliers from our analyses below because the potential confounding events occurred outside of our preferred two-day event window.

5.2. Stock prices

Figure 2, Panel A depicts the unadjusted distribution of cumulative returns for the (0,1) two-day event window (including the day of and the day after the settlement). For settlements without indication of reverse payment, the cumulative returns are normally distributed around 0%. In contrast, for settlements with indication of reverse payment, the median is above 0% and the distribution is skewed positive. Figure 2, Panel B shows that adjusting for trends in the broader market does not change the overall position of the distributions.

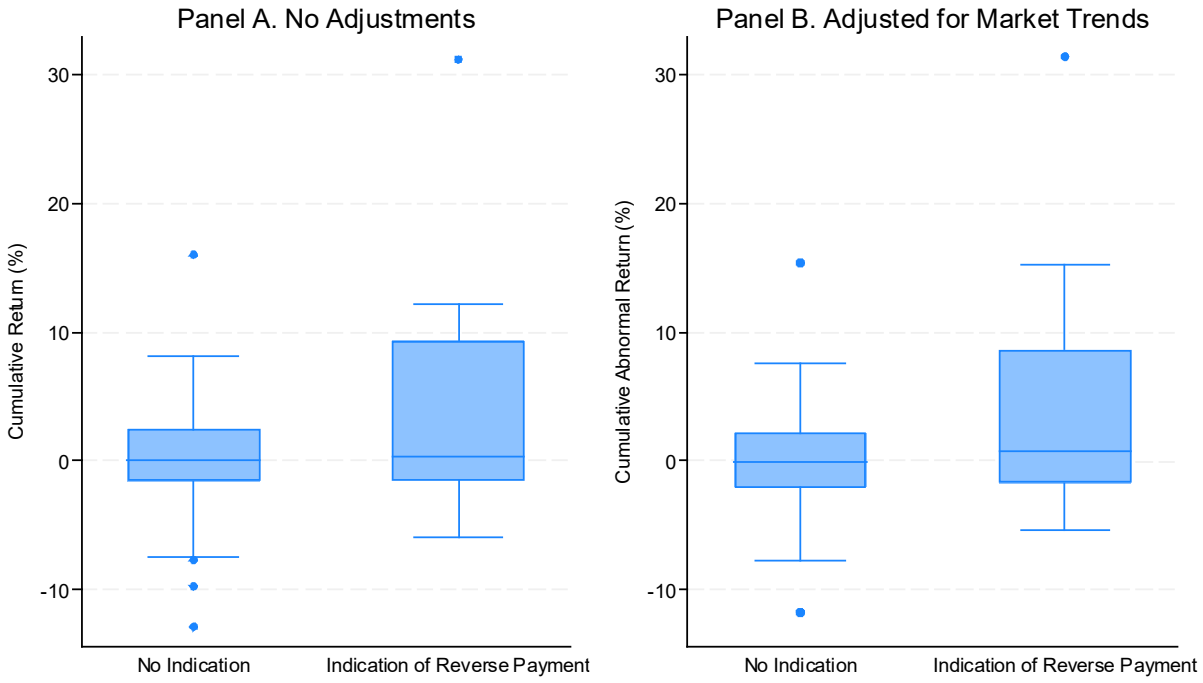

Fig. 2. Distribution of percentage changes in stock prices upon announcement of settlements with and without indication of reverse payment

Notes: The center line of each box represents the median and the top and bottom of the box define the interquartile range. The whiskers represent the full range except that outliers (defined as more than 1.5 times above or below the interquartile range) are depicted separately as dots.

Table 3 reports the event-study results for the constant mean and market models. The first panel indicates that, for all the settlements with indication of reverse payment (including both explicit and implicit forms of no-AG agreements), the average CAR is 3.3% based on the constant mean model and 3.5% based on the market model. The 95% confidence intervals indicate that the market model results are significantly different from 0% at the 0.05 level. The average CAR is not significantly different from 0% for settlements without indication of a reverse payment. The difference in CAR between settlements with and without indication of a reverse payment is 3.0% and 3.5% for the two models.

Table 3. Tests of differences in cumulative abnormal returns for settlements with and without indication of reverse payment using the constant mean model and market model

	Constant mean model	Market model	N
All cases			
Mean CAR for:			
Settlements with indication of payment	3.3% (-0.0%,7.5%)	3.5% (0.1%,6.9%)	19
Other settlements	0.2% (-0.6%,1.7%)	0.0% (-1.2%,1.6%)	56
Difference in mean CAR	3.0% (-0.5%,8.8%)	3.5% (0.3%,6.8%)	75
Cases where drug is 5% or more of the company's sales			
Mean CAR for:			
Settlements with indication of payment	5.6% (1.1%,11.4%)	5.4% (2.3%,18.9%)	12
Other settlements	0.6% (-0.8%,2.3%)	0.6% (-1.1%,2.4%)	37
Difference in mean CAR	5.0% (0.2%,11.7%)	4.8% (0.9%,16.9%)	49
Cases where drug is 10% or more of the company's sales			
Mean CAR for:			
Settlements with indication of payment	7.9% (-1.1%,15.7%)	7.8% (0.0%,18.7%)	8
Others	1.1% (-0.9%,3.2%)	0.9% (-0.9%,2.9%)	27
Difference in mean CAR	6.7% (-1.6%,13.8%)	6.9% (-1.1%,17.3%)	35

Notes: Bootstrapped 95% confidence intervals in parentheses. CAR = Cumulative abnormal return. All results are based on a two-day (0,1) event window.

Litigation outcomes can be expected to have a larger percentage impact on stock prices if a drug makes up a larger share of firm revenues, as seen in prior studies (Panattoni, 2011; Drake et al., 2015). Excluding cases where a drug makes up less than 5% of a firm's sales reduces the sample size to 49 events. Table 3 shows that the average CAR is higher for settlements with indication of a reverse payment (5.4%-5.6%) and again near zero for settlements without such an

indication. The difference between settlements with and without indication of a reverse payment is 4.8%-5.0%.

Further excluding cases where the sales ratio is less than 10% reduces the total sample size to 35. Table 3 shows that the average CAR is higher for settlements with indication of a reverse payment (7.8%-7.9%) and approximately the same (not statistically different from 0%) for settlements without such an indication. The difference between settlements with and without indication of a reverse payment is 6.7%-6.9% for the two models.

5.3. The implications of brand firms' market capitalization increases for drug purchasers

The first column of Table 4 displays the sum of the adjusted increases in market capitalization for the 17 settlements with an indication of reverse payment (corresponding to 19 events). The sum is $16.1 billion when results are based on the constant mean model and $16.5 billion when based on the market model. Unlike the percentage changes in stock prices examined above, a small number of events with the biggest changes in market capitalization have a disproportionate influence on the results. One event in particular accounts for approximately half of the total increase in market capitalization.

Table 4. Brand firms' increases in market capitalization after settlements with indication of reverse payment converted to pre-tax 2024 dollars (n = 19)

	Ten-year total ($ billions)			Annual average ($ billions)
	Unadjusted market cap change	Pre-tax	Pre-tax 2024 dollars	Pre-tax 2024 dollars
Constant mean model	16.1	23.6	30.6	3.1
Market model	16.5	24.5	31.9	3.2

Notes: Changes in market capitalization are converted to pre-tax 2024 dollars by dividing the changes in market capitalization by (100% - the corporate tax rate) and converting to 2024 dollars using the consumer price index for all urban consumers.

As shown in Table 4, the constant mean model indicates that the total increase in market capitalization for all the settlements with indication of reverse payment corresponds to a $30.6 billion increase in pre-tax 2024 dollars. Because these settlements were executed over the 10-year period from 2014-2023, the total averages to an annual increase of $3.1 billion. Based on the market model, the annual increase is $3.2 billion.

As described above, our count of settlements reached between FY2015 and FY2021 is 26.1% of the number of settlements with first filers that the FTC categorized as including "possible compensation to the generic" or explicit compensation other than for avoided litigation expenses during the same period. Assuming that the harm from potential reverse-payment settlements that the FTC identified but we did not is similar to those we have analyzed, then the total harm from settlements with pay-for-delay is approximately 3.8 times higher than what we have estimated, about $12 billion per year.

6. Conclusion

We use financial market event study methods to estimate the cost to U.S. drug purchasers from delays in generic entry achieved by collusive patent litigation settlements that may contain "reverse payments" from the brand to the generic firm, knick-named "pay-for-delay" settlements in the U.S. and the E.U. Unlike earlier efforts, our approach avoids making explicit assumptions about an unobserved counterfactual agreement to compare with what actually happened. Most prior estimates assumed, based on the FTC's study from 2010, that reverse-payment settlements delayed generic entry by 17 months compared to settlements without such payments. We instead rely on the assumption that a delay in generic entry bought in a collusive settlement constitutes

news to financial markets and the elevated brand profits (paid for by purchasers) are rapidly capitalized into stock prices. Our approach cross checks and complements prior cost estimates.

Consistent with prior research (Drake et al., 2015), settlements without indication of a reverse payment did not significantly affect stock prices, implying that these settlements tended to meet investors' expectations. On the other hand, stock prices increased by approximately 3.5%, on average, after settlements with indication of reverse payment, implying that they increased brand profits by delaying generic entry. We estimate that the increases in market capitalization after these settlements correspond to a total increase in purchaser spending of $3.1-3.2 billion per year during the ten-year period 2014-2023. Because of our reliance on publicly available information and our event study inclusion criteria, our study data includes less than 30% of the potential pay-for-delay settlements, so increases in purchaser spending may be approximately 3.8 times higher, or about $12 billion per year. This represents over 5% of the $225 billion in total spending on small-molecule drugs in the U.S. (IQVIA, 2025).

Our results support the hypothesis that pay-for-delay settlements remain an important antitrust problem that continues to cost U.S. drug purchasers billions of dollars per year. Although explicit forms of reverse payment were not observed after 2014, implicit no-AG agreements were common during the ten-year period we studied. These agreements appear to be working in the sense that they often seem to have deterred the brand from selling its AG and thus often resulted in generic markets with just one initial generic product instead of two. The magnitude of the stock price increases indicates that these agreements are also elevating brand profits by delaying the start of generic competition. Our $12 billion estimate of the industry-wide harm from pay-for-delay settlements is more than double the FTC's 2010 estimate, which converts to $5.0 billion per year in terms of 2024 dollars.

While pay-for-delay patent settlements are not unique to the U.S., they likely impose greater harm on purchasers in the U.S. than in other countries. The harm from a period of delay is roughly proportional to the difference between the monopoly brand and the competitive generic price. The U.S. pays much more for brand drugs than countries in the E.U., for example, and somewhat less for generic drugs (Mulcahy, Schwam and Lovejoy, 2024). The monopoly-competition gap capturing the per unit time cost of delay is therefore much greater in the U.S. than in the E.U. A year of delay that costs purchasers in the U.S. $1 billion might "only" cost $250 million in the E.U.[11]

In broader terms, our study of the evolution of pay-for-delay patent settlements exposes the limitations of public and private legal antitrust actions in preventing collusion in the drug industry. Courts move slowly, both in terms of real time, and in terms of keeping up with the resourcefulness of the authors of drug patent settlements. Counsel with antitrust expertise advising settling parties are aware of the legal climate and have strong incentives to craft agreements in ways designed to hinder legal scrutiny. Brand-to-generic cash payments were easy for courts to interpret as a reverse payment, but the value transfers embedded in explicit no-AG clauses took time to be understood and accepted by courts (Edlin et al., 2015). Explicit no-AG clauses have gone the way of cash payments, but instead of forgoing reverse payments entirely, we now see firms entering settlements with implicit no-AG agreements.[12] While, the FTC flags these as "potential" reverse payments, understanding the economics of royalty payments and volume limits can be challenging to explain to courts and juries as they are complex and require institutional knowledge.

[11] This rough calculation is based on Mulcahy, Schwam and Lovejoy's (2024) finding that brand prices are three to four times higher in the U.S. than in Europe.

[12] One of our colleagues refers to the evolution of the forms of reverse payment as a game of "Whack-a-Mole."

The primary limitation of this study is our reliance on publicly available information. This biases our estimates downward for two reasons. First, to the degree that settlements we classified as having no indication in our analysis in fact did include a reverse payment, our estimate of the difference in the impact between the two types of settlements is too small. And second, we undercount settlements with reverse payments. We also did not study or include settlements of patent litigation that set the entry date for medicines that are biosimilar to brand biologics, which may exacerbate the undercount.

The estimates are also conservative because of the event study methods employed. To the extent that investors anticipate that a reverse payment will be included in a settlement, the adjusted change in market capitalization may not completely capture the effect of the reverse payment on delaying generic entry. Had information about the settlement leaked out earlier, the announcement itself may not have constituted "news" to the market or impacted stock prices. Also, some settlements that were publicly announced did not meet our event study criteria so could not be included in our analysis.

To illustrate our potential undercount, multiple private antitrust complaints (*Value Drug Company v. Takeda*, 2021; *Peter Staley v. Gilead*, 2020; *Walgreen Co. v. Takeda*, 2025) have alleged that payments for delay were included in settlements that were reached during our study period but were not included in our sample because of our inclusion criteria. The four brand drugs affected by these settlements had combined annual pre-generic sales of approximately $5.5 billion.

Unlike in prior years, none of the announcements about the settlements in our data made between 2019 and 2023 revealed terms indicative of an implicit no-AG agreement or other form of reverse payment (see Table 1). This trend could give the impression that firms may have

recently stopped including reverse payments in settlements. However, the FTC's recently-released reports indicate that this is not the case as 14 settlements with first-to-file generic firms included possible reverse payments during FY2019-2021, including six during the most recent year of data, FY2021. These trends instead indicate that firms have merely become more cautious about announcing settlement terms.

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