Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Overview of Agreements Filed in FY 2011
A Report by the Bureau of Competition

During the fiscal year 2011 (October 1, 2010 to September 30, 2011), the Federal Trade Commission received 156 final resolutions of patent disputes between a brand and a generic. This preliminary assessment summarizes the types of final settlements received in FY 2011 and describes how the FY 2011 results compare to filings in other recent years.

Overview of Final Settlements

- 28 final settlements contain both compensation to the generic manufacturer and a restriction on the generic manufacturer’s ability to market its product.
  - These settlements involve 25 different branded pharmaceutical products with combined annual U.S. sales of more than $9 billion.

- 100 final settlements restrict the generic manufacturer’s ability to market its product, but contain no explicit compensation.

- 28 final settlements have no restrictions on entry.

Final Settlements Involving First Filers

- 54 settlements involve generics eligible for 180-day first-filer exclusivity.
  - 18 settlements contain both compensation to the generic manufacturer and a restriction on the generic manufacturer’s ability to market its product. 10 of these settlements include an agreement by the brand not to compete with an authorized generic or an exclusive license for the generic to market an authorized generic.
  - 29 settlements restrict the generic manufacturer’s ability to market its product, but contain no explicit compensation.
Comparing FY 2011 to Prior Years

FY 2011 witnessed the continued trends of (a) record numbers of brands and generics resolving patent litigation prior to a final court decision on the merits and (b) significant numbers of such settlements potentially involving pay-for-delay. In fiscal years 2010 and 2011, the FTC received 59 potential pay-for-delay settlement agreements, almost equal to the total number of potential pay-for-delay agreements identified in the preceding six years combined. This trend similarly applies to potential pay-for-delay settlements between brands and generics eligible for 180-day first-filer exclusivity.

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F.T.C.: 28 ‘Pay-for-Delay’ Generic Drug Deals

By DUFF WILSON

Updated: 5:30 p.m. Drug companies negotiated 28 potential “pay-for-delay” deals that slowed the marketing of cheaper generic drugs in the fiscal year ending Sept. 30, the Federal Trade Commission said Tuesday in a staff report.

In a statement, Jon Leibowitz, the agency’s chairman, called for the congressional “super-committee” that is reviewing ways to cut federal spending to also promote legislation banning certain out-of-court settlements in cases over drug patents when they involve payments and delays.

Mr. Leibowitz, who has crusaded against the practice, considers the arrangements to be illegal sweetheart deals costing consumers and government health programs $3.5 billion a year. But proposed legislation has languished in Congress because opponents, including drug makers, say the deals actually speed the entry of generics to the market.

The F.T.C. report was dismissed as “garbage” by Robert Billings, vice president of policy at the Generic Pharmaceutical Association, a Washington trade group.

This year, Mr. Billings said, cheaper, generic versions of three best-selling drugs – Lipitor, Plavix and Effexor XR – are coming to market earlier than they would have otherwise as a result of out-of-court settlements. He said generic drug companies over time have won only 48 percent of the patent challenges that are litigated to conclusion, meaning negotiated settlements usually bring cheaper drugs to market faster.

“We wish the F.T.C. would just go back to doing the good things they do – they do many good things — and quit lobbying Congress to put a ban on something that is proven to be pro-consumer,” Mr. Billings said in an interview.

Peter Kaplan, a spokesman for the F.T.C., responded that the proposed legislation would not ban the deals, but restrict them. The legislation would shift the burden of proof to drug companies to prove the settlements are pro-competitive, he said.

Mr. Kaplan also said the F.T.C. has never alleged that Lipitor, Plavix or Effexor XR were “pay-for-delay” cases. The generic drug association had not said so either, but cited them as good examples of out-of-court settlements. Mr. Kaplan said the F.D.A. supports most of those settlements.
The study by the F.T.C. Bureau of Competition said 156 drug patent challenges ended in settlements during the last fiscal year, with 28 of them including both compensation in some form and an agreement to delay a generic drug. Using those criteria, there were a record 31 such deals in the previous year, but much lower numbers, in the teens, in earlier years, the F.T.C. said.

“Honestly we wouldn’t be continuing to raise this issue unless the commission felt really strongly about it, and going back to 1999, every single Democrat and Republican on the commission has really wanted to restrict these deals,” Mr. Leibowitz said. “Whenever somebody puts a big bag of cash on the table, or a big bag of cash in disguise, they get something for it. And there are plenty of settlements that occur today that don’t have any money involved.”

The F.T.C. has challenged some of the deals. In 2009, Bristol-Myers Squibb paid $2.1 million to settle agency claims that it had failed to reveal a verbal agreement with a generic drug maker while keeping a generic version of Plavix off the market. The F.T.C. has lost some challenges.

A federal appeals court overturned a 2005 sanction against Schering-Plough, now owned by Merck, over a 2001 deal with two generic companies involving the blood pressure medicine K-Dur 20. The Supreme Court declined to hear an appeal. Earlier this year, the F.T.C. filed a brief joining a private class action suit over the same, 10-year-old issue.
INTRODUCTION

Distribution issues are at the core of many antitrust disputes. The issues often concern price differences that manufacturers charge different buyers in alternate channels of distribution and how these prices are determined. Such were the questions raised in the largest antitrust case ever brought in the pharmaceutical industry: the Brand Name Prescription Drugs Antitrust Litigation (hereafter BNPDAL).

BNPDAL began in the early 1990s when a group of retail pharmacies charged that every major pharmaceutical manufacturer selling prescription drugs in the United States: (1) price discriminated against retail drug stores in violation of the Robinson-Patman Act; and (2) conspired with each other and with the nation’s largest drug wholesalers to refuse discounts to retail drug stores in violation of Section 1 of the Sherman Act. As summarized by economics consultants for several supermarket and drug store plaintiffs in the litigation, the contested pricing scheme purportedly arose from “a series of agreements and understandings among drug manufacturers developed in response to the emergence of managed health care in the 1970s and 1980s. While drug manufacturers began discounting extensively on sales to favored buyers, they allegedly agreed not to discount to retail pharmacies” (Weinstein and Culbertson, p. 258).

The authors, both of the Department of Economics at the University of Virginia, are consultants to SmithKline Beecham, one of the defendants in BNPDAL.

1MDL 997, U.S. District Court, N. District of Ill., Eastern Division.
The defendant manufacturers claimed that the discounts were decided upon unilaterally and were motivated by “meeting competition” considerations. The pharmaceutical companies also claimed that the disputed discounts were extended to buyers, such as hospitals and managed care organizations, because of their ability to “move market share” of their products, something retail pharmacies could not do. The defendant wholesalers claimed that they were merely the conduit for the manufacturers’ discounts offered to certain buyers.

The litigation began with more than a hundred cases brought by (or on behalf of) some 40,000 retail pharmacies (i.e., independent drug stores, chain drug stores, and pharmacies in mass merchandising and food store chains). The cases were consolidated in federal court in Illinois, and a group of plaintiffs was certified (referred to as “the Class”). The Class consisted of retail pharmacies that purchased “prescription brand name drugs directly from any of the defendants.” Members of the Class ranged in size from corner drug stores to Wal-Mart. Hospitals, clinics, nursing homes, and mail-order pharmacies were not plaintiffs in this litigation. Some plaintiffs exercised their right to opt out of the class and pursue their own individual claims (referred to as “Individual Plaintiffs”).

BNPDAL became one of the largest antitrust cases in American history. More than 1400 individuals were deposed in the course of this litigation, and more than 45 million documents were produced by the defendants. Many of the premier law firms in the United States and some of the most famous litigators represented the defendants. David Boies, one of the nation’s most prominent lawyers, became involved in 2001 as lead counsel for one group of plaintiffs that opted out of the Class. Over twenty-five economists were involved in writing expert reports for the defendants. Before the trial, eleven of the seventeen original manufacturer defendants reached settlements with the class plaintiffs in which, collectively, they paid cash settlements of $700 million.

Because the allegedly unlawful price discrimination in this case supposedly was sustained by collusion, the class action focused on the Sherman Act conspiracy elements of the plaintiffs’ charges. For juridical reasons, the trial court scheduled separate trials for the Sherman Act (conspiracy) claims of the individual plaintiffs and for the Robinson-Patman (price discrimination) claims. The class action conspiracy case, thus far, is the only one to have been tried. The judge divided the conspiracy case from the price discrimination case on the grounds that the Sherman Act required proof of “un-

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2The Individual Plaintiffs include some large drug chains such as Rite-Aid and Revco. Their litigation is still pending.

3The defendants who settled were American Cyanamid, American Home Products, Bristol-Myers Squibb, Glaxo Wellcome, Eli Lilly, Merck, Pfizer, Schering-Plough, SmithKline Beecham, Warner-Lambert, and Zeneca. Companies who elected to go to trial included G.D. Searle, Johnson & Johnson, and Ciba-Geigy.
lawful concerted action” by all the defendants, while the price discrimination claims might be shown “regardless of the existence of a conspiracy.”

The Sherman Act case brought by the Class went to trial in the fall of 1998, and for eight weeks the plaintiffs presented their evidence, at which point the defendants asked the judge to grant a directed verdict against the plaintiffs. In January 1999 he did so, thereby dismissing the plaintiffs’ allegations of an industry-wide cartel. The Class appealed to the Seventh Circuit Court of Appeals. In July 1999, the appellate court affirmed the lower court’s judgment as to the Sherman Act case. Trial on the Individual Plaintiffs’ claims remains to be scheduled.

THE MARKET FOR PRESCRIPTION DRUGS

To understand the economics of this case, it is necessary to understand some of the peculiar characteristics of the market for prescription drugs. Most consumer goods are selected by consumers and purchased with consumers’ financial resources. But prescription drugs are an exception for two reasons. First, “consumer sovereignty” does not apply to the consumption of prescription drugs because patients may buy only those drugs prescribed by a physician. The demands that pharmaceutical manufacturers face for specific drugs are not simply a function of patients’ characteristics. Patients’ preferences literally are “doctored” by prescribing physicians acting as agents for patients.

Prescription drugs also are an exception to the principle of consumer sovereignty because they often are not paid for directly by the persons who consume them. Increasingly, they are paid on behalf of patients by third-party payers such as employer health benefit plans and insurance companies. Third-party payment creates a “moral hazard” to the extent that the payer has no influence in the prescription generation process. Under this arrangement, physicians and patients naturally focus on the therapeutic effects of prescription drugs and not on their costs. The cost is the payer’s problem.

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4In re Brand Name Prescription Drugs Antitrust Litigation, 1999 WL 33889 (N.D. Ill.), p. 10. The procedural history of BNPDAL is itself complex. The Sherman Act claims of the Independent Plaintiffs have not been tried nor have the Robinson-Patman claims of any plaintiffs been tried (as of April 2002).

5Directing a verdict essentially means that there is no reason for defendants to present their case because “no reasonable jury could reach a verdict” favoring the plaintiffs anyway.

6There are recent industry studies that provide a more comprehensive view of the pharmaceutical industry (Berndt 2002; Comanor and Schweitzer 1995; Deutsch 1998; Scherer 2000; Schweitzer 1997; and Spilker 1994).

7A moral hazard arises in situations where a fully insured person has the ability to change her behavior after purchasing insurance without the insurance company’s being able to detect that she has done so.
Managed Care

Although they exist for good and necessary reasons, physician prescription writing and third-party payment have indirect effects that inflate the cost of providing prescription drug benefits to consumers. In time, as the magnitude of the indirect effects grew large, hospitals began to exert more influence over their doctors’ generation of prescriptions, and managed care organizations were spawned to contain payers’ prescription drug costs. Managed care organizations include staff-model health maintenance organizations (HMOs), independent practice association (IPA-model) HMOs, and pharmacy benefit managers (PBMs). Staff-model HMOs employ physicians to provide prepaid medical care exclusively to the patients whose health care benefits they manage. IPA-model HMOs provide prepaid medical care through networks of independent physicians. PBMs specialize in administering the prescription drug benefits of health insurance plans. Some PBMs (e.g., Medco) also dispense drugs by mail.

Hospitals and managed care organizations gained influence over drugs by (1) garnering control of the pharmacy benefits of large, closed patient groups, and (2) stimulating price competition among the pharmaceutical manufacturers for the business of these patients. The number of patients that are under some form of managed care in the United States has grown dramatically.8

The ability of hospitals and managed care organizations to reduce the cost of pharmacy benefits has been enhanced by growth in the number of generic prescription drugs and by growth in the number of brand name (patented) prescription drugs within various therapeutic categories (e.g., ACE inhibitors that treat high blood pressure or Histamine Antagonists that block gastric acid secretion). To the extent that there is competition among hospitals, among managed care organizations, and among third-party payers, the cost savings secured by managed care intervention in the prescription drug market will be passed on to employers and consumers.9

While the plaintiffs charge that competition is injured because pharmaceutical manufacturers deny retail pharmacies the same discounts offered to hospitals and managed care entities, the defendant manufacturers interpret the discounts in question as payments for intervention by hospitals and managed care organizations in the prescription generation process. In blunt terms, manufacturers reason that drug discounts are extended for exerting influence over physician prescribing behavior. Retail pharmacies, they argue, play a dispensing role rather than an intervention role in the

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8 In 1980, only 5 percent of all prescription drugs were under the influence of managed care organizations (Boston Consulting Group 1993, pp. 17–18 and Fig. 2–3). Today, the “four biggest PBMs provide prescription-drug benefits for about 200 million Americans” (Martinez 2001).

9 Cost containment in the managed care segment of the health care industry is not limited to prescription drugs. Managed care organizations also exact discounts from physicians, hospitals, clinics, and retail pharmacies.
market. Retail pharmacies cannot influence physicians’ prescribing behavior easily, and pharmacists in most situations are legally or ethically constrained from doing so. That is, if a physician prescribes a particular drug, the pharmacist may not substitute another drug without first contacting the physician and getting approval. Busy pharmacists cannot contact multiple physicians hoping to persuade them to approve hundreds of switches each week. Busy physicians will not entertain multiple calls from pharmacists suggesting changes in their written prescriptions. In some circumstances, a pharmacist may not have to check with the prescribing physician if there is a generic substitute available for the particular drug that was prescribed. But, for most of the drugs at issue in BNPDAL, there are no generic equivalents available.

In short, the defendants reasoned, retail pharmacies do not exert the necessary influence with physicians to “move market share.” From the perspective of an economist, manufacturers’ discounts to hospitals and managed care organizations that move market share is a form of third-degree price discrimination, in response to differences in observed demand elasticities for individual companies’ drugs.

**The Chargeback System and Rebates**

The contested discounts in BNPDAL are distributed differently to hospitals and managed care organizations depending on whether they actually dispense prescription drugs. Discounts to hospitals, staff-model HMOs, and PBMs that dispense drugs are implemented by means of a chargeback system that evolved from manufacturers’ interactions with the drug wholesaler industry. The manufacturer charges wholesalers the wholesale price for a particular brand name prescription drug. But if a wholesaler then sells the drug to a hospital with whom the manufacturer has negotiated a discount, the wholesaler charges the hospital a price that encompasses the discount and “charges back” the discount to the manufacturer.

Discounts to managed care organizations work differently in most cases because these organizations, unlike hospitals, usually do not physically acquire and dispense pharmaceuticals. Prescription drugs that come under the aegis of managed care are distributed via the same drug wholesalers and retail pharmacies as other prescription drugs. But manufacturers’ discounts to managed care organizations are implemented via rebates paid directly to these entities for the drugs prescribed by physicians and dispensed to patients who are under their care.

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10This kind of activity is controversial. Senator Charles Schumer recently asked the Federal Trade Commission to investigate drug manufacturers’ making payments to drug chains to promote certain prescription drugs to their consumers through phone calls and letters. See “FTC Is Asked to Study Promotion of More Expensive Drug Brands,” *Wall Street Journal*, May 6, 2002.
Formularies

A formulary is the list of prescription drugs that physicians who practice in a hospital, or who treat patients whose health benefits are controlled by a managed care organization, may prescribe. One form of intervention by hospitals and managed care organizations is putting a particular brand name prescription drug on its formulary. For example, a hospital might instruct its physicians to prescribe a particular antidepressant (e.g., Paxil) to the exclusion of other antidepressants (e.g., Prozac) in the same therapeutic class (i.e., Selective Serotonin Reuptake Inhibitors, or SSRIs, for treatment of depression). The physicians and pharmacists who determine the formulary may believe that the selected antidepressant is superior, or they may believe that it is comparable to others but its manufacturer has offered it to the hospital (or to patients covered by the managed care organization) at a lower price than rival products in the same therapeutic class.

Formulary access is not necessarily limited to a single drug within a therapeutic class. Therefore, another form of intervention is granting preferential, although not exclusive, formulary status for a manufacturer’s brand name prescription drug to managed care organizations or hospitals.

THE TRIAL

The class plaintiffs and the six defendant manufacturers who did not reach a pretrial settlement with the plaintiffs proceeded to trial in 1998 on the Sherman Act conspiracy charge. The focus of the trial was whether the defendants colluded in their refusal to extend the same price discounts to retail drug stores that hospitals and managed care organizations received. The role that the plaintiffs attributed to manufacturers and wholesalers in the alleged conspiracy changed as the litigation proceeded. Before the trial began, the plaintiffs claimed that it was the manufacturers who started the cartel, and then brought the wholesalers on board—as “tools or reluctant accomplices.” But at trial, the plaintiffs alleged it was the other way around: Wholesalers started the cartel, out of fear of retail buying groups, and “importuned the [m]anufacturers to join in their illegal conduct.” The judge criticized the plaintiffs for switching theories in the middle of the litigation.

Plaintiffs’ Evidence of a Conspiracy

At trial, the plaintiffs presented four witnesses and a flood of deposition testimony in support of their conspiracy claim. Much of this testimony was of-

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11The practice of offering discounts on prescription drugs to hospitals pre-dates the emergence of managed care organizations.

12In re Brand Name Prescription Drugs Antitrust Litigation, 1999 WL 33889 (N.D. Ill.), p. 10.
ferred to support the claim that retail drug stores, like hospitals and health maintenance organizations who received discounts, also have the ability to “move market share” by influencing physician prescription patterns. If the plaintiffs could persuade the court that retail pharmacies, like hospitals and managed care organizations, were effective agents of intervention, this would undermine the defendants’ economic justification for refusing to offer discounts to retail pharmacies.

The plaintiffs presented four live witnesses who had experience in the retail pharmacy business. The cross-examination of these witnesses ended up supporting the defendants’ position instead. As the judge wrote, “[I]t was out of the mouths of [the plaintiffs’] live witnesses that the basic independent rationale for why the Defendants priced the way they did was first established in the record.”

For example, a retail pharmacist in the Seattle area admitted to having once contended that “drugstores have little influence on the drug prescribed and cannot switch to alternative products as prices increase.” Another plaintiff witness who had operated retail pharmacies admitted that for him to be involved in regularly switching his customers from the drug called for on the prescription to another drug was not only impractical but also unethical.

The factual evidence offered in support of the plaintiffs’ conspiracy theory was exclusively circumstantial and centered on trade association meetings attended by the manufacturers and meetings of the National Wholesale Druggists’ Association (NWDA) attended by the wholesalers and manufacturers. The plaintiffs claimed that these professional gatherings provided the defendants with an opportunity to meet and discuss ways to prevent the outbreak of discounting to retail pharmacies. For instance, in reference to a panel discussion at a 1985 NWDA marketing conference in Atlanta, the Class offered as proof of conspiracy the “fact that the agenda for the panel discussion referred to [retail pharmacy] buying groups as a ‘threat,’” even though, as the trial judge observed, “the presence of retail buying group representatives at this discussion undermines” this interpretation of events.

In reference to a 1986 study commissioned by NWDA that forecasted certain future developments in the brand name prescription drug industry, the plaintiffs inferred an attempt by manufacturers and wholesalers to coordinate a refusal to offer discounts to retail pharmacies. The judge reviewing the evidence presented about professional gatherings wrote that “[t]he fundamental weakness with the Class Plaintiffs’ approach, and fatal to it, is that the Plaintiffs rely on speculation and conjecture rather than fair or reasonable inferences . . .”

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13 In re Brand Name Prescription Drugs Antitrust Litigation, 1999 WL 33889 (N.D. Ill.), p. 6 (emphasis added).
14 In re Brand Name Prescription Drugs Antitrust Litigation, 1999 WL 33889 (N.D. Ill.), pp. 2–3.
15 In re Brand Name Prescription Drugs Antitrust Litigation, 1999 WL 33889 (N.D. Ill.), p. 8.
16 In re Brand Name Prescription Drugs Antitrust Litigation, 1999 WL 33889 (N.D. Ill.), p. 9.
 Plaintiffs’ Economic Expert

Unable to present direct evidence for the alleged conspiracy, it was left to the plaintiffs’ economic expert to resurrect the case. That expert testified that the manufacturers’ discounts could not be explained by the ability of hospitals and health maintenance organizations to “move market share” because retail drug stores also had the ability to move market share in brand name prescription drugs. Further, having concluded that the defendants’ economic justification for discounts was invalid, he testified that the circumstantial evidence presented by the plaintiffs was enough to prove that manufacturers’ refusal to grant discounts to retail pharmacies was the product of collusion.

The plaintiffs’ expert relied heavily upon the existence of price discrimination in the market for brand name prescription drugs to analyze the question of whether a conspiracy was afoot. He reasoned that if the market for brand name prescription drugs was competitive, competition should drive prices to the same level for all sales. His argument went like this: If a drug such as Lipitor sells at a high price to one customer, and a low price to another customer, arbitrage should eliminate (or narrow) the price differential unless there is collusion somewhere in the distribution chain. Because wholesalers did not abandon the low price managed care business to exploit opportunities in the high price retail business, and because manufacturers did not “go after” the business of the high price retailers by offering discounts that would eliminate the differential, he inferred that a cartel existed to maintain this profitable price discrimination scheme.

Upon cross-examination, the plaintiffs’ economic expert admitted that, even without a cartel, different demand elasticities in different distribution channels could account for the observed price discrimination. He conceded that he had not studied whether pharmaceutical manufacturers faced different demand elasticities for brand name prescription drugs in different distribution channels.

The expert was unable to show to the court’s satisfaction that retail pharmacies had the power to “move market share” the way that hospitals, nursing homes, and mail order pharmacies could. Upon cross-examination he was unable to back up his claim that retail pharmacies had even attempted to gain discounts based on their ability to deliver groups of customers to particular manufacturers.

Defendants’ Motion for a Directed Verdict against Plaintiffs

In their mid-trial motions for a directed verdict against the plaintiffs, the defendants maintained that the Class had failed to prove a conspiracy to refuse discounts to retail pharmacies and, further, that discounts actually arose out of unilateral, profit-seeking behavior by the defendant manufacturers. The defendants argued that their pricing decisions to give discounts to hospitals
and managed care organizations that influence the prescribing decisions of physicians were made independently. Likewise, the companies’ refusals to extend discounts on single-source prescription drugs (e.g., those sold under the protection of a patent) to retail drug stores that lack effective intervention services were made independently. This explanation for discounts is supported by the manufacturers’ practice of giving discounts to retail pharmacies to fill prescriptions for multisource drugs (e.g., those whose patents had expired)17 where the pharmacy does have some ability to “move market share.”18

Notwithstanding their independence, manufacturers acknowledged that their decisions concerning discounts were not made in a vacuum. The companies’ chargeback and rebate contracts began as defensive measures to recover from or prevent lost sales in the burgeoning managed care sector as large hospitals and managed care organizations became more aggressive intervention agents. In effect, each manufacturer’s discounts to managed care organizations were that company’s unilateral response to the fact that it sells prescription drugs to customers with different elasticities of demand. The differing elasticities were created by the intervention capability of managed care organizations. By introducing price competition at the pre-prescription stage, managed care organizations elasticized prescription drug demands in the managed care sector. A 5 percent price reduction in this sector would increase unit sales of a manufacturer’s product by a greater percentage than in the cash-pay (pharmacy) sector because managed care organizations can move large groups of patients from one drug to another so long as they have similar therapeutic effects. In response to the argument put forward by the plaintiffs’ economic expert that price differences for brand name prescription drugs would be arbitrated were it not for collusion by manufacturers, the defendants attributed the absence of arbitration to the separation created by managed care organizations.

The plaintiffs’ failure to prove a conspiracy, combined with the defendants’ economic justification for the contested discounts, persuaded the court to grant the defendants’ motion for a directed verdict. “Based on the evidence presented at trial, and viewing the evidence in the light most favorable to the Class Plaintiffs,” the judge ruled that “no reasonable jury could reach a verdict in favor of the Class Plaintiffs” and entered judgment in favor of the defendants.19

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17For instance, SmithKline Beecham had contracts with some retail pharmacies that gave rebates on the sale of Amoxil, the company’s once-patented brand of the multisource antibiotic amoxicillin.

18Ironically, managed care entities also drive down the fees that retail pharmacies charge for dispensing drugs to patients under the control of HMOs. The dispensing fee for a prescription filled by a neighborhood pharmacist for a managed care customer is about 31 percent less than for a cash customer purchasing the same drug.

19In re Brand Name Prescription Drugs Antitrust Litigation, 1999 WL 33889 (N.D. Ill.), p. 17.
The Court of Appeals

The plaintiffs appealed this ruling to the U.S. Court of Appeals for the Seventh Circuit. In July 1999 the court of appeals upheld the directed verdict on the collusion allegations, but with one exception. The circuit court expressed concern that there could have been an agreement among the defendant drug manufacturers (but not the defendant wholesalers) to increase their prices in line with the Consumer Price Index (CPI). If a group of manufacturers, at one point, agreed to increase their prices in lockstep with the CPI, this arrangement could eliminate the need to have meetings about the timing and magnitude of future price increases. But limiting drug price increases to increases in the CPI was considered by drug manufacturers as a means of warding off more direct government price controls. The judge held that such discussions among defendants were not a violation of the antitrust laws; corporations, like private citizens, have a right to petition their government and seek to avoid adverse regulations; and they have a right to do so collectively. Subsequently, on February 9, 2000, the trial judge dismissed the “CPI conspiracy” element of the case.

PRICE DISCRIMINATION AND PRESCRIPTION DRUGS: THE ROBINSON-PATMAN ISSUE

In a conventional Robinson-Patman Act case, a group of buyers of some input or product are in head-to-head competition but some of them allegedly are disadvantaged because they pay a higher price for the input or product than their rivals pay. The plaintiffs in BNPDAL claimed that this was their situation. The defendants responded that conventional Robinson-Patman analysis does not apply in BNPDAL because the favored customers are not in head-to-head competition with retail pharmacies. Retail pharmacies in fact are not generally in competition with hospitals for access to a hospital’s in-patient customer base; in like fashion, they generally do not compete with managed care entities in the provision of intervention services to steer prescriptions for large patient groups. As discussed earlier, the defendants reasoned that retail pharmacies are dispensing agents rather than intervention agents.

Functional Discounts

In some markets, simply buying in large volume results in a customer receiving a “quantity discount.” The pricing practice at issue in this case, however, differs from a quantity or volume discount. Prescription drug dis-

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20 In re Brand Name Prescription Drugs Antitrust Litigation, 186 F.3d 781, 787 (CA 7, 1999). If tying prices to the CPI was a political strategy on the part of drug companies to ward off government price controls, a “CPI conspiracy” might have resulted in lower prices.
counts are paid for intervening on a large scale in the prescribing process, not for dispensing large quantities of prescription drugs.\textsuperscript{21} For example, the American Association of Retired Persons (AARP) operates one of the nation’s largest mail-order pharmacies. But during the relevant period, the AARP did not generally receive rebates or chargebacks from pharmaceutical manufacturers because it did not have a formulary, and it does not control prescribing patterns for its member-customers.

If volume discounts \textit{were} granted to a large drug store chain, this would not increase total sales of any particular drug. This is because retailers, even large chains, do not actively manage their prescription customer base; they do not have formulary control, and they have not made the extensive investment in information technology that is necessary to intervene effectively on a large scale. With a discount, the favored retail pharmacy might expand its own sales of a particular drug (at the expense of sales of the same drug at other pharmacies); but without inducing additional prescriptions this would not increase the manufacturer’s overall sales.

In BNPDAL, the manufacturers maintained that from an economic perspective, chargebacks and rebates are not “discounts” from wholesale prices given to dispensing firms, such as the plaintiffs, but payments to firms who intervene to affect prescribing patterns. The overarching goal for the manufacturer is that the payment would increase the probability that its drugs will be chosen over generic or name brand therapeutic substitutes. In antitrust parlance, the defendants claimed that these payments properly should be viewed as \textit{functional discounts}: payments for a marketing function that pharmaceutical companies would find costly to perform themselves.\textsuperscript{22}

In support of the functional discount interpretation, manufacturers pointed out that rebates and chargebacks were arrived at on a contract-by-contract basis, after weighing the expected cost of the discounts against the expected gain from the customer’s proposed intervention services. On the basis of these calculations, a customer would be offered one discount for listing a manufacturer’s brand name prescription drugs on a formulary, a larger discount for giving that drug preferred status on a formulary, and an even larger discount for an explicit market share achievement on behalf of that drug.

For example, one defendant’s contract provided discounts on one of its drugs for formulary access and for market share performance at a nursing home. The contract provided “a 4% rebate on all [usage if the drug] is made

\textsuperscript{21}“Price discounts depend more on the ability to substitute among alternative suppliers than on sheer buyer size” (Ellison and Snyder 2001).

\textsuperscript{22}Functional discounts are not unique to the drug industry. For example, in the food industry, a manufacturer might offer a grocery chain a 3 percent functional discount to induce the grocer to build an end-of-the-aisle display of the manufacturer’s product, to be in place for two weeks, at each store location in the chain. From an economic perspective, through the vehicle of the discount, the manufacturer is purchasing marketing services for its brand, trying to swing customers to it and away from competitors.
available, unrestricted, on the . . . formulary” and provided additional rebates based on the “internal market share” achieved by the drug. These additional rebates ranged from 3 percent, for an internal share of 25–30 percent, to a 10 percent rebate for an internal share of 70 percent or more.

The defendant manufacturers claimed that retail pharmacies are offered discounts for products where they are positioned to influence the interbrand choices of consumers. Multisource drugs, as mentioned previously, provide examples. Other examples are over-the-counter medicines and consumer medical products, where pharmaceutical companies recognize that retail pharmacies can “move market share” by influencing interbrand choices of consumers.

Meeting Competition

Under the Robinson-Patman Act, a seller is permitted to charge a lower price to one customer if the lower price is offered to meet the low price of a competitor. In Robinson-Patman Act terms, this is called the “meeting competition” defense to a charge of price discrimination. Individual defendants in BNPDAL argued that this defense should apply to them.

For example, a particular pharmaceutical company would argue that its discounts (whether in the form of rebates or chargebacks) to managed care and hospital customers began as a defensive reaction. The manufacturer might notice that its efforts to influence physicians associated with the managed care entities through office visits were not working; the manufacturer might then learn that its competitors were gaining preferential access on the formularies of these customers by offering price breaks. The firm losing out would offer a discount or rebate in return for the buyer’s favor. As this firm “met” the price of its various competitors, the divergence between list prices that retail pharmacies paid and the discounted price that intervention specialists were offered began to increase. “Meeting competition” became the process by which functional discounts were tendered and grew.

“Meeting competition” is not just a legal concept under the Robinson-Patman Act. Analyzing the “meeting competition” process in the drug industry affords an opportunity to understand both the economic concept of “price” and how competitive market processes operate in many oligopolistic markets.

In economic analysis, the “price” a seller charges includes all the terms of trade associated with the transaction. This means that in order to assess whether a firm “meets” the price of a rival, one cannot simply compare nominal prices; it is not a matter of simple arithmetic observation. Two firms might offer a drug in the same therapeutic category at different nominal prices, and a customer might view the offers as equally attractive. This would be the case if there were an offsetting advantage to the higher price drug in its ease of use, the absence of side effects, its relative lack of drug interactions, its delivery time, or other attributes.
Case 12: The Brand Name Prescription Drugs Antitrust Litigation (1999)

Competition being “met” through price differentials is not unique to the pharmaceutical industry. If the products offered by two rivals in a market are different in quality, then this difference may require that their market prices be different (the lower quality product selling for less) in order for one seller to “meet” the price of the other. If a customer is evaluating an offer from a new supplier, comparing it with the terms offered by its current supplier, the customer may recognize that it will incur switching costs if it changes suppliers. In such a case, a new supplier may not be able to “meet” the price of a rival unless it offers a price sufficiently below the incumbent supplier’s to cover the buyer’s costs of switching vendors. If a manufacturer bundles different products together, where the aggregate price of the bundled assembly is less than the sum of the list prices for the products in the bundle, another drug company that cannot replicate that bundle may have to offer a very attractive price on products that it does sell in order to “meet” the price of the bundle.

This means that the economic focus of “meeting competition” should be on a notion of price that embraces all aspects of the contract, and not just the nominal price of the drug alone. The implication of this for BNPDAL is that “meeting competition” may mean offering a price low enough to get on a formulary. If a pharmaceutical company does not offer a price attractive enough to get on formulary, it may never be a vigorous competitor for the patient base served by that formulary. Such a company obviously has not “met” the competition.23

Economic analysis explains what keeps a firm, in the drug industry or elsewhere, from charging a price substantially below “meeting competition.” In economic theory, firms are profit maximizers. Consequently a seller will not want to exceed by very much the reduction that is required to meet the competition and gain the business. Such a firm would be sacrificing profit unnecessarily. Unless firms in the pharmaceutical industry were adopting a predatory pricing strategy, or behaving irrationally, they would have no unilateral incentive to offer prices more attractive than is necessary to get the business.24

Third Degree Price Discrimination, Prescription Drugs, and Consumer Welfare

Class plaintiffs reason that manufacturers’ refusal to offer discounts on prescription drugs to retail pharmacies is the product of collusion. They claim

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23How do pharmaceutical companies learn about the “prices” they may have to meet? Customers may share this information (though they have an obvious incentive to dissemble); sales representatives may gather intelligence about rivals’ prices; and a firm’s market research may uncover what its competitors are charging.

24The evidence about competition in the pharmaceutical industry does not suggest predatory pricing on the part of the defendants (i.e., charging prices below cost so as to drive rivals from the marketplace); nor is there evidence that the defendants offered low prices to favored buyers because the defendants were irrational or that they were doing so for eleemosynary reasons.
that if drug manufacturers were compelled to extend to retail pharmacies discounts like those offered to hospitals and managed care organizations, prices would fall uniformly to their lowest levels for all the defendants’ customers. Competition among retail pharmacies and other customers, they argue, would enforce uniform low retail prices. Defendants counter this reasoning by claiming that discounts were extended to any and all customers who demonstrated an ability to “move market share” for their brand name prescription drugs.

From an economic perspective, the manufacturers’ pricing practices are best explained by the theory of third degree price discrimination (Scherer 1997). Third degree price discrimination occurs when a firm with market power separates its customers into classes distinguished by demand elasticities and charges different prices to the separate customer groups. These prices vary among groups according to the “inverse elasticity rule,” which holds that customers with low price elasticities of demand are charged high prices and customers with high price elasticities of demand are charged low prices. If the firm can identify such customer classes, and if arbitrage between classes can be prevented, price discrimination is more profitable than charging a uniform price to all.

Viewed through the lens of third degree price discrimination, the contested discounts in BNPDAL are explained by differences in the observed price elasticity of demand for individual companies’ drugs in different channels of distribution in the industry. Retail pharmacies’ demands for specific brand name prescription drugs are less elastic than the demands of hospitals and managed care organizations. This is because retail pharmacies do not maintain formularies and do not intervene on a large scale with physicians to steer prescriptions to particular drugs.

Under the plaintiffs’ theory of the discounts, a ruling that eliminated preferential pricing to favored buyers would cause all prices to fall to the levels paid by the most favored customers. However, under the defendants’ theory, such a ruling would cause prices to seek a higher, uniform level that reflects underlying market power. As one Robinson-Patman scholar put it, “[i]f a seller by law must lower all his prices or none, he will hesitate long to lower any” (Rowe 1951, p. 959). Under the defendants’ hypothesis, the prices retail pharmacies pay would not fall, if uniform pricing were imposed on the industry, but the prices hospitals and managed care organizations pay would rise.

The consequences of the discounts in BNPDAL for aggregate economic welfare obviously would be different under the theories offered by the plaintiffs and the defendants. The plaintiffs contend that uniform pricing would reduce prices and increase aggregate economic welfare. The defendants contend that uniform pricing would raise prices and decrease aggregate economic welfare. Of course, whether aggregate economic welfare increases or decreases when a price discriminating firm is forced to charge uniform prices is not transparent. In some circumstances, economic welfare
may increase. But in other circumstances, it may decrease. Scherer (1997, p. 253) examines this issue in BNPDAL and concludes “that the deadweight losses attributable to discrimination are likely at most to be small.”

One reason why third degree price discrimination in the brand name prescription drug industry may increase aggregate economic welfare vis-à-vis mandatory uniform pricing is found in the Ramsey pricing principle. This principle, which has familiar implications for pricing in regulated industries and for tax policy, holds that in markets where scale economies are so great that marginal cost pricing is neither feasible or desirable, welfare-maximizing prices are not uniform. Instead, welfare-maximizing prices in different segments of the market vary according to the inverse elasticity rule. Danzon (1997) has taken this line of reasoning one step further, arguing that Ramsey pricing, rather than uniform pricing, is the proper benchmark for socially optimal pricing in the pharmaceutical industry because of scale economies lodged in low marginal production costs and high, fixed, research and development costs. Danzon shows that competition among drugs that are therapeutic substitutes drives prices in the direction of Ramsey-optimal prices. That is, the price differentials that arise in the competition among the manufacturers of differentiated but substitutable drugs maximize overall welfare. These prices are better for consumers than uniform prices.

The generally ambiguous effect of third degree price discrimination on aggregate economic welfare in a given market stems from the consequence that the uniform price that would emerge in the absence of price discrimination is lower than the discriminatory price for some buyers and greater than the discriminatory price for others. Whether the welfare gains from lower prices to some buyers exceed or fall short of the welfare losses from higher prices to others varies from case to case. Elsewhere, we have given another reason why price discrimination in the market for prescription drugs would increase aggregate economic welfare vis-à-vis mandatory uniform pricing in the industry (Elzinga and Mills 1997). We argue that in the case of price discrimination in the drug market, the gains exceed the losses because there likely are no losses. That is, price discrimination of the kind that arose in the market for prescription drugs lowered the price to some patients and increased the price to none.

Unlike standard textbook examples of third degree price discrimination, the price discrimination in this litigation was not provoked by a monopolist separating its customers into existing groups with different given demand elasticities. Rather, it was provoked by managed care entities garnering control of the prescription drug benefits of large groups of patients and bargaining for the best deal with the manufacturers of drugs that are therapeutic substitutes. As a result of this intervention, the demands for prescription drugs in the managed care segment of the market were elasticized, resulting in discounts from the manufacturers. Since the demands for prescription drugs outside the managed care segment were not affected by this
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activity, the discounts elicited by managed care did not cause the price of prescription drugs to increase for any patient. Prices fell in one segment of the market but did not rise in another segment. In such a situation, the effect of discriminatory prices on aggregate economic welfare would be positive.

Economists who submitted expert reports for the defendants echoed one theme repeatedly: Using the antitrust laws to enforce uniform pricing would be unfortunate public policy. If uniform prices were required, they contended, this would raise the cost to a manufacturer of offering a discount, since the discount would have to be applied to all buyers. Thus, if uniform prices were required, manufacturers would be discouraged from giving any discounts.25

Status of the Remaining Cases

Several of the Independent Plaintiffs’ cases have been transferred to the U.S. District Court for the Eastern District of New York for trial on the Sherman Act claims. But all of the Robinson-Patman claims remain before the original court. With the failure of the Class to prove that drug manufacturers colluded to deny discounts on brand name prescription drugs to retail pharmacies, the best remaining hope for plaintiffs in BNPDAL is a favorable judgment on the Robinson-Patman claim. As of this writing, some of the defendants have reached settlements with plaintiffs on the price discrimination charge, and the judge has not yet scheduled a trial to resolve the dispute among the remaining litigants.

REFLECTIONS ON BNPDAL

To appreciate the social backdrop of this case, it is helpful to recall the political philosophy of populism in which small business units, be they farmers, independent retailers, or manufacturers, are accorded social precedence over large organizations. BNPDAL appears to pit the independent pharmacist against the giant drug manufacturer.26 At the same time, BNPDAL pits the efficiency philosophy of antitrust enforcement against the populist philosophy. The Robinson-Patman Act in particular reflects the populist philosophy. The act was New Deal Depression-era legislation passed in part to protect the existence of small, independent businesses against the superior buying power of new and larger competitive organizations. If antitrust were

25Mandating uniform pricing is akin to offering all buyers what in international trade is called a “most favored nation” status. Most antitrust economists are opposed to “most favored customer” clauses because they can reduce price competition and therefore harm consumers (see Berndt [1994] and Baker [1996]).

26This appearance is deceiving in that many of the plaintiffs, such as Rite-Aid, Wal-Mart, and CVS, are large corporations in their own right.
decided on the basis of populist sympathies, the “little guy” would always win.

The last quarter-century of antitrust has subordinated those populist sympathies to economic principles that stress consumer welfare and economic efficiency more than protecting small firms. Directing antitrust’s focus to efficient resource allocation rather than the protection of any particular form of business organization is the most important contribution economic analysis brings to antitrust policy.27

The Sherman Act claim of the Class failed at trial for the lack of proof that manufacturers conspired to deny retail pharmacies discounts. The trial judge and the Seventh Circuit Court of Appeals found that the chargebacks and rebates that manufacturers extended to hospitals and managed care organizations, but not to retail drug stores, were arrived at independently and were a competitive response by the manufacturers to changes in the health care sector caused by the growth in managed care. While the Robinson-Patman claim has not yet been tried, the plaintiff’s cannot win the price discrimination dispute unless they can discredit the defendants’ economic justification for discounts in the managed care sector of the prescription drug market, namely that discounts are paid for intervention in the prescription generation process and occur as part of the process of meeting competition.

The paradox of this part of the case is that the retail pharmacists’ problem is not manufacturers’ refusal to discount prescription drugs per se, but their own reluctance or inability to introduce practices that effectively “move market share” of brand name prescription drugs. The response of pharmaceutical manufacturers to the emergence of intervention by managed care entities strongly suggests that if retail pharmacies develop mechanisms for intervention, as distinguished from dispensing prescription drugs, payments for intervention services would be forthcoming.

Evidence of responsiveness to intervention on the part of the manufacturers is provided by recent developments involving the states in their capacities as health care insurers. The Maine legislature passed a law in 2000 that sought to leverage the state’s drug-purchasing power over Medicaid patients to negotiate discounts that would apply to residents who lack private health insurance with prescription drug benefits. The U.S. First Circuit Court of Appeals upheld this law in a decision in 2001 (Connolly 2001).28

As reported in The Wall Street Journal, in May 2001 “Florida lawmakers approved an innovative effort to slow Medicaid spending increases by creating a list of preferred drugs. To get on the list, manufacturers had to offer the state a 10% supplemental rebate on top of a federal rebate, which

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27“...The view that the guiding principle of the antitrust laws should be efficiency, rather than the taking of resources from one group and granting them to another, has gained increasing acceptance among legal and academic scholars” (Carlton and Perloff 2000, p. 604). “The only legitimate goal of American antitrust law is the maximization of consumer welfare” (Bork 1978, p. 51).

averages 15.1%. If a drug isn’t on the list, doctors must get verbal authorization from a phone bank of pharmacists and pharmacy technicians before the prescription can be filled” (Gold 2002, p. A3). The “added inconvenience” of getting authorization is intended to shift prescriptions toward the preferred drugs. Subsequently, the state of Michigan introduced a similar program.

Other states have implemented programs to reduce the cost of prescription drug benefits for state employees and retirees. West Virginia led the way in this effort. The state found in 2001 that the number of patients covered by its health plans was insufficient to win significant rebates from the pharmaceuticals industry, so it approved a plan to form a multistate drug-purchasing pool. Since then, officials from Maryland, Mississippi, Missouri, North Carolina, South Carolina, and Washington have formed a drug-purchasing pool to control the cost of their employees and retirees’ prescription drug benefits. The Wall Street Journal reports that the “states plan to develop a common preferred-drug list for their employee health plans. By using lower co-payments to persuade many plan members to take certain drugs, the states hope to negotiate rebates from makers in return for having their products included” (Gold 2001, p. B6). Subsequently, eight northeastern states met to discuss a similar plan.

CONCLUSION

The cost of health care is one of the nation’s most talked-about social problems. Prescription drugs are only about 8 percent of this cost. Physician services and hospital care involve even larger resource costs. But the nation’s aggregate bill for prescription drugs is not small. In 2001, pharmaceutical expenditures in the United States exceeded $130 billion.

Price competition for pharmaceutical sales became more intense in the 1970s and 1980s because of managed health care organizations that, along with hospitals and nursing homes, began to direct groups of patients to particular firms to secure lower prices. Hospitals and nursing homes also found that they could gain more attractive prices through the strategic use of their formularies and prescribing patterns for patients under their care. The resulting price competition was positive for consumers of (and payers for) prescription drugs in the managed care sector.

Retail pharmacies, which merely dispense the product but do not prescribe or control its use, were unable to leverage this competition to their

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29Pharmaceutical Research and Manufacturers of America v. Rhonda M. Medows, 184 F. Supp. 2d 1186, 2001. The Pharmaceutical Research and Manufacturers of America, a trade group representing the manufacturers of brand name prescription drugs, brought a lawsuit in federal district court in Tallahassee that challenged the law. In January 2002, a federal judge let the law stand.

advantage. The result is the antitrust lawsuit described in this article. If the plaintiffs were to prevail in BNPDAL, pharmaceutical companies might be required to offer the same contract terms to all buyers. This could make pharmaceutical manufacturers reluctant to extend discounts to any of their customers, and could discourage further experimentation in pricing and marketing strategies by the defendants. At a time when these pricing strategies serve to hem in the costs of health care, an outcome that discourages discounting is not likely to benefit consumers.

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