1 Entry Barriers, Personal Relationships, and Cartel Formation

Generic Drugs in the United States[*]

Emily Cuddy, Robert H. Porter, Amanda Starc, and Thomas G. Wollmann

1.1 INTRODUCTION

In July 2014, a *New York Times* article titled "Rapid Price Increases for Some Generic Drugs Catch Users by Surprise" caught the attention of Mike Cole, supervisor of the Connecticut AG office's unit of antitrust and fraud. The article highlighted how the prices of several generic drugs had risen sharply over the prior year. Curiously, the increases could not be attributed to ingredient shortages or manufacturing troubles. "On a hunch," according to the *Connecticut Post*, Cole forwarded the article to a staff attorney, who began issuing subpoenas (Pazniokas, 2019). This marked the start of the case against "the largest domestic corporate cartel in our nation's history" (Office of the Connecticut AG, 2020).

The ensuing investigation, which combined witness testimonies, private communications within and between the rival drugmakers, and internal documents outlining pricing strategies, reached three broad conclusions. First, the sharp increases cited by the *Times*, such as the doubling of the price of levothyroxine, were by no means unique. Second, instead of reflecting fluctuations in costs or disruptions in supply, the price hikes were the result of explicit collusion

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among key salespeople at many of the world's largest generic drugmakers.[1] Third, and perhaps most striking, while many firms took measures to soften competition in the generic drug industry, most of the large, abrupt price hikes could be traced to a single personnel decision. Namely, in April 2013, Teva Pharmaceuticals, the world's largest generic drugmaker, hired NP,[2] a salesperson with especially strong industry relationships, and tasked her with "price increase implementation."[3]

In the eighteen months between her joining Teva and the government publicizing its investigation, NP and co-conspirators cartelized over 100 markets for generic drugs (i.e., substance-delivery-release-strength combinations). During that period, the scheme generated $12 billion of additional profit for the drugmakers (Cuddy, 2020), and even more in the years that followed. Details came to light when Connecticut, joined by forty-two other states and Puerto Rico, sued nineteen firms and fifteen individuals. The legal case *Connecticut et al.* v. *Teva Pharmaceuticals USA Inc. et al.* (2019, Complaint hereafter), which was filed on May 10, 2019, alleges that the defendants violated Section 1 of the Sherman Act, which prohibits price fixing. Other claims based on these and related allegations have been made by the US Department of Justice, which has obtained grand jury indictments against a subset of the defendants, and various private plaintiffs, who are seeking to recover billions in damages.

In this case study, we examine collusive behavior catalyzed by NP joining Teva by combining the rich array of facts presented in

[1] We use terms such as "collusion," "cartel," and "price fixing" throughout to characterize the conduct of certain firms and their employees. This usage reflects our interpretation of events described in the May 10, 2019 Complaint, which we assume are truthfully reported. However, the litigation against many of these organizations and individuals is ongoing (see Section 1.4). From the court's perspective, the conduct of those defendants is merely "alleged." Further, with respect to criminal charges against them, those defendants are innocent until proven guilty.

[2] Since their names are unimportant to our analysis, we refer to individuals by their initials.

[3] See page 158 of the Complaint, which is referenced in the following paragraph.

the Complaint with data from generic drug markets. To do so, we exploit unique features of our setting that are especially conducive to diagnosing cartels. First, the hiring of NP by Teva does not coincide with any discrete changes in the industry, and the cartels rolled out in quick succession shortly after she joined the firm. Hence, collusion represents an abrupt "shock" to conduct that is plausibly independent of outcomes we wish to examine. Second, at the point at which NP joined Teva, the firm operated in a large number of drug markets that differed from one another in ways that can be easily measured. We can use these differences to test theoretical predictions. For instance, we can use variation in the number of firms competing with Teva in each market to study how much easier it is to form a cartel when fewer firms need to reach an agreement. Third, although the Complaint was initially released with redactions, the original was unsealed by the court the following month. It contains internal spreadsheets, call logs from wireless service providers, and private messages exchanged within and between the firms that provide novel insight into how cartels operate internally. For example, we not only learn that NP factors the cooperativeness of other drugmakers into her decision to cartelize a market but we also observe the quantitative measure she personally ascribed to each.

In Section 1.2, we describe the vertical relationships and contracting arrangements in the retail pharmacy industry. Section 1.3 contains a discussion of the formation of the cartel and the factors that were conducive to collusion. In Section 1.4, we recount how state and federal investigators unearthed the cartel and summarize the ensuing litigation. Section 1.5 contains an assessment of the initial price effects of the cartel, and how vertical relationships affected the incidence of the price increases. In Section 1.6, we discuss the role of entry in response to the price increases. Section 1.7 considers the aftermath of the investigation, focusing on civil lawsuits and research investigating strategic behavior by manufacturers. In Section 1.8, we conclude.

1.2 CHARACTERISTICS OF GENERIC DRUG MARKETS

Generic drugs represent over 90 percent of prescription drug fills by volume in the USA. Although generics are bioequivalent to branded drugs,[4] they are often significantly cheaper due to competition among firms that sell generic drugs. As a result, once marketing exclusivity of a branded drug ends after patent expiration and subsequent FDA approval of a generic entrant, the market for that molecule effectively is taken over by generic formulations. The rapid transition is facilitated not only by drug insurance formulary design, which subsidizes generic use through reduced patient cost sharing, but also by law in many states, which require pharmacists to dispense the generic drug by default (NCSL Health Program, 2019).

Once market exclusivity restrictions lapse, generic drug markets allow for competition between manufacturers. Most markets have multiple manufacturers producing generic versions of the branded molecule. The majority of the collusive activity was concentrated among solid-dose drugs (e.g., capsules and tablets). Solid-dose drugs witnessed higher levels of generic entry than other drug forms (e.g., injectables and topical products). Berndt et al. (2017) found that solid-dose markets had between two and three more manufacturers on average between 2004 and 2016. These manufacturers often specialize in the production of generic molecules and are multinational. While some firms specialize in the production of a handful of similar drugs (e.g., those in the same therapeutic class), others offer a comprehensive portfolio that includes hundreds of unique molecules.

The vertical aspects of generic drug markets are similar to those of other health care products and services. In the retail prescription market, manufacturers sell to both large retail pharmacy chains (e.g., CVS) and wholesalers (e.g., McKesson Corporation), which, in turn,

[4] A generic drug must be bioequivalent, i.e., the generic drug must have an equivalent rate and extent of absorption of the active ingredient as the branded drug. That said, they may include different inactive ingredients.

supply independent pharmacies.[5] Although mail-order prescriptions are increasing in popularity, the majority of prescription drug fills still take place at retail pharmacies. Starc and Swanson (2021) document substantial concentration within the retail pharmacy market. In their sample, four companies – CVS, Walgreens, Rite Aid, and Walmart – account for 51 percent of retail prescription revenues. These retail pharmacies then sell to consumers, who are at the bottom of the vertical chain. Consumers visit their preferred pharmacy and are given their prescription, which is manufactured by the firm that has contracted to supply that particular retail pharmacy.

Most consumers have insurance coverage with a prescription drug benefit. These benefits typically favor the use of generic drugs via low coinsurance or a small copayment. As a result, many consumers pay little or nothing at the point-of-sale for generic prescription drugs. However, some insurers may attempt to steer consumers to some distribution channels or retail pharmacies. For example, within the Medicare Part D program, which covers elderly Americans, preferred pharmacy networks are common. These plans offer consumers additional discounts when filling their prescription drugs at an in-network pharmacy. Starc and Swanson (2021) show that consumers are willing to switch pharmacies and travel further to obtain these discounts.

Insurance plans reimburse retail pharmacies for each prescription fill. In many contracts, the reimbursement is calculated as an ingredient cost plus a dispensing fee. Dispensing fees are typically similar for drugs within a plan-pharmacy bargaining pair, but ingredient costs vary across drugs. Historically, average wholesale costs have been used to estimate acquisition costs and served as a benchmark for ingredient costs. Thus, wholesale costs were used by large payers to determine

[5] As of this writing, direct purchasers of generic drugs, including drug purchasing cooperatives (e.g., GPOs) and retail pharmacy operators, indirect purchasers (e.g., independent pharmacies), and end-payers (e.g., employee benefits funds, labor unions, and private insurance firms) have filed complaints against the cartel. See MDL 2724 from the United States District Court for the Eastern District of Pennsylvania for a summary.

reimbursement. However, wholesale costs were unverified numbers self-reported by generic manufacturers. These wholesale prices have been shown to be imperfect and manipulable, akin to "sticker prices" (Alpert et al., 2013). Recently, bolstered by the creation of the Center for Medicare and Medicaid Services (CMS) National Average Drug Acquisition Cost (NADAC) Survey, both public and private payers began indexing ingredient costs to the true acquisition costs of retail pharmacies and wholesalers, often using fixed reimbursement caps or so-called maximum allowable costs (MACs).[6] Nevertheless, NADAC indexing is imperfect, with considerable lags in cost updates. As we discuss below, imperfect indexing exposes retail pharmacies to fluctuations in wholesale prices. In summary, deciding which products from generic manufacturers to stock is strategically important: pharmacies earn profits from the "spread" between contractual reimbursement and the true cost of acquiring the drugs.

Wholesalers and most large chains, such as CVS and Walgreens, purchase drugs directly from manufacturers. In the early 2000s, most purchasers relied on relationship-based contracting. There was a rapid shift to auction-based procurement in the years preceding the formation of the cartel. In practice, each large purchaser solicits bids to supply a particular drug from all generic firms that have the requisite marketing rights. However, such requests are erratic, insofar as they are prompted by an unexpected change in the market, such as a new firm receiving marketing rights from the FDA or an incumbent firm exiting the market. Generic drugs are highly regulated and quasi-homogeneous goods. The resulting competition among manufacturers for a given contract is predominantly on price, where purchasers award their contracts to the lowest bidder, and the winning bid effectively becomes the pharmacy's acquisition cost.

Under this procurement mechanism, the entry (exit) of a new generic firm typically leads to a reduction (increase) of the average

[6] See, for instance, the Federal Upper Limit Program (FUL) and state maximum allowable costs (MAC), a fixed maximum reimbursement cap.

market price. For example, a 2019 FDA study found that the average market price of a generic molecule (relative to the brand molecule) is 39 percent lower with a single generic producer, 54 percent lower with two generic producers, and more than 95 percent lower with six or more generic producers (Center for Drug Evaluation and Research, 2019). As we explain in the next section, the formation of the cartel and the subsequent manipulation of this procurement mechanism brought an abrupt end to the typical price patterns in many generic drug markets.

1.3 CARTEL FORMATION

In this section, we describe the formation of the cartel and discuss the features of generic drug markets that may have facilitated collusion. We divide our discussion between factors that explain variation across generic drug markets in the incidence of collusion and factors that are common to all markets in the generic drug industry.

Although there may be many reasons why the cartel formed, lagging profits across the generics segment likely accelerated firms' willingness to participate in the conspiracy. For instance, at Teva, net income was down 26 percent in the first quarter of 2013. Ultimately, at least nineteen generic drug firms joined the cartel, including many of the world's largest, e.g., Actavis, Apotex, Dr. Reddy's, Glenmark, Heritage, Lupin, Mylan, Sandoz, Taro, and Teva. In effect, they formed a bidding ring, where the bidders varied across the different product markets due to their different portfolios – for instance, Teva, Lupin, and Mylan colluded in the market for fenofibrate whereas only Teva and Mylan colluded in the market for tolterodine ER because Lupin did not market that drug. According to the Complaint, "the shared objective ... [was] to attain a state of equilibrium, where no competitors are incentivized to compete for additional market share by eroding price." In manipulating the outcomes of retailer auctions, the ring's scheme was twofold – one, allocating market share for a particular drug product (e.g., across retail customers) between incumbents and new entrants (their so-called fair share principle) and, two,

avoiding price erosion and/or raising prices. These allocations were greatly simplified due to the high level of concentration in the pharmacy sector: each ring member would be allocated enough retail pharmacy chains to reach their desired market share for a particular product, e.g., a 60 percent market share might entail winning the CVS and Walgreens contracts. Because the Complaint contains detailed information about Teva's participation in the ring, it is possible to trace out its role in greater detail than its co-conspirators. Thus, we focus on Teva in what follows; however, we note that Teva was not involved in all product markets where ring members colluded.

The proximate cause of Teva's involvement was that Teva hired NP on April 22, 2013 as the Director of Strategic Customer Marketing and tasked her with "price increase implementation" (Complaint, page 158). Besides the job description, the event was pivotal for at least two other reasons. First, Teva had been the world's leading generic drugmaker for several years. In early 2013, it manufactured over 500 different tablets, capsules, and solutions. Second, NP had close ties to key salespeople at nearly all of the major generic drugmakers as a result of her previous employment. Immediately prior to joining Teva, she spent eight years at Amerisource Bergen, one of the largest US drug distributors, where she most recently served as its Director of Global Generic Sourcing.

Within days of joining Teva, NP determined which markets were candidates for price hikes. First, around May 1, she assigned each of Teva's rivals a score ranging between −3 and +3 based on the strength of her relationships with salespeople at these other generic drugmakers. NP called this score the "quality" of the competition, since it measured the likelihood that a firm would cooperate with her.[7] Most large generic drugmakers received high scores,

[7] The Complaint alleges that "as part of her process of identifying candidates for price increases, Patel started to look very closely at Teva's relationships with its competitors, and also her own relationships with individuals at those competitors" (page 160). Based on other facts presented in the Complaint, we believe that "Teva's relationships" refers to ties between her colleagues with individuals at other firms.

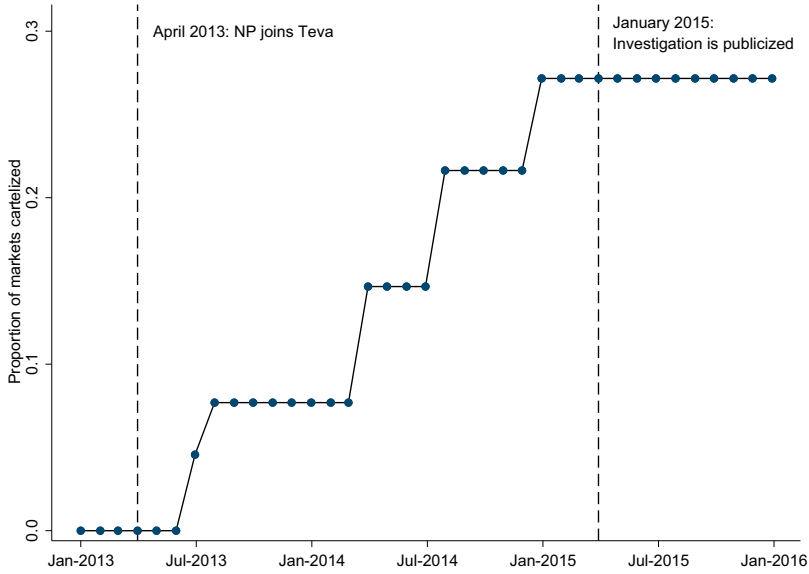

FIGURE 1.1 Price increases rollout over eighteen months.
In this figure, we plot the cumulative proportion of drug markets that have been cartelized on the y-axis against calendar quarter on the x-axis. We date market cartelization by the month of the first price increase. The proportion is calculated with respect to all drugs manufactured by Teva in the first quarter of 2013, which is the period that immediately precedes NP joining the firm. Source: Authors' calculations from the Complaint and FDA's National Drug Code Directory.

presumably reflecting frequent interactions in her prior role. For example, due to her relationships with executives later named in the complaint, Taro, Mylan, Sandoz, and Upsher-Smith all received scores of 3. Next, NP ranked each drug produced by Teva based on these scores and "certain other factors" (Complaint, page 162). On May 24, she selected a subset of drugs, entered them in a spreadsheet titled "Immediate [Price Increase] File," and sent the document to her superiors. Finally, on July 3, in concert with other cartel members, Teva began announcing price increases.

Figure 1.1 illustrates how the price increases rolled out across markets over time. The first round occurred just four months after NP joined Teva and was followed almost immediately by more price increases the following month. The final round occurred eighteen

months later, just prior to when NP learned that state and federal investigators were scrutinizing the cartel members' behavior (see Section 1.4). After the initial two rounds, the remaining rounds were evenly spaced, with the exception that no increases occurred between September 2013 and March 2014. According to the Complaint, the hiatus has an obvious explanation: NP was on maternity leave at this time. The cartel increased the prices of 122 drugs altogether, or in 29 percent of the markets in which Teva operated just prior to NP joining the firm.

1.3.1 Drug-Specific Determinants of Collusion

Since Teva was active in a large number of heterogeneous markets when it hired NP, our setting provides a rare opportunity to study determinants of collusion with rich variation across markets in terms of their characteristics. We focus our attention on two of these determinants, the number and average "quality" of the other firms in the market. Both criteria differ across markets, and they should affect the dynamic incentives associated with maintaining collusion. Moreover, both were carefully considered by NP when she selected markets to cartelize, which is evident from internal communications presented in the Complaint.

Market structure may be correlated with firms' ability to initiate and sustain collusion (Harrington, 2017). Since an illegal collusive scheme cannot be enforced by binding contracts, firms must rely on dynamic incentives to enforce compliance. Successful collusion entails raising price above competitive levels, which creates a short run incentive to cheat and undercut one's co-conspirators. A collusive scheme will be stable if cheating is detected and punished relatively quickly, limiting the gains from cheating. Punishment might involve the collapse of the agreement, thereby relinquishing future collusive profits. The more firms in a market, the greater are the gains from cheating relative to the consequent foregone share of future collusive profits, and hence the less likely is a cartel to form.

The role of rival "quality" in supporting collusion is less standard. However, the literature on the formation of trading relationships in the absence of legally enforceable contracts is related. Greif (1993) and Greif et al. (1994) describe how establishing reputations and sharing information within a coalition might facilitate contract enforcement absent legal recourse. The strength of relationships is highlighted in the Complaint:

> From September 17–19, for example, high-level executives from Defendants Teva, Apotex, Actavis, Amneal, Lannett, Par, Zydus and others were invited to a gathering at a country club in Bowling Green, Kentucky where they would play golf all day and socialize at night ... At the conclusion of the outing, one of the executives – Defendant [KO] – sent an e-mail to the other attendees, stating: "This is a crazy biz but I am grateful to have friends like all of you!!!! Happy and honored to have you all as 'fraternity brothers.'"
>
> *(Complaint, page 31)*

To study these relationships, we base our analysis on information that is similar to what NP had available to her at the time she decided which markets to cartelize. Mirroring her selection process, our analysis is at the drug level. Sales data yields the list of drugs produced by Teva in early 2013 and the market shares of each firm, while the Complaint reports the competition quality score assigned to each firm and the list of drugs for which prices were fixed. Using this information, we calculate the average competition quality of each drug and the number of firms (other than Teva) that manufacture the drug, and we construct an indicator for collusion.

In Table 1.1, we report how the probability of collusion varies with the composition and number of other firms in the market. Two important patterns emerge. First, cartelization is much more likely to form in a market where NP has strong relationships. For instance, consider markets in which Teva and up to two other firms are present. Cartels form in 86 percent of the markets where NP assigns the other drugmakers her highest competition quality of score of 3. Yet, cartels

Table 1.1 *The probability of collusion varies with the number and composition of active firms*

	Number of active firms			
Competition quality	1 other	2 others	3 others	4+ others
{–3, –2, –1}	15% (13)	15% (20)	15% (20)	15% (27)
0	22% (9)	38% (21)	31% (13)	12% (33)
1	57% (7)	50% (24)	28% (18)	17% (23)
2	50% (8)	57% (14)	67% (6)	0% (6)
3	85% (13)	89% (9)	60% (5)	0% (1)

The sample consists of drugs manufactured by Teva in the first quarter of 2013. The row variable measures the quality of the competition (i.e., the strength of NP's relationships with the other producers of the drug). The column variable measures the number of firms other than Teva that produce the drug. To compute quality, we (a) start with the scores assigned to each firm by NP, (b) calculate their average at the drug-quarter level, weighted by the firms' market shares, and (c) select the maximum value between the quarter NP is hired and the quarter the government's investigation is publicized. The quarter that corresponds to the maximum value is the quarter for which we calculate the number of active firms. Each cell contains the proportion of markets that were cartelized. Alongside it, we report the number of markets in the cell. Source: Authors' calculations from the Complaint and the FDA's National Drug Code Directory and Orange Book.

form in only 22 percent of the markets with negative competition quality scores. Second, cartelization is much more likely to form in a market with fewer drugmakers. To illustrate, consider markets to which NP assigns positive average competition quality. Cartels form in 68 percent of the markets with just one other firm, 59 percent of markets with two others, 45 percent of markets with three others, and just 13 percent of markets with four or more others.

Consistent with these findings, new opportunities to form cartels arose over time when drug makers' competition quality scores were revised upwards. Leadership changes at rival drug makers' sales

departments provided one source of these revisions. For example, NP originally assigned Zydus a competition quality score of –3. This score was sufficiently low that the firm's presence effectively precluded collusion, as evidenced by Table 1.1. However, in November 2013, KP, a colleague of NP at Teva, moved to Zydus, prompting her to raise the firm's competition quality score to +2. Clarithromycin ER tablets, Warfarin sodium tablets, and Topiramate Sprinkle capsules were included in the next round of price increases. All three were produced by both Teva and Zydus.

1.3.2 Industry-Wide Factors Conducive to Collusion

As just described, variation in the traits of drug markets can help explain variation in cartelization. At the same time, there are many factors conducive to collusion which were common to all generic drug markets.

1. **Firms compete mostly on price via manipulable procurement auctions.** The allocation mechanism is best described as a scoring auction, with buyers evaluating bids along several dimensions (e.g., fill rates, frequency of recalls, accuracy of invoices, timeliness of deliveries, and backhaul utilization) (Cardinal Health (2020)). However, many, if not all, of the non-price characteristics are pre-specified, since they reflect historical operating performance and/or large fixed capital investments. A cartel need only coordinate submission and bid decisions, and not other characteristics of the product, which simplifies its operations.
2. **Cartel members could detect "cheating" from collusive agreements quickly.** Confusion in the market for Moexipril Hydrochloride tablets provides a clear example. Teva and Glenmark cartelized the market around July 2013. On August 5, 2013, Teva learned that Glenmark undercut its price to a major distributor (apparently due to internal miscommunication within Glenmark). That afternoon, a Teva employee sent NP an email whose subject line was "Loss business on Moexipril" and whose only contents were "???". Five minutes later, NP emailed her colleague back, stating that she was aware of the loss and had "made the call already." The following day, NP spoke to her contact at Glenmark. Later that same day, Glenmark withdrew its bid to the distributor, and a

colleague of NP reported that "[t]oday is a new day and today . . . [the distributor] has now informed me that they will NOT be moving the Moexipril business to Glenmark" (Complaint, page 134).

3. **Cartel members could also retaliate quickly against "bad citizenship."** Most buyers acted on their own, with procurement decisions for individual drugs spread throughout the year. The staggered letting of contracts (as opposed to all contracts for a given buyer being let together, for example) allows cartel members to adjust bidding behavior over time to allocate market shares. Together with rapid detection, swift retaliation enables the cartel to punish defection quickly, making it easier to sustain cooperation.
4. **Demand is relatively insensitive to the price charged.** Since aggregate demand is price-inelastic (Starc and Wollmann, 2022), revenues increased substantially following the 2013–2015 cartel-induced price hikes. In turn, profits rose sharply (see Cuddy (2020) and our Figure 1.2, described below). Internal documents show that Teva explicitly forecasted the effect of these price changes on cash flow (Complaint, page 221), which is presumably what motivated its employees to participate in the collusion despite the legal risk.
5. **Demand is stable.** Demand in mature generic prescription drug markets exhibits steady, acyclic growth, which ensures that threats of future retaliation in response to deviations are credible and severe.
6. **Markets are clearly defined.** Buyers define the markets, which correspond to particular drugs. For instance, internal communications reveal that simply by referencing "ranitidine tabs," everyone understands this to mean "ranitidine hydrochloride tablets in 150 or 300 milligrams." Clearly defined markets make it easier to communicate and make agreements.
7. **Entry was slow and expensive due to the regulatory approval process.** Beyond the typical setup costs associated with entry, generic drugmakers must receive substance-delivery-release specific authorization from the FDA to begin production. The entire process costs between $1 million and $12 million and takes between two and five years (Starc and Wollmann, 2022) and was exacerbated by a backlog of applications to the agency (Cuddy, 2020). If cartel nonmembers could enter quickly and cheaply, then their free-riding would reduce the profitability of collusion, and the scheme might have unraveled. (Igami and Sugaya (2022) describe such a dynamic in the context of the vitamin cartel.) The costs and delays associated with generic drug entry facilitated cartel stability.

8. **Firms have similar cost structures.** Manufacturers typically pay about the same amount for the chemical ingredients, and they use much the same technology to produce, package, and deliver. We would also expect incremental costs to be constant and similar across suppliers. The similarity of potential suppliers makes it more likely that a group of firms could come to an agreement on joint behavior.
9. **Firms have good information about competitors' costs.** Since most cost changes affect all firms similarly, there are unlikely to be substantial informational advantages in the market. Symmetric information also makes it easier to reach an agreement on joint behavior.
10. **Cartel members encounter one another in more than one market.** Contact between competitors in multiple markets means defection in one market can be punished in another, facilitating collusion (see Bernheim and Whinston, 1990). The more severely members can punish cheating, the more incentive firms will have to cooperate.
11. **Salespeople met socially on a regular basis to discuss issues of mutual interest.** According to the Complaint, agreements were refined and coordinated at regular lunches, parties, golf outings, "girls' nights out" (commonly abbreviated "GNOs" by the participants), and "Women in the Industry" dinners. Besides the exchange of competitively sensitive information, social gatherings might have caused the participants to form strong bonds, further strengthening the cartel, as illustrated by the "fraternity brothers" quotation above. Meetings could also be a place to resolve disputes, or to come to agreement about how to respond to changing market conditions.

1.4 INVESTIGATION AND GOVERNMENT LITIGATION

Shortly after the July 2014 *New York Times* article appeared, the Connecticut Attorney General's office filed subpoenas, obtaining thousands of internal documents, an "industry-wide phone call database" comprising more than 11 million records, cooperation from several as-yet-unidentified witnesses, and the assistance of forty-eight other states and US territories (Complaint, page 3). Around the same time as the states' civil investigations, the US Department of Justice opened a criminal investigation into Sherman Act violations, followed a few years later by a civil investigation into False Claims Act violations.

By early 2015, the conspirators became aware of the investigations because "the government was showing up on people's doorsteps" (Complaint, page 341). Around that time, DR, NP's superior, warned her to be careful when communicating with competitors. Following that conversation, NP deleted text messages exchanged with co-conspirators and stopped cartelizing new drug markets. According to the Complaint, the last cartel-induced price increase occurred on January 28, 2015 (see Figure 1.1).

State attorneys general have filed a series of complaints against the cartel members. The first, filed in December of 2016, targeted six firms in two markets, but concurrent public statements by investigators at the time implied that collusive conduct was more pervasive than the first claim suggested. Then-Connecticut Attorney General George Jepsen stated, "I can't stress enough this is just the tip of the iceberg" (Aiello, 2017). Consistent with his assessment, a second lawsuit – "the Complaint" – with over more than one hundred products was filed against twenty firms in May 2019. The unsealed version of the second indictment included 524 pages of internal communications acquired via the investigation, and it serves as the source text for much of the content of this chapter, as well as the academic studies by Cuddy (2020) and Starc and Wollmann (2022). A third complaint arrived just over a year later in June 2020, revealing a further conspiracy in the topical-formulation market. While most litigation is still pending as of this writing, several states – including Arkansas, Georgia, Louisiana, Mississippi, and Texas – have settled independently with certain indicted firms.

The first federal lawsuit was filed in December 2016. It charged two former Heritage executives with fixing prices, rigging bids, and allocating customers. The Justice Department subsequently obtained grand jury indictments against six other firms – Apotex, Glenmark, Rising, Sandoz, Taro, and Teva – as well as several of their senior executives. At the time of writing, many parties have settled. The two former Heritage executives and one former Sandoz executive have pled guilty. All await sentencing. Moreover, all seven firms have

admitted to fixing prices of at least certain drugs in their portfolios and have agreed to both civil and criminal fines via deferred prosecution agreements. In total, the Department of Justice has collected over $681 million in criminal penalties as of August 2023. Additionally, the firms entered into five-year integrity agreements that include internal monitoring and price transparency provisions. Violations of these agreements would lead to prosecution, and if convicted, firms would be debarred from all Federal health care programs. Additional federal and civil litigation is also ongoing (Department of Justice, 2023).

1.5 CARTEL EFFECTS

Once the cartel became active in mid- to late-2013, its members immediately began increasing prices by manipulating the outcomes of retailer procurement auctions for drug products in the portfolios of cartel members. Executives coordinated significant increases through a flurry of communication. They met their "fair share" market allocation objective by divvying up "the market for an individual drug based on the number of competitors and the timing of their entry so that each competitor obtains an acceptable share of the market" (Complaint, pages 39–40). Then, with winners predesignated, they raised prices via bid rotation and cover bidding.

With the drugs marketed jointly by cartel members numbering in the hundreds, the collusive scheme led to an immediate divergence in price from the drugs still subject to competitive pricing. Figure 1.2 plots the changes over calendar time of average drug prices in Teva's portfolio, differentiating between drugs now identified as collusive targets and those that were not. Before 2013, all markets – including those that were to be cartelized and those that were not – experienced similar price declines, on the order of 8 percent per year. Prices in uncartelized markets continued to fall after 2013, by approximately 20 percent through 2017. In contrast, the average price of cartelized drugs increased more than 30 percent between 2013 and 2015, and remained high thereafter. The relative price of drugs in cartelized markets therefore increased by 50 percent by 2015.

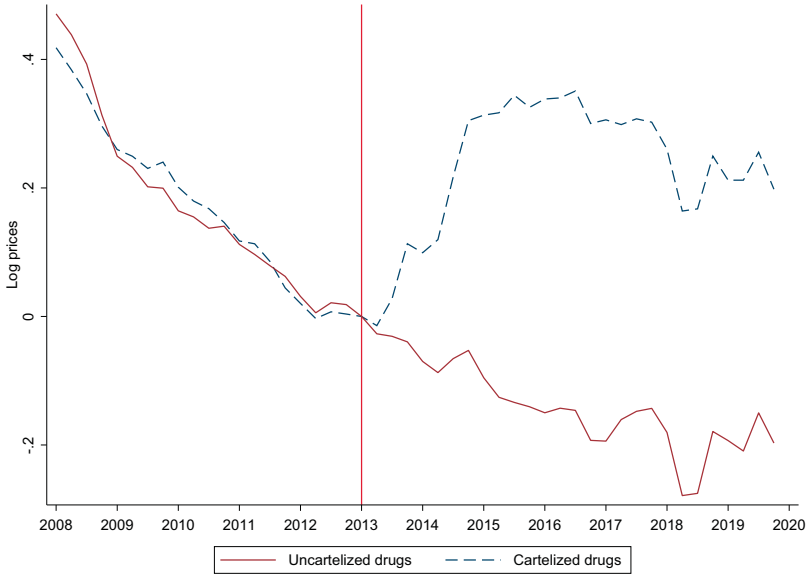

FIGURE 1.2 The cartel increased the prices of cartelized drugs by an average of 50 percent.

In this figure, we plot log prices on the y-axis against calendar time on the x-axis. The sample consists of all drugs manufactured by Teva in the first quarter of 2013. Prices are normalized to zero in that period, which is marked with a vertical line. Log prices are an unweighted average across drugs within each group. If each drug is weighted by the number of prescriptions filled in the year prior to NP joining Teva, similar price paths are observed, at least until 2015. Starting around 2016, the weighted average price of cartelized drugs falls faster than the unweighted price due to cartel-induced entry, which primarily occurs in large markets (see section 7). Source: Authors' calculations from the Complaint, Medicaid State Drug Utilization Data, and IQVIA's National Prescription Audit.

Given these large price increases, what were the likely effects and by whom were they borne? The initial effects were predominantly financial and concentrated among the firms that purchased drugs from these collusive firms, that is, large pharmacy chains and wholesalers. However, the harm eventually spread down the vertical supply chain, including payers. As a result, the price hikes affected numerous market participants and yielded both financial and non-financial repercussions. We describe this progression next.

1.5.1 *Initial Effects*

Quantifying the effects from the cartel's activities depends crucially on the extent to which one can plausibly estimate what prices would have been in the absence of any collusive activity. So far, both structural and reduced form approaches have been used to evaluate financial effects.

Cuddy (2020) adopts a structural approach, modeling the retail drug procurement process itself, where generic manufacturers bid to supply national pharmacies and wholesalers with their drugs. She estimates the model using an estimator for aggregate data of firms' winning bids as captured in the monthly NADAC survey data, which allows her to estimate firms' costs of goods delivered. She uses these cost estimates to reconstruct a counterfactual competitive price series for the collusive drugs. With this price series, she can quantify the extent of overcharge among a large set of drugs affected by the collusive ring's activities and also determine how the FDA's concurrent application backlog may have exacerbated these effects.

Among her sample of over one hundred collusive markets, she estimates total effects exceeding $12 billion over the eighteen months when the cartel was documented as most active – July 2013 to January 2015. As in Clark et al. (2021), she finds that there is significant dispersion in the amount of overcharge across markets: from negligible (or even negative) to nearly 4000 percent. On average, the unweighted average (median) overcharge is nearly 350 (60) percent. As shown in Figure 1.3, she demonstrates how the dispersion in price effects translates to dispersion in annual expenditures effects across collusive drug markets.

In their analysis, Clark et al. (2021) adopt a reduced-form approach, leveraging quarterly Medicaid data from 2011 to 2018 and a difference-in-differences methodology using a group of carefully selected competitive control drugs. They focus on six solid-dose drug markets (doxycycline monohydrate, meprobamate, nystatin,

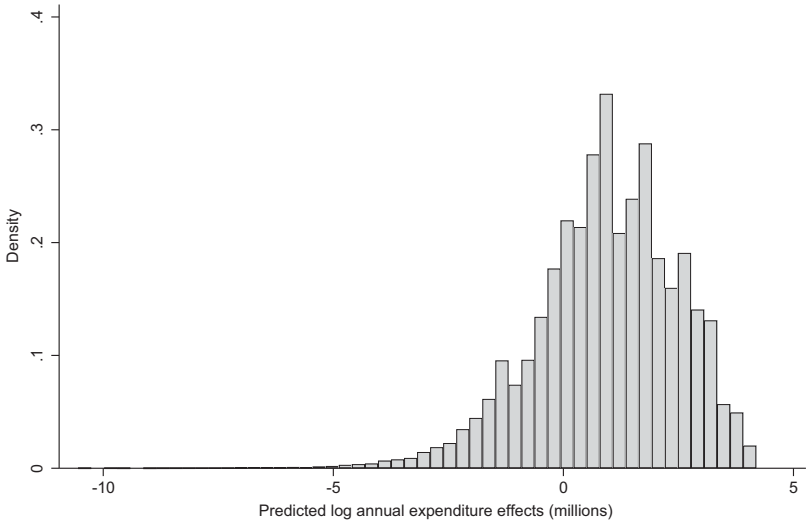

FIGURE 1.3 Estimated effects on annual expenditures across collusive drug markets, 2012–2015.

In this figure, the distribution of simulated effects across collusive drug markets is plotted. Source: Authors' calculations from the Complaint, FDA's National Drug Code Directory and Orange Book, and the pharmacy claims of a large private health insurance provider. See Cuddy (2020) for more detail.

paromomycin, theophylline, and verapamil). They estimate that collusion led to price increases of between 0 percent and 166 percent for each of the six drugs and damages of between $0 and $3 million for the Medicaid market, which are consistent with the product-level estimates from Cuddy (2020).

Of course, the immediate losses to direct purchasers were the immediate gains to cartel members. Profitability estimates are unavailable for the universe of cartel members, but the available evidence confirms that they enjoyed historic profits upon the instigation of their illegal operation. Figure 1.4 shows the profit margins over calendar time for the generic drug divisions of three key cartel members, Teva, Mylan, and Actavis. The profit margins all increased substantially after 2013. The reported margins understate the increase in profit margins in cartelized markets, insofar as the measures are average margins across all markets served by the colluding firms.

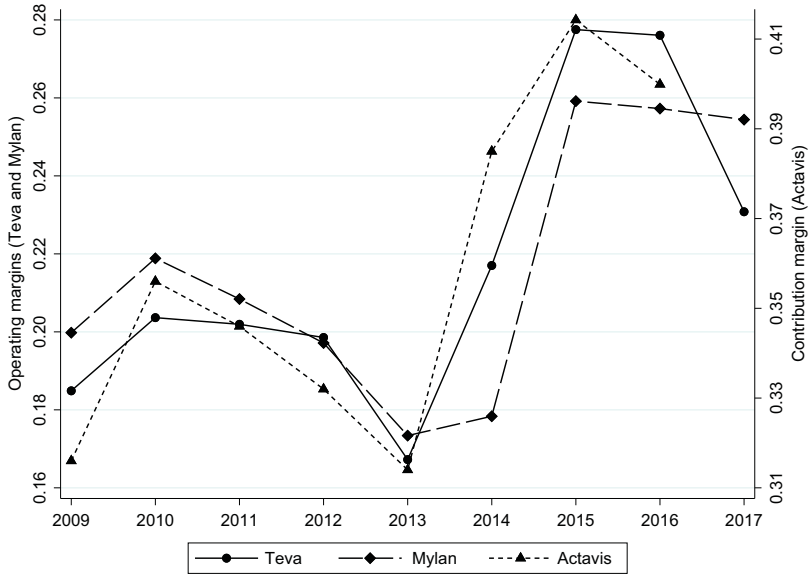

FIGURE 1.4 Profit margins for major generic drugmakers rise sharply upon cartel formation.

In this figure, profit margins are plotted in calendar time for the generic drug divisions of key cartel members. The primary y-axis measures operating income as a percentage of sales, which Teva and Mylan report, while the secondary y-axis measures "contribution" as a percentage of sales, which Actavis reports. Operating income equals net sales less the cost of goods sold, selling and marketing expenses, and research and development expenditures. Contribution is similarly defined except that all R&D costs and certain product costs (i.e., impairments of intangibles related to product rights) are explicitly excluded. Actavis was acquired in 2016, so results of its operations are not available for 2017. Mylan reports firm-wide rather than generic drug division profit margins, but generics account for the vast majority of its sales. Source: Authors' calculations from annual reports filed by Teva, Mylan, and Actavis with the Securities Exchange Commission.

Another striking implication of Figure 1.4 is the extended time frame for elevated manufacturer profits. It suggests that the effects were likely not confined to the aforementioned effects on direct purchasers of the collusive drugs. Recall that payments to pharmacies are based on an ingredient cost (plus a dispensing fee), which reflects the average acquisition cost in the market, albeit with a lag. Accordingly, over time reimbursement schemes adjust to the new, collusive market price, and upon adjustment, the direct purchasers

pass on the price increases to third-party payers, ranging from the government (both state and federal) to private insurers, which are the next link in the vertical supply chain. While it is still too early to estimate empirically the extent of pass-through to third-party payers and, in turn, consumers, we next discuss how they may have been affected.

1.5.2 Pass-Through Effects

Existing reimbursement rules for generic drugs meant that pass-through from direct purchasers to third-party payers was mechanical, even if it took some time to phase in. A natural question, therefore, is why private insurers were not more attuned to the possibility of such price hikes and more strategic in their reimbursement contracting.

One obvious explanation is that generic drug price instability may not have been a first-order managerial concern before 2014. Despite large price hikes on a subset of drugs in the years preceding the creation of the cartel, generic drugs had been a "good deal" overall. Only 5 percent of generic drugs experienced price increases greater than 1 percent in 2013 (Joyce et al., 2018). The average price of a generic prescription actually decreased between 2006 and 2015 in both Medicare and Medicaid. Simultaneously, the use of generics had been increasing over time just as branded drug prices were rising, leading to greater savings relative to branded competitors (Congressional Budget Office, 2022). In a single high-profile example, several drugs for the treatment of Hepatitis C were released during our time period that cost the Medicare Part D program $4.7 billion – nearly four percent of the total annual program spending. Unsurprisingly, several payers noted in financial documents shortly thereafter that controlling *specialty* drug spending, rather than generic drug spending, was an important strategic goal.[8]

[8] United Health Care 2013 10-K.

That said, there was some awareness of potential issues in the generic market. At least one payer remarked that "in recent years, there has been significant consolidation within the generic manufacturing industry, and it is possible that this dynamic may enhance the ability of manufacturers to sustain or increase pricing of generic pharmaceuticals and diminish our ability to negotiate reduced acquisition costs," indicating awareness of the threat of rising prices.[9] This is especially important as pharmacies' gross profit margins are often higher for generic drugs than branded ones (Sood et al., 2017).

What about consumers? To what extent could rising upstream drug prices translate to higher out-of-pocket costs? This is an important question for at least two reasons. On the one hand, the demand side may discipline price increases and restrain the cartel. On the other hand, consumers may reduce drug consumption in response to higher out-of-pocket costs, even if doing so puts them at risk of negative health consequences.[10]

To quantify the potential scope of out-of-pocket changes, we need to understand the source and nature of prescription drug coverage. Nearly 18 percent of Americans have coverage through the Medicaid program, which has limited cost sharing because of its low-income enrollees (Keisler-Starkey and Bunch, 2021). Out-of-pocket costs will not increase for this group. Another 18 percent of people are eligible for Medicare, which subsidizes private drug coverage through Medicare Part D (Keisler-Starkey and Bunch, 2021). A recent study notes that, initially, a "relatively small portion of the price increases was passed on directly to Medicare beneficiaries in the form of higher out-of-pocket costs" (Joyce et al., 2018). This may change over time, as plans change formularies (the list of covered drugs) or move from fixed copayments to coinsurance (i.e., a fixed percentage of the upstream price).

[9] CVS 2013 10-K.

[10] See, e.g., Chandra et al. (2021) in the context of out-of-pocket increases in Medicare and Barkley (2022) in the context of cartel-induced insulin price increases in Mexico.

Outside of public health insurance, the majority of Americans obtain privately sponsored coverage from their employers. Most employer-sponsored plans have prescription drug coverage (Kaiser Family Foundation, 2020). These plans typically include tiered cost sharing with generic drugs on the "lowest" (cheapest) tier, as insurers want to encourage their use. Fixed dollar copayments are the most common form of cost sharing. In the case of copayments, consumers will be insured against upstream price increases. Of course, payers may increase premiums and employers may reduce wages in response to higher drug costs.

Taken together, our description of the supply chain illuminates the incidence of price increases. In the short- to medium-run, variable profits fall for the companies who are direct purchasers. Over time, price indices will evolve to account for rising prices, and insurers will face rising prices for generic drugs. We note that both government and private insurers face these rising costs but may react differently. In particular, private insurers may respond by altering plan design, such that a subset of consumers face higher out-of-pocket costs. From an economic perspective, it is interesting to note that while direct purchasers may switch suppliers, the aggregate demand response is likely to be small. This has a countervailing impact on welfare, as it limits the possible negative health consequences while implying a limited ability to discipline the cartel.

1.6 MARKET-BASED REMEDIES

Cooperatively raising prices to the extent shown in Figure 1.2 can clearly affect drugmakers' incentives. Stigler (1964) argues these changes tend to work toward mitigating harm caused by the cartel, giving the market a natural safeguard against collusive behavior. Two such mechanisms exist. One involves secret deals, that is, discounts off the collusive price. Conceptually, as a cartel hikes price, each unit sold generates greater profit, so members' incentives to undercut one another in an effort to win additional business rise as well. However, as we discussed in Section 1.3.2, cheating is unprofitable in generic

drug markets because detection and retaliation are almost immediate. Consistent with this view, if one holds the number of suppliers fixed, then collusive prices are very stable in the years following the formation of the cartel. The other mechanism involves entry. Conceptually, when a cartel raises a price, it also makes the market more attractive to entrants, whose efforts to gain market share may undermine the members' agreement. Starc and Wollmann (2022) find that entry plays an important role in the evolution of cartelized generic drug markets. Three patterns in the data support this claim.

The first relates to the filing of Abbreviated New Drug Applications (ANDAs). For background, generic manufacturers must file a drug-specific ANDA to the Food and Drug Administration and gain the agency's approval before entering a market. Thus, ANDA filings provide the most immediate measure of entry. Similar to the path of prices plotted in Figure 1.2, ANDA filings for cartelized and uncartelized drugs track closely prior to NP joining Teva but diverge sharply thereafter, with cartelized markets experiencing a 30–40 percent increase in this measure of entry compared to uncartelized markets.

Second, entrants faced long delays. For example, between 2013 and 2019, the time from ANDA filing to approval typically exceeded two years. As a result, most cartelized markets did not experience *actual entry* until three to five years after cartel formation. An interesting exception, though, are markets with "dormant" ANDAs.[11] In these cases, the drug manufacturer is not currently active in the market but is authorized to manufacture the drug, so it could restart production at any time. Cartel formation induced almost immediate re-entry in many of these cases, but there were a limited number of firms holding inactive approvals (Starc and Wollmann, 2022).

The third relates to price effects. In theory, entry can destabilize cartels, precipitating their demise. This idea is not without precedent.

[11] Firms often obtain approval to produce a drug and begin manufacturing it, but then discontinue production, presumably because it is no longer profitable.

For instance, Igami and Sugaya (2022) argue that expansion of production by fringe entrants employing nascent technology caused some vitamin cartels to unravel in the 1990s. However, absent a competitive advantage on the part of potential entrants, such as lower costs, entrants are unlikely to earn economic profits if their entry causes the cartel to collapse and prices revert to competitive levels. (If such entry were profitable under competitive prices, then it would have been profitable prior to cartel formation, so it would have occurred already.) Alternatively, entrants could be brought into existing collusive agreements, resulting in little to no price effect. This scenario is equally unlikely, since NP lacked relationships with about two-thirds of post-cartel entrants. Finally, the cartel could survive entry, with entrants' behavior resembling that of incumbents. Since nonmembers best respond to cartel prices, one can reasonably expect prices to decline.

Empirically, entry exerted downward pressure on prices. One way to illustrate the effect of entry is to restrict attention to cartelized drugs and compare small markets to large ones. Since the decision to enter hinges on whether the discounted sum of expected future profits exceeds up-front investments, large markets should experience more entry than small ones whereas their price paths absent entry should not otherwise differ. If entry disciplines cartel prices but most entrants experience delays, then one should observe two patterns in the data. First, directly after cartel formation, the average prices of small- and large-market drugs should rise by similar amounts. Second, several years after cartel formation, the average price in small markets, which experience little entry, should remain stable, while average prices in large markets, which experience significant entry, should decline substantially. Starc and Wollmann (2022) show that entrants are drawn almost exclusively to large markets, and that prices exhibit both of the aforementioned patterns.

1.7 AFTERMATH

In light of the tremendous profits earned by cartel members and the price effects suffered by their customers, it is not surprising that in

addition to the government proceedings described above, private parties have also sought damages under antitrust laws. For example, direct purchasers such as Kroger and other grocery chains as well as health insurers like Humana and UnitedHealthcare are currently suing Mylan, Teva, Endo, and other manufacturers. The plaintiffs allege that the defendants conspired to "fix, increase, stabilize, or maintain prices of the specified generic pharmaceutical drugs." At the time of writing this case study, the litigation is ongoing.

Legal action has also expanded beyond downstream buyers. Taro shareholders argued that the firm misled investors. The lawsuit states, "Defendants repeatedly told investors that 'Taro's sales and earnings growth [was] attributable to upward price adjustments and a prudent lifecycle management of [the Company's] product portfolio[;]' that '[t]here [was] a very strong market mechanism which we believe is fully in operation[;]' and that margins 'largely depend[ed] on competitive intensity which is not in our hands' while Defendants knew or recklessly disregarded that Taro was fixing prices – eliminating competition between the Conspirators for the Drugs" (brackets in original text). Further, it alleges that defendants "concealed the fact that they were threatening the Company with substantial liabilities from Taro's ongoing antitrust violations" (*Speakes* v. *Taro Pharmaceutical Industries et al.*, 2017).

Outside of the legal system, both direct purchasers and private insurers have amended contracts in an effort to hasten the pass-through of manufacturer-induced price increases. As noted above, both wholesale prices and maximum allowable charges evolve over time, shifting the burden of price increases. Small pharmacies are especially supportive of policy change, perhaps because they are the most likely to experience short-run damages. For example, the National Community Pharmacists Association has supported a wide range of reforms (National Community Pharmacists Association). Among these are the new maximum allowable cost (MAC) transparency rules, which require clear criteria for inclusion in MAC lists and frequent updating. Updating MACs is especially important for

pharmacies in the event that anti-competitive manufacturer behavior leads to sudden price increases. On the insurer side, many generic drugs have been moved to higher tiers over time where coinsurance – rather than copayments – applies (Sloan and Young, 2021). In addition, more consumers are now in high-deductible health plans. While only 20 percent of workers were in HDHPs in 2013, the number has increased to approximately 30 percent in 2020 (Kaiser Family Foundation, 2021).

What about the drugmakers' response? Did the discovery of the cartel cause it to unravel? While the government's investigations stopped new cartels from forming, it does not appear to have affected existing collusive agreements. As Figure 1.2 shows, prices of cartelized drugs were relatively stable throughout the investigatory period, and, as Figure 1.4 shows, profit margins reported by cartel members far exceeded pre-2013 levels through at least 2017. The durability of high prices despite limited potential for communication (i.e., after the firms were under surveillance) suggests that the frictions that make it difficult for firms to coordinate initially are also likely to be important in sustaining the collusive agreements (see Asker and Nocke (2021) for additional discussion). Indeed, as NP states, once coordination is achieved, "price increases tend to stick and markets settle quickly" (Complaint, page 160).

Taken together, it becomes clear that the financial effects discussed in Section 1.5 were just one dimension of the harm the cartel caused. In some sense, one could make the argument that the nonfinancial repercussions of the cartel's activities may yield the most lasting impact on the generic drug market. For example, the contractual adjustments to drug insurance expose far more consumers to any future short-term price volatility than ever before.

1.8 LESSONS LEARNED

The US generic drug cartel provides a unique opportunity to study the origin and impact of collusion in an economically important market. Some aspects of behavior in this market are likely to be unique to the

setting. For instance, the vertical industry structure muted aggregate demand responses to price hikes. However, most aspects are common to many markets, meaning the lessons presented here apply quite broadly.

One key takeaway is that interpersonal relationships can be critical to cartel formation. In this setting, we are fortunate to observe a quantitative measure, based on a ringleader's own assessment, of how close she was to the key salesperson at each drug manufacturer. Although this factor is rarely emphasized in the economics literature, it plays a pivotal role here. Perhaps most strikingly, cartels form in about 90 percent of markets where NP has close ties to all of the other market participants, but only about 20 percent of markets where she lacks such relationships.

Another key takeaway is that the effects of collusive behavior may persist long after explicit communication between the cartel members has ended. The conspirators learned in early 2015 that they were being investigated by the government. They severely limited direct communication with one another thereafter. That response prevented new cartels from forming in other generic drug markets. However, the data strongly suggests that collusive prices persisted for many years afterwards. In all likelihood, high prices were sustained by a tacit understanding that if any cartel member were to undercut the others then the market would revert to much lower prices. This view is consistent with remarks made by the cartel ringleader, which imply that collusion is hard to initiate but easy to maintain in generic drug markets. Given the estimated magnitude of the damages between 2013 and 2015, sustained price fixing probably produced significant additional harm.

Finally, our setting illustrates that cartels attract entrants that undercut collusive prices, in an effort to gain market share. However, it also highlights the limitations of entry in regulated markets, where firms must endure high costs and long delays before beginning production. As a result, many cartelized markets did not attract any entry, and in markets that did attract entry typically two to four years

passed before entrants began production. Notably, the FDA has introduced reforms that aim to reduce the entrance delay, which have resulted in the elimination of 90 percent of the pre-2017 backlog of ANDAs. However, new ANDA applications also grew rapidly, so backlogs persist.

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