THE NEGLECTED CONCERN OF FIRM SIZE IN PHARMACEUTICAL MERGERS

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Pharmaceutical markets are complex. Multiple agents, including doctors, insurers, and pharmacies, play critical roles that affect competition between manufacturers and patient choice between drugs. This complexity, however, is neglected in standard merger analysis of pharmaceutical firms. In evaluating proposed "horizontal" mergers, the antitrust agencies have focused almost exclusively on whether the merging firms have potentially competing or overlapping products in specific drug markets. If they do, the remedy sought in nearly every case is divesture of the overlapping products.[1]

This approach is consistent with the Horizontal Merger Guidelines,[2] which the federal antitrust agencies have followed, and which the courts have accepted.[3] These Guidelines focus on ensuring that the combined entity does not have increased market power in specific drug markets, which includes ensuring that the buyer of any divested products can compete with the merged entity.[4] The traditional approach is also consistent with the Hart-Scott-Rodino

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[1] *See, e.g.*, FED. TRADE COMM'N, NEGOTIATING MERGER REMEDIES: STATEMENT OF THE BUREAU OF COMPETITION OF THE FEDERAL TRADE COMMISSION 4 (2012), www.ftc.gov/system/files/attachments/negotiating-merger-remedies/merger-remediesstmt.pdf ("Anticompetitive horizontal mergers are most often remedied by a divestiture.").

[2] U.S. Dep't of Justice & Fed. Trade Comm'n, Horizontal Merger Guidelines § 4 (2010), ftc.gov/os/2010/08/100819hmg.pdf ("In any merger enforcement action, the Agencies will normally identify one or more relevant markets in which the merger may substantially lessen competition.").

[3] *See, e.g.*, Hillary Greene, *Guideline Institutionalization: The Role of Merger Guidelines in Antitrust Discourse*, 48 WM. & MARY L. REV. 771 (2006).

[4] *See Frequently Asked Questions About Merger Consent Order Provisions*, FED. TRADE COMM'N, www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/merger-faq (explaining divestiture packages, buyers, and goal "to preserve fully the existing competition in the relevant market").

Antitrust Improvements Act, which, in providing the agencies with the ability to review transactions before completion, "create[s] a natural opportunity for negotiation as the government identifies possible problems and brings them to the attention of the merging parties."[5] A market-by-market analysis can be viewed as reflecting the burden on the agencies to show a "likely effect" of "substantially . . . lessen[ing] competition"[6] in a setting in which courts tend to be guided by precedent and may be skeptical of novel theories of harm.[7] In many cases, this approach adequately addresses competitive concerns.

There is growing unease, however, with analysis of pharmaceutical mergers that focuses solely on overlapping products in individual markets. For example, then-Commissioner Rohit Chopra dissented from the majority's analysis in AbbVie's acquisition of Allergan, lamenting that "[t]he FTC's strategy of focusing on whether pharmaceutical companies have any overlaps in their drug product lineup is narrow, flawed, and ineffective" because it "fails to account for how executives make decisions about their drug product portfolios, how larger portfolios can suppress new entry, and how companies use portfolios to increase bargaining leverage across the supply chain."[8] Similarly, Commissioner Rebecca Kelly Slaughter dissented from the majority's disposition of Bristol-Myers Squibb's (BMS) acquisition of Celgene, "support[ing] the Commission's effort to remedy [the] drug-level overlap" but "remain[ing] concerned that this analytical approach is too narrow" and that "the Commission should more broadly consider whether any pharmaceutical merger is likely to exacerbate anticompetitive conduct by the merged firm or to hinder innovation."[9]

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[5] ANDREW I. GAVIL ET AL., ANTITRUST LAW IN PERSPECTIVE: CASES, CONCEPTS AND PROBLEMS IN COMPETITION POLICY 867 (3d ed. 2017).

[6] Statement of Chairman Joseph J. Simons, Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson Concerning the Proposed Acquisition of Allergan plc by AbbVie Inc. 1 (May 5, 2020), www.ftc.gov/system/files/documents/public_statements/1574619/abbvie-allergan_majority_statement_5-5-20.pdf. *See* FTC v. Procter & Gamble Co., 386 U.S. 568, 577 (1967) ("The core question is whether a merger may substantially lessen competition, and necessarily requires a prediction of the merger's impact on competition, present and future.").

[7] *See* Jonathan B. Baker & Carl Shapiro, *Detecting and Reversing the Decline in Horizontal Merger Enforcement*, ANTITRUST, Summer 2008, at 29, 32 (criticizing *United States v. Oracle Corp.*, 331 F. Supp. 2d 1098 (N.D. Cal. 2004), for "clear error in economic reasoning" in applying unilateral-effects theory by requiring plaintiff to "prove a relevant market in which the merging parties would have essentially a monopoly or dominant position").

[8] Dissenting Statement of Commissioner Rohit Chopra at 3, AbbVie, Inc./Allergan plc, FTC File No. 191-0169 (May 5, 2020).

[9] Dissenting Statement of Commissioner Rebecca Kelly Slaughter at 1, Bristol-Myers Squibb and Celgene, FTC File No. 191-0061 (Nov. 15, 2019). *But see* Statement of Commissioner Noah Joshua Phillips at 2, Bristol-Myers Squibb and Celgene, FTC File No. 191-0061 (Nov. 15, 2019) ("First, to block a merger outright, U.S. antitrust enforcement agencies must convince a judge that it violates the law. . . . Second, we need to articulate a viable theory of harm to competition posed by the merger and produce evidence to support that theory.").

A recent comprehensive report by the American Antitrust Institute (AAI) found that between 1994 and 2020, the Federal Trade Commission "challenged 67 pharmaceutical mergers worth over $900 billion, moved to block only one, and settled virtually all of the remainder subject to divestitures."[10] As the AAI report explained, the result of this narrow focus on drug-specific markets has been "the swapping of assets within a relatively small group of large and increasingly powerful firms."[11] After examining all 67 pharmaceutical mergers the FTC challenged between 1994 and 2020, AAI concluded that the largest companies "have grown through hundreds of mergers and acquisitions."[12]

This article examines potential inadequacies of the traditional analysis for mergers of originator pharmaceutical firms by evaluating the potential firm-wide effects of mergers, particularly those involving large firms. By focusing on individual product markets in isolation, the traditional analysis neglects the advantages of overall firm size and the potential for spillover or cross-market effects across product markets. Size, measured by a firm's number of products and overall sales value, conveys significant advantages in negotiations, marketing, and financing that a large firm can exploit to impede entry and thwart competition in multiple drug markets. Mergers and acquisitions (collectively "mergers") involving large firms exacerbate these size advantages.[13] These cross-market effects, however, are not considered in the standard antitrust analysis that focuses more narrowly on increased concentration in individual drug markets to determine whether—as the Clayton Act provides—the merger threatens to "substantially lessen competition."[14]

In this article, we first document the stability of leading firms in the pharmaceutical industry and contend that mergers, not innovation, have enabled these firms to maintain their dominance. We then identify three contexts of

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[10] DIANA L. MOSS, AMERICAN ANTITRUST INSTITUTE, FROM COMPETITION TO CONSPIRACY: ASSESSING THE FEDERAL TRADE COMMISSION'S MERGER POLICY IN THE PHARMACEUTICAL SECTOR 10 (Sept. 3, 2020) [hereinafter AAI REPORT], www.antitrustinstitute.org/wp-content/uploads/2020/09/AAI_PharmaReport2020_9-11-20.pdf; *see id.* at 2–4 (pointing to the FTC's merger policy as a "major root" of the problems of industry consolidation and "high drug prices" and citing examples from the generic drug industry). The AAI Report does not distinguish between originator and generic drugs. Our focus in this article is on mergers of originator drug firms. The differences between originator and generic pharmaceutical mergers are discussed in Patricia M. Danzon, *Firm Size and Pharmaceutical Mergers: A Cross-National, Cross-Sector Perspective*, CONCURRENCES, Sept. 2021, www.concurrences.com/en/review/issues/no-3-2021/law-economics/firm-size-and-pharmaceutical-mergers-a-cross-national-cross-sector-perspective-en.

[11] AAI REPORT, *supra* note 10, at 3.

[12] *Id.* at 11. For example, during that period, Johnson & Johnson and Roche each made more than 40 acquisitions while Pfizer made more than 30. *Id.*

[13] Our observations on size apply equally to mergers and acquisitions.

[14] 15 U.S.C. § 14.

originator prescription drug markets in the United States in which advantages related to overall firm size can lead to potentially anticompetitive cross-market effects, including exclusion of competitor products, that are ignored by the traditional market-by-market merger analysis. First, insurance and reimbursement create size-related advantages in negotiations for preferred formulary placement. This leverage can be used to disadvantage or exclude competitor products, which limits consumers' access to potentially better or cheaper products and harms competition from rival firms, including biosimilar alternatives to blockbuster biologics. Second, size conveys benefits in marketing to physicians and in contracting for physician-administered drugs, which may also disadvantage or exclude products from smaller firms and may harm consumers. Third, size-related advantages in retained earnings provide a relatively low-cost source of financing for marketing and acquisitions that may enable the largest firms to maintain their dominance. In all three contexts, any real efficiency savings are unlikely to be passed on to consumers through lower prices because insurance and imperfect information undermine consumer price sensitivity and competition on price.[15] In this context, mergers between large firms are likely to increase their leverage and market power and harm consumers.

After explaining the advantages possessed by large firms, we outline a framework for applying these size considerations to the antitrust analysis of pharmaceutical mergers. When two large firms (for example, firms in the top ten firms ranked by national or global pharmaceutical sales) merge, the already significant size-related advantages each firm has are compounded in a manner likely to harm competition across many drug markets in the combined firm's portfolio (not just markets with overlapping products).[16] Disadvantaging competitor products harms consumers and rival firms, may reduce incentives to innovate, and entrenches the enlarged firm's dominance. Harm from mergers of large firms is particularly likely when the merging firms bring one or more "must-have" products (that payers cannot exclude from their formularies) or blockbusters (drugs with very high sales and potential rebate volume), since such products can be leveraged in cross-market contracting to favor the firm's other products and disadvantage or exclude competitors.

As a result of these size-related advantages and their potential for competitive harm, we suggest a presumption that a merger between two large pharma-

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[15] Further research is needed to quantify these cross-market effects in pharmaceuticals, but is impeded by data confidentiality. For evidence of alleged cross-market effects, see *infra* note 44 and accompanying text.

[16] The United States accounts for 46% of global pharmaceutical sales. *Market Share of Top 10 National Pharmaceutical Markets Worldwide in 2020*, STATISTA, www.statista.com/statistics/245473/market-share-of-the-leading-10-global-pharmaceutical-markets/. Firm rankings by global and U.S. sales are similar.

ceutical firms substantially lessens competition, thereby shifting to the firms the burden of showing that expected efficiencies outweigh potential competitive harms. Because competitive advantages are likely to increase as the firms' size grows, mergers involving mid-size pharmaceutical firms (e.g., roughly the second decile of firms ranked by national or global pharmaceutical sales) are less likely to harm competition, with the extent of harm depending on the size of the merged entity and whether the merger involves dominant products that could be leveraged for cross-market exclusionary strategies. We therefore recommend heightened scrutiny of mergers involving mid-size pharmaceutical firms, especially where one of the merging firms has a dominant product. We recommend the continuation of the current approach for mergers involving relatively small pharmaceutical firms.

Our analysis applies primarily to the originator pharmaceutical industry. But similar concerns about cross-market effects may apply to mergers in other industries in which large firms span multiple markets. Gregory Vistnes and Iannis Sarafidis[17] and Leemore Dafny et al.[18] have shown that even if there is no increase in concentration in separate product markets, mergers of hospitals in different geographic or diagnostic markets can increase the merged hospitals' leverage in bargaining with insurers and lead to higher prices. Such cross-market effects are expected when the two merging firms contract with an intermediary (such as an insurance company) that serves customers with demand for both hospitals, for example, employers with employees in both areas. In such contexts, failure to reach a bargaining agreement with the merged hospital system may increase the loss incurred by the insurer, relative to bargaining with each hospital separately, which enables the merged hospital system to extract higher prices in a simple Nash bargaining context.[19] Dafny et al.'s empirical analysis confirms that hospitals involved in mergers in unrelated markets raised prices more than similar hospitals not involved in mergers.[20] Similarly, mergers of two hospitals in distinct therapeutic niches,

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[17] Gregory S. Vistnes & Yianis Sarafidis, *Cross-Market Hospital Mergers: A Holistic Approach*, 79 ANTITRUST L.J. 253 (2013).

[18] *See* Leemore Dafny, Kate Ho & Robin S. Lee, *The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry*, 50 RAND J. ECON. 286, 286–87 (2019) and references cited therein; *see also* Case COMP/M.2220—General Electric/Honeywell, Comm'n Decision, ¶ 353 (July 3, 2001), ec.europa.eu/competition/mergers/cases/decisions/m2220_en.pdf (noting ability of GE and Honeywell to "cross-subsidise discounts across . . . products composing the packaged deal").

[19] "Nash bargaining" describes a simple bargaining situation in which two rational, self-interested actors decide how to share a surplus that they can generate.

[20] Similar price effects are explained by a different mechanism and using different empirical measures in Matthew S. Lewis & Kevin E. Pflum, *Diagnosing Hospital System Bargaining Power in Managed Care Networks*, 7 AM. ECON. J.: ECON. POL'Y 243 (2015); Matthew S. Lewis & Kevin E. Pflum, *Hospital Systems and Bargaining Power: Evidence from Out-of-Market Acquisitions*, 48 RAND J. ECON. 579 (2017). For a review of the different mechanisms by which cross-market hospital mergers may raise prices in apparently separate markets, see Keith Brand

for example, pediatrics and geriatrics, may increase the hospitals' market power in bargaining with insurers because loss of the combined system would reduce the insurers' appeal to employers and/or families who anticipate needing either service.

Our analysis breaks new ground in considering cross-market concerns in the context of branded pharmaceuticals, where large firms' product portfolios span multiple therapeutic markets that increase their bargaining leverage in negotiations with pharmacy benefit managers (PBMs). As in the hospital context, consumer price-sensitivity is blunted by extensive insurance coverage. But pharmaceutical markets create different opportunities for firms and raise different issues in analysis due to the role of PBMs as intermediaries between insurers/payers[21] and firms; physicians as customers for firms and agents for patients and payers; and patients and payers, who know less about the range of drugs potentially available than they do about which hospitals are conveniently located within their market area. These factors, along with confidentiality of firm-PBM contracts and rebates, make it hard for patients, payers, and antitrust authorities to observe net prices and to determine whether observed product exclusions reflect a reasonable and procompetitive restriction on choice in return for lower net prices or an anticompetitive restriction on patient access resulting from firm abuse of market power.

Granted, some of the potential harms we discuss can in theory be addressed directly through enforcement actions outside the merger setting. As discussed below, plaintiffs have filed lawsuits challenging exclusionary contracts as monopolization.[22] The confidentiality of pharmaceutical contracts and rebates, however, is a significant barrier to potential plaintiffs bringing such suits, as the factual data needed to support a case can only be obtained through discovery. The agencies should therefore also consider the risk of anticompetitive, cross-market effects as part of their analysis of mergers, in particular, those involving large firms. Such analysis would limit the harm of cross-market mergers and reduce the need for costly litigation that takes years to resolve and that comes after a company's increased size has exacerbated the problem.

I. PERSISTENCE OF LARGE FIRMS: ACQUISITIONS VERSUS RESEARCH AND DEVELOPMENT

Research and development (R&D) of new products is critical to the pharmaceutical industry, as firms develop new drugs to replace older drugs facing

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& Ted Rosenbaum, *A Review of the Economic Literature on Cross-Market Health Care Mergers*, 82 ANTITRUST L.J. 533 (2019).

[21] We use "payer" to refer to both insurers and self-insured employers who contract directly with PBMs.

[22] *See infra* notes 76–77 and accompanying text.

patent loss or product obsolescence. If market leadership in the industry only reflected each firm's relative success in R&D of new products, we would expect to see turnover of leading firms in the industry as R&D success has shifted over time towards smaller firms. Contrary to this expectation, in fact, the pharmaceutical industry is characterized by the persistent dominance of the same large firms over time. The top 20 pharmaceutical firms in 2019, by global pharmaceutical sales, are remarkably similar to the top 20 in 2009, with modest shifts in ranking driven more by acquisition of other firms with innovative product portfolios or blockbuster products than by discoveries of their own R&D departments. Of the 20 top firms in 2009, three firms in the top decile (Pfizer, Merck, and Roche) each acquired one firm in the second decile (Wyeth, Schering, and Genentech, respectively) and another second-decile firm (Astellas) exited the group. This made space for four new entrants to the 2019 top 20 firms, and two of these (Allergan and Celgene) have already been acquired by larger firms (AbbVie and Bristol Myers Squibb (BMS)).

The top firms in 2009 already owed their persistent industry dominance to M&A, as has been noted by previous authors.[23] For example, Pfizer acquired Warner-Lambert to obtain its blockbuster statin, atorvastatin (Lipitor), and then, when the Lipitor patent approached expiration, acquired Wyeth in 2009 to obtain its pneumococcal conjugate vaccine (Prevnar) and other biologics. Other recent mergers include Merck with Schering-Plough (Schering's five lead products disappointed but pembrolizumab (Keytruda) became an unexpected blockbuster); BMS with Celgene (both built on prior acquisitions, especially in cancer drugs); and AbbVie with Allergan. AbbVie obtained its lead product, adalimumab (Humira), through the acquisition of Knoll Pharmaceuticals) but faced with approaching patent expiration, AbbVie acquired Allergan, whose own lead product Botox (obtained from an ophthalmologist) was also facing increased competition.

In contrast to this success in M&A, the in-house innovation of these large firms has played a modest and declining role in their continued success. Large firms' share of the New Active Substances (NAS) submitted each year to the U.S. Food and Drug Administration (FDA) declined from 30 percent in 2009 to roughly 20 percent in 2018. In contrast, the share of NAS originated by

[23] The 12 leading pharmaceutical firms, ranked by worldwide sales in 2010, were influenced by 19 significant mergers and acquisitions from 1989 to 2011, not including smaller consolidations. William S. Comanor & F.M. Scherer, *Mergers and Innovation in the Pharmaceutical Industry*, 32 J. HEALTH ECON. 106, 107 (2013).

TABLE 1:
TOP 20 BIOPHARMACEUTICAL COMPANIES, BY GLOBAL PHARMACEUTICAL SALES, 2009 AND 2019

Company	2009 Rank[i]	Company	2019 Rank[ii]
Pfizer	1	Pfizer	1
Sanofi-Aventis	2	Roche	2
GlaxoSmithKline	3	Novartis	3
Novartis	4	Johnson & Johnson	4
AstraZeneca	5	Merck & Co.	5
Merck	6	Sanofi	6
Johnson & Johnson	7	Abbott Labs/AbbVie	7
Roche	8	GlaxoSmithKline	8
Eli Lilly	9	Takeda	9
Bristol Myers Squibb	10	Bristol Myers Squibb	10
Wyeth[a]	11	AstraZeneca	11
Schering-Plough[b]	12	Amgen	12
Abbott Labs	13	Gilead	13
Amgen	14	Eli Lilly	14
Takeda	15	Bayer	15
Bayer	16	Novo Nordisk	16
Boehringer-Ingelheim	17	Allergan[d]	17
Genentech[c]	18	Boehringer-Ingelheim	18
Astellas	19	Celgene[e]	19
Novo Nordisk	20	Biogen	20

[i] Sources: *2009 Top 20 Pharmaceutical Companies Report*, CONTRACT PHARMA, www.contractpharma.com/issues/2009-07/view_features/2009-top-20-pharmaceutical-companies-report/; *2009 Top 10 Biopharmaceutical Companies Report*, CONTRACT PHARMA, www.contractpharma.com/issues/2009-07/view_features/2009-top-10-biopharmaceutical-companies-report/?widget=listSection. Based on 2008 pharma revenues.

[ii] Sources: *The 2020 Top 25 Pharma and Biopharma Companies*, CONTRACT PHARMA, www.contractpharma.com/issues/2020-07-01/view_top-companies-report/top-25-pharma-and-biopharma-companies-751659/. Data from EvaluatePharma, June 2020. We omit Teva (ranked 17 in both years) because generics account for a large share of its sales.

[a] Wyeth was acquired by Pfizer.

[b] Schering-Plough was acquired by Merck.

[c] Genentech was acquired by Roche.

[d] Allergan was acquired by AbbVie in 2020.

[e] Celgene was acquired by BMS in 2020.

very small "emerging" firms has increased to roughly 70 percent.[24] Many of these very small firms are formed around promising research compounds, often spun out from academic laboratories funded by the National Institutes of Health (NIH). Similarly, in its comprehensive report, AAI found that the industry's "pattern of consolidation" in the past 30 years "reveals the extent to which many pharmaceutical companies have expanded through M&A, as opposed to through organic growth and innovation."[25]

This disconnect between small-firm dominance in innovating new compounds and a stable pack of large firms dominating product sales is reconciled by the extensive, industry-wide pattern of acquisition, as mid-size firms acquire smaller firms and large firms acquire small, mid-size, and large firms. This chain of acquisition serves large firms' need for products and small firms' need for financing and expertise. Although small firms discover and do early development on most new drugs, they typically face higher costs in acquiring the financing and expertise needed to develop their drugs through large clinical trials and regulatory approval and then market and sell the drugs nationally and globally. The R&D cost of bringing a new drug through regulatory approval at the FDA has been estimated to range between $790 million[26] and $2.7 billion.[27] Small firms typically obtain initial funding from venture capital and other sources of private and public equity. But for funding costly late-stage clinical trials and undertaking sales and marketing, many small firms either out-license their drugs or accept acquisition by larger companies that need new drugs as patents expire on their older drugs and their in-house R&D fails to replenish their product pipelines. Early-stage investors in small firms welcome such acquisition as a financial exit that enables them to recoup a return on their investment.

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[24] New Active Substances (NAS) is a measure of innovative, novel compounds, in contrast to new formulations and new indications that simply extend uses for older compounds. Data from IQVIA INST., THE GLOBAL USE OF MEDICINE IN 2019 AND OUTLOOK TO 2023 (2019). Companies are assigned to segments based on 2018 revenues or 2017 R&D spending (because the smallest firms have no sales revenues). Segments are defined as: Large > $10 billion; Mid $5–10 billion; Small $500 million–$5 billion; Emerging < $500 million or R&D Spending < $200 million. If multiple companies of different sizes are involved in a project, it is assigned to the larger segment.

[25] AAI REPORT, *supra* note 10, at 12.

[26] Vinay Prasad & Sham Mailankody, *Research and Development Spending to Bring a Single Cancer Drug to Market and Revenues after Approval,* 177 JAMA INTERNAL MED. 1569, 1572 (2017). This median estimate appropriately includes the cost of failures and cost of capital prior to launch; however, it is unrepresentative because it is based solely on very small firms.

[27] Joseph A. DiMasi, Henry G. Grabowski & Ronald W. Hansen, *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20, 27 (2016). This mean estimate appropriately includes the cost of failures and cost of capital prior to launch; however, it is unrepresentative because it is based solely on the largest firms, and it uses proprietary data that cannot be verified.

This pattern of acquisition of innovation-focused small firms by larger firms with expertise in marketing and sales can create real resource savings. And it generally poses no significant antitrust concerns, as we discuss below. In contrast, when mergers occur between larger firms, each of which already has significant sales revenues and marketing expertise, the efficiency gains are lower and the risks of harm to competition are greater, due to the potential increase in size-related bargaining leverage we elaborate below.

Although large pharmaceutical firms often rationalize their mergers by claiming synergies in R&D and marketing,[28] the evidence on the declining R&D productivity of large firms relative to smaller firms, despite the large firms' sequence of mergers, casts doubt on both the claimed scale economies and the effectiveness of merging two large firms in enhancing R&D efficiency.[29] Empirical studies confirm that larger pharmaceutical mergers are often a response to patent expirations on a large firm's major products and gaps in its own pipeline of follow-on products.[30] Such patent expirations generate excess capacity in the firm's administration, sales, and marketing functions and threaten to erode its future revenues and profitability. A large firm facing such patent expirations often acquires another large firm as a means to rapidly replenish its portfolio of marketable products and reduce costs by eliminating overlapping functions and capacity, including some in the target company.[31]

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[28] For example, see *infra* note 79 for AbbVie's rationalization of its acquisition of Allergan.

[29] Comanor and Scherer argue that the pharmaceutical merger waves between 1989 and 2011 may have contributed to the decline in R&D productivity over the same time period, reflected in the declining number of new drug approvals despite rising aggregate R&D spending, as the consolidation of large firms reduced the number of independent pathways seeking to solve major medical problems. Comanor & Scherer, *supra* note 23.

[30] Patricia M. Danzon, Andrew Epstein & Sean Nicholson, *Mergers and Acquisitions in the Pharmaceutical and Biotech Industries*, 28 MANAGERIAL & DECISION ECON. 307 (2007) (confirming that mergers tend to be undertaken by firms that anticipate distress (low expected earnings growth as measured by Tobin's Q)). This implies that measurement of the effects of mergers must adjust for the non-random selection of merging firms. In a study of 202 biotech and pharmaceutical mergers between 1988 and 2001, controlling for merger propensity, Danzon et al. found that firms that merged experienced, in the three years following a merger, a similar change in enterprise value, sales, employees, and R&D as similar firms that did not merge, and slower growth in operating profit. A more limited sample of 160 R&D-related acquisitions by 60 public firms between 1994 and 2001 also found that firms with a high "desperation index" (few years of patent life remaining on marketed drugs or potential pipeline products) were more likely to acquire another firm. Matthew J. Higgins & Daniel Rodriguez, *The Outsourcing of R&D Through Acquisitions in the Pharmaceutical Industry*, 80 J. FIN. ECON. 351, 351 (2006). This study found that pre-merger alliances between the parties were positively correlated with both announcement-period abnormal returns and one-year post-merger pipeline improvement. Higgins and Rodriguez conclude that pre-merger alliances are a means to reduce information asymmetries. *Id.* at 352–53.

[31] *See infra* note 79 for AbbVie's rationalization of its acquisition of Allergan.

The empirical evidence, however, provides no confirmation that such mergers improve the firms' underlying R&D productivity through economies of scale or scope,[32] and much of the cost-cutting in marketing and sales is not merger-specific, in other words, is possible without the merger.[33] There is a possible exception if one firm brings global expertise and marketing reach that the other firm lacks, as the synergies in such a case would be merger-specific. On the other hand, in certain settings, size also brings the potential for increased bargaining leverage that may benefit the merged firm and enhance its market dominance, but to the possible detriment of consumers. Unfortunately, we lack empirical evidence to tease out the extent to which each of these effects—real efficiencies versus increased leverage—contributes to the continued dominance of incumbent large firms. Our objective here is simply to explain how mergers increase the size-related advantages of large pharmaceutical firms—especially in contracting, marketing, and financing—and to point out that the potential harms of size-increasing mergers should be considered alongside any claimed synergies in evaluating such mergers.

The next sections describe how the institutional context of pharmaceutical markets in the United States creates competitive advantages for large firms and reveals potential anticompetitive effects not captured absent the consideration of overall firm size in merger analysis.

II. NEGOTIATING WITH INSURERS FOR REIMBURSEMENT[34]

In standard consumer-product markets, firms set their prices and consumers choose and pay for products based on their preferences, product quality, and price. In contrast, because pharmaceuticals can be risky and costly, consumer access to pharmaceutical products generally requires a physician's prescription, and most of the cost is covered by the patient's insurance, provided that it is on their insurer's formulary (list of covered drugs). Physicians and payers are therefore critical customers of pharmaceutical companies, along with patients. While pharmaceutical firms have focused their marketing on payers and physicians as key customers, antitrust agencies have placed little empha-

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[32] *See supra* note 29.

[33] For example, Merck announced sales force cuts of about 8% in 2017 and 20% in 2013, to cut costs. Peter Loftus, *Merck to Lay Off About 1,800 U.S. Sales Reps in Cost-Cutting Move*, WALL ST. J. (Oct. 20, 2017), www.wsj.com/articles/merck-to-lay-off-about-1-800-u-s-sales-reps-in-cost-cutting-move-1508532828.

[34] For detail on the effects of insurance, reimbursement rules, and PBMs, see Patricia M. Danzon, *Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues*, 36 PHARMACOECONOMICS 1395 (2018) [hereinafter Danzon, *Differential Pricing of Pharmaceuticals*]; Patricia M. Danzon, *Pharmacy Benefit Management: Are Reporting Requirements Pro- or AntiCompetitive?*, 22 INT'L J. ECON. BUS. 245 (2015); Patricia M. Danzon, *Pricing and Reimbursement of Biopharmaceuticals and Medical Devices in the USA*, *in* 3 ENCYCLOPEDIA OF HEALTH ECON. 127 (Anthony J. Culyer ed., 2014).

sis, in the context of horizontal pharmaceutical mergers, on the size-related advantages enjoyed by large pharmaceutical firms in dealing with these customers.[35] This section explains why size is an advantage for drug companies in their contracting with payers for coverage and reimbursement, and the following section describes size-related advantages in marketing to physicians.

Insurance is a "necessary evil" that creates a third-party payer norm in pharmaceutical markets. Patients desire insurance as protection from the high and unpredictable costs of health care. But insurance means that "someone else is paying." This makes patients insensitive to price, which creates incentives for health care producers to raise prices unless insurers adopt constraints through their reimbursement rules.[36] In all high-income countries other than the United States, payers limit the prices they pay for pharmaceuticals, for example, using cost-effectiveness or other measures of a drug's value. In contrast, in the United States, pharmaceutical firms set their list prices freely. Private and public payers (insurers, employers, Medicare, and Medicaid) then use PBMs[37] to negotiate rebates off list prices in return for favorable formulary placement.

In reimbursement negotiations with insurers, a large firm may enjoy size-related advantages. Of course, large firms may have advantages unrelated to mergers. Nevertheless, permitting large mergers that expand the portfolios of already large firms likely exacerbates these risks, including for firms with non-overlapping products. The mechanisms through which size advantage operates depend on the specifics of the payers' reimbursement rules, which differ across dispensing channels and payers in the United States. We focus here on the two main channels, which together account for more than 80 percent of pharmaceutical sales: (1) pharmacy-dispensed drugs (pills, capsules, and liquids) and (2) physician-dispensed drugs (injections and infusions, such as cancer drugs).

A. PHARMACY-DISPENSED DRUGS

For pharmacy-dispensed drugs, PBMs are specialized agents that manage drug benefits for payers. PBMs establish tiered formularies, negotiating re-

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[35] The role of insurers has been recognized in hospital markets, which are modeled as having two tiers. In the first tier, insurers negotiate with hospitals over prices for their services and access to insurer networks; in the second tier, employers/patients choose between insurance plans based on their hospital networks and coverage. *See supra* notes 18 & 20.

[36] Although most insured patients are responsible for co-payments, such cost-sharing is usually modest and capped by an annual "catastrophic" limit on a patient's out-of-pocket expenses.

[37] Medicare Part D uses intermediaries called Prescription Drug Plans (PDPs) that are similar to PBMs but bear some insurance risk. We use "PBMs" to refer to both PDPs and PBMs. As discussed below, Medicaid covers all drugs and obtains statutory discounts rather than negotiated rebates. *See infra* note 56.

bates from drug firms in return for placing their drugs on preferred tiers with lower patient co-payments that steer market share towards these preferred drugs.[38] Non-preferred drugs have significantly higher patient cost-sharing, which deters patient acceptance. This PBM strategy of giving preferred access only to drugs whose manufacturers give rebates can encourage procompetitive rebating without significant harm to patients in classes with several drugs that are close therapeutic substitutes (for example, anti-ulcerants), so that patients/physicians are willing to switch to the preferred drugs in response to lower cost-sharing. Specialty drugs that are more therapeutically differentiated and more expensive[39] are generally placed on separate tiers with high co-insurance (20 to 33 percent of the list price), and PBMs may impose administrative barriers to coverage, such as prior authorization or step edits,[40] which may be linked to rebates.

As agents for insurers and self-insured employers, PBMs typically contract to pass through to these payers most rebates related to formulary structure. However, drug-specific rebates are confidential, and this confidentiality has been deemed necessary to preserve the incentives of drug firms to engage in competitive rebating.[41] But the full pass-through of rebates is unlikely and indeed would undermine the incentives of PBMs to negotiate rebates.

One unfortunate by-product of competition through confidential rebates is that drug firms and PBMs both have incentives to prefer a strategy of high list prices and large rebates, rather than lower list prices and smaller rebates. This

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[38] For example, a formulary with only two drugs per class on the preferred tier will get larger rebates from drug firms than a formulary with five preferred drugs per class, because each of the two preferred drugs on the more restrictive formulary will gain larger market share than each of the five drugs on the less restrictive formulary.

[39] Medicare defines specialty drugs as any drug for which the negotiated price is $670 per month or more. Memorandum from Amy Larrick Chavez-Valdez, Dir., Medicare Drug Benefit & C&D Data Grp. (May 22, 2020), www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2021%20mtm%20and%20specialty%20thresholds%20final%20part%20d%20bidding%2005.22.2020_8.pdf.

[40] Prior authorization means that the physician must obtain the insurer's approval in order for the drug to be reimbursed. Step edits require that a patient fail on a preferred drug before gaining coverage of a less-preferred drug.

[41] George J. Stigler, *A Theory of Oligopoly*, 72 J. POL. ECON. 44 (1964); CONGRESSIONAL BUDGET OFFICE, COST ESTIMATE FOR H.R. 1 MEDICARE PRESCRIPTION DRUG AND MODERNIZATION ACT OF 2003, AS PASSED BY THE HOUSE OF REPRESENTATIVES ON JUNE 27, 2003, AND S. 1 PRESCRIPTION DRUG AND MEDICARE IMPROVEMENT ACT OF 2003, AS PASSED BY THE SENATE ON JUNE 27, 2003, WITH A MODIFICATION REQUESTED BY SENATE CONFEREES 15 (2003); Danzon, *Differential Pricing of Pharmaceuticals*, *supra* note 34. For a discussion of the interchangeability of rebates with other financial benefits provided to PBMs, see Michael A. Carrier, *A Six-Step Solution to the PBM Problem*, HEALTH AFFS. (Aug. 30, 2018), www.healthaffairs.org/do/10.1377/forefront.20180823.383881/full/.

incentive structure contributes to the high and rising list prices for brand-name drugs and the increasingly acrimonious debate over rebates.[42]

A second unfortunate by-product of competition through rebates rather than list prices is that it creates advantages for large firms. Specifically, a drug company with a large portfolio of products, including "must-have" and blockbuster drugs, has more leverage and flexibility in negotiating with PBMs than a company with fewer or smaller products.[43] This size advantage can be used to exploit cross-market effects that are harmful to competition and to consumers but would not be captured by standard merger analysis of product-level overlaps.[44] For example, a large, multiproduct firm with must-have or blockbuster products (that cannot be excluded or that generate significant rebate revenue for a PBM) can leverage the blockbuster through a bundled strategy, tying access and rebates on the blockbuster drug to preferred or even exclusive positioning for its other drugs, which effectively limits or blocks access to rival drugs in these classes for the customers of this PBM, even if the rival drugs have therapeutic advantages or offer a lower list and net price.[45] A merger involving two large firms magnifies these advantages, giving the combined firm greater leverage and broader scope when negotiating with PBMs.

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[42] Note that the argument here, that drug firms have a profit-driven incentive to raise prices in order to give larger rebates to PBMs, is different from the argument often made by the drug industry, that PBMs' demand for rebates forces them to raise prices to cover the cost of the rebates. Also note that in hospital markets, each payer negotiates its prices with hospitals, which bill payers directly at their negotiated prices, so that any agreed discounts are fully passed through to payers.

[43] In a Nash bargaining model, a firm with a large portfolio, including a must-have blockbuster product with high sales and rebate volume, can impose a large loss of rebate revenue if it fails to reach agreement with the PBM, compared to a small firm with a single product with small sales.

[44] As we discuss below, the agencies can challenge horizontal mergers under unilateral effects theories. These theories are usually grounded in market power within specific markets, but they could be extended to address the cross-market or portfolio effects of concern here. *See infra* note 67 and accompanying text.

[45] The pharmaceutical firm may make a large rebate on a high-volume, must-have blockbuster product conditional on each of its products being one of at most two preferred drugs in their classes on the formulary. If the PBM were to add a new drug to any of these classes as a third option, it would forgo large rebate revenue on the blockbuster drug that it could not make up from a low-volume new entrant, especially if the entrant has a lower price and lower rebate. In *Shire US, Inc. v. Allergan, Inc.*, for example, Shire alleged that Allergan made its rebates on its dry eye drug, Restasis, and rebates on its glaucoma eye products conditional on Restasis being the sole preferred drug on formularies of most large Medicare Part D drug plans, which allegedly blocked the adoption by Medicare Part D plans of Shire's superior drug for dry eye, Xiidra. Shire US, Inc. v. Allergan, Inc., 375 F. Supp. 3d 538, 544–45 (D.N.J. 2019). Shire argued that it would be required to offer its drug below average cost to compensate the PBM for its loss of rebate revenue from Allergan, which was conditional on preferred-tier exclusivity for Restasis. This conduct differs from standard predation because the incumbent is not offering its product below cost; rather, it relies on its large volume and product bundling to offer a combined rebate that Shire could not match and cover its average cost. Unlike standard predation, this approach is a sustainable strategy for the incumbent.

In theory, a large pharmaceutical firm could use its bargaining leverage to raise its list prices or reduce its rebates (raising net prices) or improve formulary positioning and exclusivity of its products. In hospital markets, the evidence shows that mergers lead to higher hospital prices. However, in the case of pharmaceutical mergers, several factors make it likely that a merger of two large firms would result in the merged firm using its increased leverage to improve the formulary positioning of its products and exclude competitors, rather than raise either its list prices or reduce its rebates. First, an increase in list price applies nationwide to all customers, whereas leverage may differ across health plans, depending on the demographics and medical needs of their patients. Moreover, raising list price in excess of general inflation may trigger an excess inflation rebate that a firm must pay to Medicaid. Second, if a large firm with a must-have product uses its leverage to raise net prices by reducing the rebates it pays to PBMs, such rebate reduction makes its products less attractive to the PBM.

In contrast, if the firm uses its leverage to require an exclusive contract that obstructs the entry of rival products in one or more classes, this could be win-win for the firm and the PBM, because entry of competitor products would reduce the incumbent's revenue and the PBM's rebate revenue if the new competitor enters at a lower list price and at lower share, such that the rebates it can offer the PBM are less than those that the incumbent can offer. Essentially, competitive entry is a negative-sum outcome for the incumbent firm and for the PBM if class-level demand is price-inelastic and entry reduces average net prices.

The risk that an incumbent firm and a PBM can both benefit from excluding a would-be entrant is particularly great in the category of biologic drugs, which entail complex natural processes and for which the FDA regulates related new entrants (i.e., biosimilars) as close but not perfect substitutes for originator biologics. Specifically, the FDA generally does not authorize pharmacy substitution of biosimilars, as it does for generic small-molecule drugs, and PBMs therefore treat biosimilars as new branded drugs, not as generics. A biologic originator has a strong incentive to use exclusive contracting, including rebates tied to limiting the number of competitors in the class, to bar biosimilar entry that would undercut originator pricing and erode originator share. In contrast, for small-molecule (chemical) drugs, it is generally futile for the originator firm to attempt to block generic entry following patent expiry, because generics are required by regulation to be bioequivalent[46] and are generally substitutable by pharmacies, even if the physician prescribes the originator brand. PBMs generally place generics on their lowest co-payment

[46] Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355).

tier, to encourage patient acceptance of these cheaper products. Moreover, PBMs profit directly from generic substitution of small molecule drugs through their own mail-order pharmacies. Given pharmacy substitution of generics, it would be futile for the producer of the originator chemical drug to attempt to bar generic entry through an exclusive contract with a PBM. In contrast, for a biologic drug, both the originator and the PBM can gain by agreeing to a contract that excludes the biosimilar, as, for example, the plaintiffs alleged in *Pfizer Inc. v. Johnson & Johnson*, discussed below.[47]

In short, although large firms may use their bargaining leverage to either raise list prices, reduce rebates, or exclude competitor products, excluding competitors is likely to be the more profitable strategy, especially for products in classes with inelastic class-level demand or when the large firm has a biologic facing potential biosimilar entry.

Such concerns were raised by a group of unions and consumer and public-interest organizations in objecting to the proposed merger between AbbVie and Allergan.[48] The groups warned that the merger "would enable AbbVie to use exclusionary practices . . . to limit the ability of rivals to expand and enter."[49] In particular, they pointed to "rebate wall[s]," which occur when "a manufacturer leverages its market-dominant position to secure preferred formulary access for its products by offering lucrative incentives to PBMs and health insurers in the form of volume-based rebates."[50] The rebates "are often offered across multiple products, indications, and therapeutic specialties, the breadth of which cannot be matched by new and innovative therapies."[51] The groups worried that

> combining AbbVie's blockbuster drugs with Allergan's is likely to exacerbate . . . anticompetitive conduct, because the merged firm will have an increased ability to bundle rebates across its enlarged drug portfolio in order to keep competing branded drugs, generics, and biosimilars off of PBMs' and insurers' preferred position on their drug formularies.[52]

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[47] 333 F. Supp. 3d 494 (E.D. Pa. 2018). The FTC is investigating this conduct as a civil non-merger matter. *J&J Says FTC Probing Efforts to Protect Arthritis Drug Remicade*, REUTERS (July 29, 2019), www.reuters.com/article/us-johnson-johnson-ftc-antitrust/jj-says-ftc-probing-efforts-to-protect-arthritis-drug-remicade-idUSKCN1UO27Q.

[48] Letter from Families USA et al. to Joseph J. Simons, Chairman, Fed. Trade Comm'n (Sept. 12, 2019), www.fdanews.com/ext/resources/files/2019/09-16-19-LetteronMerger.pdf?1568653634.

[49] *Id.* at 4.

[50] *Id.*

[51] *Id.*

[52] *Id.* at 5.

The FTC settled its investigation into the merger by requiring divestiture of overlapping products.[53] Then-Commissioner Chopra, in contrast, would have gone further. Stating that "[t]he evidence in the investigation suggests that AbbVie currently uses its bargaining leverage from its blockbuster drug Humira to preference its other immunology drugs," Chopra worried that rebating "might act as a barrier to entry and expansion for other drugmakers with less bargaining leverage."[54] Citing cases in which the FTC and Department of Justice have prohibited contracting practices that make entry and expansion difficult for a divestiture buyer, he therefore offered "[o]ne potential way to increase the likelihood" that the divestiture buyer "would fully replace lost competition and bring [the drug] to market[:] . . . to restrict certain contracting practices by the combined AbbVie and Allergan."[55]

One final advantage large firms can exploit comes from Medicaid's "best price" rule, which requires that a drug company give Medicaid the "best price" it offers to private buyers.[56] This benefits large firms, including firms that may gain size-related advantages through mergers, which can allocate their rebates across products to achieve a given overall price concession to the PBM with minimum revenue losses. A smaller firm with only a single drug lacks the flexibility to allocate its rebates strategically across a portfolio of products and thus has less leverage and faces higher overall contracting costs. The large firm's ability to bundle its rebates in order to avoid best-price payments to Medicaid can result in higher prices (lower rebates) for Medicaid and act as a barrier to entry for smaller firms that are at a disadvantage in competitive rebating for formulary placement. Although in theory the enforcement of Medicaid best-price rebates is the responsibility of Medicaid, it is simply not practical for Medicaid to monitor evasions that occur through the bundling of rebates across drugs in complex, multi-product contracts that are confidential. Although the use of bundled rebating to avoid giving Medicaid the best price is not directly an antitrust issue, any size-related advantage for the firm is a loss to taxpayers. Bundled rebating may also result in less competitive drug

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[53] Press Release, Fed. Trade Comm'n, FTC Imposes Conditions on AbbVie Inc.'s Acquisition of Allergan plc (May 5, 2020), www.ftc.gov/news-events/press-releases/2020/05/ftc-imposes-conditions-abbvie-incs-acquisition-allergan-plc.

[54] Dissenting Statement of Commissioner Chopra, *supra* note 8, at 16.

[55] *Id.*

[56] Companies selling branded drugs are required to give Medicaid a discount equal to the greater of 23.1% or the best price given to private buyers. A large firm that wants to give, say, a 30% rebate on drug A to PBM X may avoid having to give the same 30% discount to Medicaid on drug A if the equivalent rebate value is achieved through a bundled rebate contract with PBM X that simultaneously specifies, say, a 20% rebate on several drugs including but not limited to A. This bundled contract could achieve the same overall rebate revenue for the PBM while allowing the drug company to avoid paying a "best price" rebate to Medicaid beyond the required 23.1%. Firms are required to report their rebates to Medicaid, but in this case the 20% rebate on all drugs would appear within allowable limits and not trigger a best-price penalty.

markets, to the extent that smaller firms with better or cheaper products are unable to gain formulary coverage.

In summary, mergers between large firms, including those with no overlapping products, can expand the combined firm's ability to use bundled contracting and rebate strategies as an effective barrier to formulary coverage or preferred placement for competitor drugs in multiple therapeutic categories. By doing so, large firms created through mergers can block new drugs from smaller companies from the preferred tier status that is needed to gain widespread adoption by patients, even if the new drugs are superior, lower-priced, or both. Since the advantages increase with value and number of products in a firm's portfolio, they are magnified when two large firms merge. The risks are even greater when a large firm has one or more must-have or blockbuster products that it can leverage in its contracting for the other drugs in its portfolio, to gain preferred position and exclude competitors. This potential for portfolio contracting that generates cross-market, anticompetitive effects from mergers of large pharmaceutical firms is neglected by traditional, market-specific merger analysis.

B. PHYSICIAN-ADMINISTERED DRUGS

The size-related advantages of large firms in contracting for pharmacy-dispensed drugs have parallels but also differences in contracting for physician-administered drugs, which include injections and many expensive, infused biologics. Although the high and rising prices of these drugs is due more to Medicare's reimbursement rule than to mergers, mergers can lead to size-related advantages that harm consumers, as in the case of pharmacy-dispensed drugs. Physician-dispensed drugs are distributed by specialty pharmacies to the dispensing physicians, who usually practice in multi-specialty clinics or hospital outpatient departments, and who "buy and bill" the insurers directly.[57] "Buy and bill" means that dispensing physicians, rather than PBMs, have a financial stake, because physicians profit (or incur loss) from the difference between the price they pay to acquire the drug and their reimbursement by payers.

Medicare pays dispensing physicians the drug's Average Sales Price (ASP) + 6 percent. This creates incentives for firms to compete by raising—not reducing—their price, because a higher ASP increases the value of the 6 percent margin captured by dispensing physicians.[58] This rule also discourages com-

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[57] These drugs are treated as part of physicians' services and are therefore covered under an insurer's medical benefit, not under the drug benefit, for both private insurance and Medicare.

[58] ASP is the average price at which the manufacturer sells the drug, net of all discounts, with a two-quarter lag. Medicare's 6% markup is intended to cover acquisition/stocking costs. Most private payers follow this reimbursement rule but some add a larger percentage markup.

petitive rebating or discounting, because any rebates or discounts given in the current period reduce the ASP at which all customers are reimbursed in the future.

Although PBMs lack formulary control over these drugs and firms lack incentives for rebating, large firms nevertheless have size-related advantages in contracting with physician customers. A large, multi-product firm may be able to offer a bundled contract, in which it ties a must-have product with its other products, for which potentially superior or cheaper, rival products exist. The large firm may also use a bundled contract to spread a desired rebate over a portfolio of products, to minimize the negative effect of the rebate on its future ASP. In particular, the large firm might be able to do a bundled contract across its physician-administered drugs and its pharmacy-dispensed drugs. Such contracting across physician- and pharmacy-dispensed drugs has become feasible as PBMs have acquired specialty pharmacies and now increasingly play some role in managing both physician-administered and pharmacy-dispensed drugs for Medicare Advantage and many private health plans, and as specialty physicians operate in clinics or hospital settings that also have outpatient pharmacies. Thus, physician-administered drugs provide a different context in which large firms can use bundled contracting across multi-product portfolios to gain favored or expanded use of their products and exclusion of rivals, including in markets without overlapping products. These advantages of overall firm size are neglected in traditional merger analysis.

The contracting effects for physician-dispensed drugs are thus in some respects analogous to the portfolio rebating advantages large firms enjoy in dealing with PBMs for pharmacy-dispensed drugs. Again, the increased leverage of a large firm in these price/access negotiations could be used by the firm to gain higher prices for a given exclusivity level, but is more likely to be used to increase exclusivity for the firm's products or reduce patients' access to competitor products, including new products from smaller companies. The confidentiality of these contracts makes it very difficult for harmed patients or competitors to document and challenge such harms after the event. Expanding the traditional product-by-product merger analysis to consider these potential cross-market harms before they occur therefore seems warranted.

III. MARKETING AND SELLING

In addition to negotiations with insurers for reimbursement, large pharmaceutical firms enjoy advantages from marketing and selling to physicians. Physicians are key customers for pharmaceuticals because they advise patients on drug choice and write the prescriptions that are required to obtain all

prescription drugs.[59] Drug companies therefore invest significant resources in marketing to physicians.

This section discusses two related contexts in which a firm's size, specifically the number and sales value of its overall product portfolio, can convey marketing advantages over smaller firms in marketing to physicians. The potential competitive harms from increasing these size-related effects are neglected by traditional merger analysis.

A. Scale Economies in Detailing to Physicians

The primary marketing tool used by drug companies to persuade physicians to prescribe their drugs is detailing, that is, the practice of sending representatives to physicians' offices to provide information about the drugs and leave free samples for patients. Detailing is expensive. It requires knowledgeable representatives who spend time traveling between offices and awaiting openings on doctors' busy schedules. Relationships between representatives and physicians are crucial and are built through frequency and scope of contact.

In this context, a large, multi-product company that has two or more drugs that can be promoted on the same visit saves time and adds more value for the company and the physician, compared to a smaller company with only one product relevant to a particular physician's specialty. Although the small company can seek some benefits of scale by hiring a contract marketing organization that markets drugs produced by multiple, smaller firms, such a strategy offers each small firm less control over the timing and messaging of detail visits. As a result, contract marketing is considered less effective than an in-house sales force trained and dedicated to a company's products. Gaining access to a large company's sales force and expertise in marketing is a major reason why smaller companies sell the company or out-license their products to larger companies, and we generally support such mergers (see Part V below). While scale advantages in marketing are present in many industries, in the pharmaceutical context they exacerbate the already significant barriers for smaller firms to obtain preferred formulary coverage for reimbursement, as explained above.

B. Scope Economies in Marketing to Multi-Specialty Groups

In recent years, most physicians have organized into large, multi-specialty groups or clinics, often with an onsite lab and pharmacy—for example, multiple primary care or oncology specialties in one location. Marketing to large, multi-specialty groups increases the potential for a large pharmaceutical firm

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[59] PBMs are now also important customers because, as discussed above, insurance coverage is necessary for patients to afford expensive drugs.

to realize economies of scope in marketing its drugs across multiple therapeutic areas. A large firm with a broad portfolio of drugs can offer one-stop-shopping convenience to these multispecialty customers, for example, drugs to treat multiple cancers. This size advantage can create or exacerbate a barrier to entry for a smaller company with only one or two products for one disease, e.g., breast cancer, even if the small company offers lower prices on its few drugs. A merger analysis that focuses solely on whether the merging companies have overlapping products in breast cancer ignores the merged company's enhanced marketing advantage from the number and importance of its products across multiple cancers. Focusing only on breast cancer will underestimate the merger's adverse effects on potential entry for other firms in other disease classes where the merged entities do not have overlapping products but where the merged firm has an increased size advantage due to its overall portfolio breadth and the one-stop-shopping convenience it offers.

Note that these size-related advantages in marketing to multi-specialty groups are separate from (and in addition to) the size-related advantages in contracting for reimbursement in multi-product negotiations for physician-administered drugs, discussed in Part II.B. Marketing and contracting are separate functions in pharmaceutical companies, and their size-related advantages are distinct—standard economies of scope in marketing versus increased bargaining leverage and opportunities for cross-market bundling of rebates and product positioning in contracting. Both effects increase with the firm's portfolio size. These size-related advantages also spill over across product lines, including those for which merging firms may have no overlapping products.

In evaluating the antitrust implications of these size-related economies of scale and scope in marketing, it could be argued that the detailing advantages may entail real resource savings for drug companies and their physician customers that could be considered cognizable efficiency savings from a merger. While acknowledging this potential, we suggest two offsetting factors that warrant consideration.

First, any such efficiencies are unlikely to be passed on to consumers; rather, they are likely to be captured by large drug firms as increased market share and ultimately profits for their products. In normal price-competitive markets, marketing efficiencies might be passed on as firms lower their prices to compete for price-sensitive customers. But as discussed above, patient price-sensitivity in drug markets is very low because insurance covers most of the price, with the patient paying only a relatively modest co-payment that is often independent of the drug price and is capped by "catastrophic" annual limits on a patient's out-of-pocket cost. Moreover, compared to consumers' choosing between most consumer products, patients are relatively uninformed about the relative merits of alternative drugs. Drug choices are therefore heavily influenced by physicians, who are influenced by detailing, and by PBMs

that may benefit from higher list prices with larger rebates and from the exclusion of new or cheaper competitor products. Patients are typically unaware of these influences on the choices being made on their behalf.

Second, the U.S. pharmaceutical industry's expenditure on marketing and sales is already very large, driven by the huge margins between prices and marginal cost.[60] While some marketing is informative, providing physicians and consumers with information about new products, heavy marketing of well-established products is more likely intended to persuade and promote brand loyalty, which is of questionable social value, particularly for health care products that are heavily tax-subsidized. For these reasons, all developed countries except the United States place significant restraints on the volume and forms of pharmaceutical marketing.[61] A full evaluation of pharmaceutical marketing is beyond the scope of this article. But to the extent that the antitrust evaluation of pharmaceutical mergers involves weighing efficiency savings against the risks of anticompetitive harm, the questionable social value of much pharmaceutical marketing calls into question whether any claimed marketing efficiencies should be treated as standard cognizable efficiencies in analyzing mergers of large pharmaceutical firms.

IV. FINANCING

The third advantage of size is that large firms with portfolios of marketed drugs generate huge revenue flows from current sales. Large firms use these retained earnings to fund their marketing, in-house R&D, and acquisitions, turning to external capital markets only occasionally, when additional funding is needed for the largest acquisitions. By contrast, start-ups and smaller firms with few or no marketed products must rely on venture capital and private equity to fund their drugs through early R&D and then turn to public capital markets and licensing or acquisition deals with larger companies to fund their more costly late-stage clinical trials and drug commercialization. Large firms' flow of retained earnings from marketed products gives them a lower cost of

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[60] Estimates of total marketing spending as a percent of sales is very sensitive to whether the cost of free samples is measured at input cost or full potential sales price.

[61] For example, the EU Code for Human Medicines Directive includes the "[g]eneral principles" that "[p]rescription-only drugs and drugs containing ingredients that are psychotropic or narcotic must not be advertised to the public" and "[m]ember states can choose to ban the advertising to the public of drugs that are reimbursed." Alison Dennis & Taylor Wessing, *Distribution and Marketing of Drugs in the EU: Overview*, THOMSON REUTERS (Nov. 1, 2019), uk.practicallaw.thomsonreuters.com/0-618-7218?transitionType=default&contextData=(Sc.Default)&firstPage=true#co_anchor_a528301. Regulating drug advertising directly is less feasible in the United States, where advertising is considered protected commercial speech.

capital than is available to smaller firms that must raise capital from external private or public capital markets.[62]

This lower cost of retained-earnings financing might be considered a real efficiency saving that large firms bring to their mergers and acquisitions of small and medium-size firms. But such saving benefits consumers directly *only* if it is passed through as lower drug prices. As argued earlier, the lack of price-conscious customers for pharmaceuticals makes savings pass-through unlikely in U.S. pharmaceutical mergers.

However, larger firms' acquisition of smaller firms can also offer real efficiencies by eliminating the need for small firms to build additional regulatory, marketing, and sales functions. Instead, the merged entity can realize economies of scale and scope by using the large firm's established capabilities—indeed, large firms often seek out acquisitions to replenish their pipelines of new products when they anticipate excess capacity in their overhead and sales capabilities relative to their in-house products. In such contexts, acquisitions of smaller firms may have benefit in bringing their innovations to market more quickly, even if cost savings for the firms are not reflected in lower prices to consumers. Larger firms' acquisition of smaller firms also encourages early investment in small firms, by providing a financial exit for venture capital and private equity investors. The efficiency case for merger is even greater where a small company's lead products have already been licensed to a large firm, such that shared expertise already exists and this large firm is the only likely acquiror of the small firm.[63] These efficiency arguments, based on R&D financing through retained earnings and avoiding duplication of marketing and sales capabilities, argue in favor of allowing large and mid-sized firms to acquire smaller firms, once any overlapping product issues have been addressed.

However, these efficiencies from lower cost of capital and elimination of the need to build new capabilities do not apply to mergers between large firms that each already have established marketing and sales capabilities and marketed products that generate retained earnings for funding future R&D. Rather, mergers of large firms simply result in expanded leverage due to the broader scale and scope of the portfolio of the combined firms. Although such large-firm mergers might appear to exemplify the sound functioning of the market for corporate control, in which more efficient firms acquire less efficient firms, to the extent that such mergers are simply enabled by massive

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[62] Stewart C. Myers & Nicholas S. Majluf, *Corporate Financing and Investment Decisions When Firms Have Information that Investors Do Not Have*, 13 J. FIN. ECON. 187 (1984).

[63] For example, Medarex's lead product had been licensed to BMS before BMS acquired Medarex, and this licensing deal made BMS the only likely acquiror of Medarex. Disclosure: Patricia Danzon was on the Medarex board when it was acquired by BMS.

flows of retained earnings, they are more likely to enable the largest firms to maintain their dominant positions by acquiring potential rivals with blockbuster products.

One measure of the dominance of large firms is their dominance of blockbuster products. Specifically, the top 50 drugs by global sales in 2018 were owned by 16 companies. These top 50 drugs generated $136 billion in U.S. sales after rebates, or almost 30 percent of total pharmaceutical spending in the United States in 2018.[64] Of these 16 companies, 15 are in the top 20 firms listed in Table 1.[65] Most of these top-selling drugs were discovered by other firms, which were acquired by the dominant firms, whose cash and marketing prowess made them powerful suitors. Thus acquisition by large firms of smaller firms offers potential efficiencies through lower cost of capital and elimination of the need for the smaller firms to build duplicative capacity. By contrast, although large-firm mergers are enabled by these firms' relatively low cost of internal capital, such mergers offer no merger-specific efficiencies but can harm consumers by increasing the contracting and marketing leverage of the resulting very large firms, which can be used to obstruct entry by and competition from smaller firms, as described above.

V. ANTITRUST IMPLICATIONS

In this article, we have described the significant advantages of overall firm size in the pharmaceutical industry that have contributed to the continued dominance of the largest firms and that threaten to undermine competition. Multi-product portfolios, especially those including must-have and blockbuster products, convey advantages to large firms in contracting with insurance payers and PBMs for pharmacy-dispensed drugs and with physician groups for physician-administered drugs. Size also conveys marketing advantages in detailing to physicians and multispecialty physician groups. And size assures a stable flow of retained earnings, providing a relatively low-cost source of financing for R&D, marketing, and acquisitions. While these advantages may offer some real resource efficiencies, any efficiency savings are unlikely to be passed on to consumers as lower prices, and they may in fact be used to exclude competitors and harm competition. These anticompetitive effects include the leveraging of broad portfolios and must-have products to contract for preferred positioning of the firm's own products or exclusion of competitor products across markets with no overlapping products.

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[64] David Belk, *Pharma's 50 Best Sellers*, TRUE COST OF HEALTH-CARE, truecostofhealthcare.org/pharmas-50-best-sellers/.

[65] The one exception is that Eylea was discovered and marketed in the United States by Regeneron, which was not in the list of Top 20 firms, but it is marketed outside the United States by Bayer, which is in the Top 20. *See supra* Table 1.

An important implication of this thesis, that overall firm size conveys advantages that can be used for anticompetitive, cross-market effects, is the inadequacy in certain cases of traditional merger analysis, which focuses narrowly on increased concentration in specific drug markets, with divesture of specific overlapping products as the only remedy and condition for merger approval. Market-by-market analysis is an important first step, and the divestiture of overlapping products may be necessary to preserve market-specific competition. But this should not be the *only* consideration. Cross-market effects that may span product markets in which the merging entities have no overlapping products should also be considered. These effects may enable mergers to "substantially lessen competition," contrary to the Clayton Act, in the various settings to which we now turn.[66] At the core of our proposals is the size of the merging entities.

What constitutes "large" or "midsize" for these purposes may depend not only on total sales but also on such portfolio characteristics as, for example, the number and relatedness of therapeutic areas, possession of blockbuster or must-have products, and involvement of biologic products rather than chemical drugs that are susceptible to generic entry. As a first approximation, we suggest that "large" includes the top 10 firms and "mid-size" includes at least the next decile, ranked by global pharmaceutical sales as in Table 1 above.

Our proposed approach fits within the agencies' recognition of potential harms based on unilateral effects. Antitrust law has recognized the importance of unilateral effects: that mergers may increase the market power of the merged entity, with the agencies explaining that "[t]he elimination of competition between two firms that results from their merger may alone constitute a substantial lessening of competition."[67]

The concepts of ability and incentives are central to the unilateral effects theory. The Merger Guidelines explain that mergers "enhance[ ] market power" if they "harm customers as a result of diminished competitive constraints or incentives."[68] The Guidelines also note that "[a] merger between two competing sellers prevents buyers from playing those sellers off against each other in negotiations," which "can significantly enhance the ability and incentive of the merged entity to obtain a result more favorable to it."[69] Although our focus in this article on cross-market effects is not directly covered by unilateral-effects theories applying in a single market, we believe that similar concepts, based on enhanced leverage across multiple markets, apply.

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[66] 15 U.S.C. § 18.

[67] Horizontal Merger Guidelines, *supra* note 2, § 6.

[68] *Id.* § 1.

[69] *Id.* § 6.2.

The FTC has used the concept of bargaining leverage in settings as varied as hospitals,[70] pharmacy chains and insurers,[71] and broadband.[72] Leverage refers to the ability of one party in the bargaining context to harm the other party by refusing to deal. How this leverage is used may depend on the context. As we discuss above,[73] mergers between pharmaceutical firms that are large, in terms of total sales or number and type of products, can enhance their leverage in negotiations with PBMs and in marketing to physician customers. We have argued that in this context, leverage is more likely used to exclude rivals and expand their own market share, rather than raise prices.

A. MERGERS BETWEEN LARGE FIRMS

The most significant concern is presented by mergers between two large pharmaceutical companies. We suggest that these mergers be presumed to harm competition. The reason stems from large firms' unique advantages, as detailed above. In particular, a large firm can benefit from bundled, cross-market contracting with PBMs and some physician customers and from coordinating detailing and other marketing to physician customers. Since these

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[70] ProMedica Health Sys., Inc. v. FTC, 749 F.3d 559, 563 (6th Cir. 2014) (noting larger hospitals' greater bargaining leverage over insurers known as managed care organizations (MCOs) and explaining that "[i]t is harder for an MCO to exclude the county's most dominant hospital system than it is for the MCO to exclude a single hospital that services just one corner of the county"); DEP'T OF JUSTICE & FED. TRADE COMM'N, COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES 35 (2006) [hereinafter COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES], www.ftc.gov/sites/default/files/attachments/merger-review/commentaryonthehorizontalmergerguidelinesmarch2006.pdf (full-service acute care hospital's proposed acquisition of the only other such hospital in the area would have confronted insurers with "the choice of either meeting [the acquirer's] price terms or excluding [the two hospitals] from their provider network"); FTC v. OSF Healthcare Sys., 852 F. Supp. 2d 1069, 1083, 1084 (N.D. Ill. 2012) (explaining that "the merger of two closely substitutable hospitals will increase the combined system's bargaining leverage," that this leverage "would in turn allow the combined entity to extract higher prices," and that a defense based on "large, sophisticated insurance companies . . . defeat[ing] any threatened post-merger price increases" by refusing to contract with the merged entity "ignores the current realities of the health insurance market").

[71] COMMENTARY ON THE HORIZONTAL MERGER GUIDELINES, *supra* note 70, at 35 (noting that a merger between the two largest U.S. retail drug store chains, Rite Aid and Revco, would have left "less attractive options for assembling networks that did not include the merged firm," which would have led the merged firm to "unilaterally . . . demand[ ] higher dispensing fees as a condition of participating in a network"); Revised Competitive Impact Statement at 13, United States v. Aetna Inc., No. 3-88CV1398-H (N.D. Tex. Aug. 3, 1999), www.justice.gov/atr/case-document/file/483491/download (explaining that Aetna's proposed acquisition of health insurance assets from Prudential "would give Aetna the ability to unduly depress physician reimbursement rates . . . likely leading to a reduction in quantity or degradation in the quality of physicians' services").

[72] Cecilia Kang & Emily Steel, *Regulators Approve Charter Communications Deal for Time Warner Cable*, N.Y. TIMES, Apr. 25, 2016, at B1 (noting that merged company resulting from Charter Communications' acquisition of Time Warner Cable and Bright House Networks "would have greater incentive and ability to impose or broaden contractual restrictions on programmers that limit their ability to distribute their content through [online video distributors]").

[73] *See supra* Parts II through IV.

advantages increase with the number of products in the individual firm's portfolio, they are magnified when two large firms merge. The harms to competition can include bundled contracts/rebates by which the larger firm takes advantage of flexibilities not available to smaller competitors or, more egregiously, imposes contract/rebate provisions that set limits on the number or formulary positioning of competitor products with which the PBM may contract, in one or more classes, as a condition of access to the merged firm's products.

These risks are most pronounced when a large firm has one or more must-have or blockbuster products that it can leverage to gain advantage in other classes where its products are "me-toos" with several similar competitors.[74] By contrast, classes that already include multiple similar products are less likely to provide a source of leverage for anticompetitive contracting strategies, particularly if generics are or will soon become available for one or more products in a class.

Recent lawsuits outside the merger setting illustrate how incumbents can use rebate contracting to impede new competitors' entry.[75] One example involves Pfizer's claims that Johnson & Johnson (J&J) and its subsidiary Janssen Biotech, to protect the market share of its tumor necrosis factor blocker infliximab (Remicade), employed exclusionary contracts, bundled discounts, and coercive rebates with insurers aimed at thwarting Pfizer's biosimilar Inflectra and future entrants from gaining market share.[76] In a second example, Shire alleged that Allergan impeded the marketing of Shire's dry-eye disease product, lifitegrast (Xiidra), through bundled discounts that were so aggressive that Medicare Part D plans would not purchase Shire's product even if it were offered for free.[77]

In these cases, the alleged exclusionary behavior involves requiring that payers exclude biosimilars from their formulary or forgo rebates on prescriptions for both incontestable (existing) and contestable (new) patients on a blockbuster biologic product, as well as access to rebates and other related products in the incumbent firm's portfolio. Although Pfizer itself has a large

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[74] Must-have blockbuster pharmaceutical products that cannot be excluded from a PBM's formulary are somewhat analogous to "crown jewel" or dominant hospitals that cannot be excluded from a health insurer's hospital network. *See supra* note 70.

[75] We provide these allegations in lawsuits as the best available evidence on anticompetitive rebate contracts. The confidentiality of all rebate contracts precludes public access to hard data on these agreements.

[76] Pfizer Inc. v. Johnson & Johnson, 333 F. Supp. 3d 494, 498 (E.D. Pa. 2018).

[77] Shire US, Inc. v. Allergan, Inc., 375 F. Supp. 3d 538, 542 (D.N.J. 2019). For additional discussion of these cases, see HERBERT HOVENKAMP, MARK D. JANIS, MARK A. LEMLEY, CHRISTOPHER R. LESLIE & MICHAEL A. CARRIER, IP AND ANTITRUST: AN ANALYSIS OF ANTITRUST PRINCIPLES APPLIED TO INTELLECTUAL PROPERTY LAW § 15.03[D] (Supp. 2020).

portfolio, its expected biosimilar sales would initially be small, making it prohibitively costly for it to attempt to compensate the payers for the rebate revenue they would lose from J&J if they put the biosimilar on formulary. The court found that tying the highly price-inelastic, incontestable patients with contestable new patients could effectively bar competition for the latter.[78] Combining two large firms increases the potential for such anticompetitive behavior, particularly when the merged entity has widely used blockbuster products that a PBM can neither exclude from its formulary nor afford to forgo rebates on. Even if the merger has offsetting efficiencies in marketing or overhead, any savings are unlikely to result in lower prices for consumers because, as discussed above, insurance blunts consumer price-sensitivity, and PBMs benefit from higher, not lower, list prices.

As a result, we suggest a presumption that a merger between large firms is anticompetitive, with the burden on the merging parties to demonstrate cognizable, merger-specific efficiencies that outweigh the significant risks of anticompetitive effects, which depend on portfolio composition, especially the presence of must-have or blockbuster products. The standard efficiencies that acquirors have claimed in order to rationalize megamergers have been the elimination of duplicative R&D, administration, and sales functions.[79] As discussed in Part I, larger firms have usually undertaken large acquisitions when they face patent expiration on their blockbuster products and gaps in their own pipeline of new products to replace the expiring products, which implies excess capacity in administration, sales, and other functions.[80] Significant cost-cutting in support functions is thus arguably inevitable and largely not specific to the opportunities created by the merger, as required by the notion of cognizable efficiencies. Moreover, post-merger integration is also disruptive, con-

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[78] The court in *Pfizer* highlighted the effects of the rebating strategy on new patients. It found that J&J's "[b]undling Remicade's incontestable demand could create anticompetitive consequences by foreclosing competition" for new patients; that "[t]aking Pfizer's allegations as true," new patients "are contestable because they have not yet been anchored to a specific . . . product"; and that "[i]f incontestable demand is truly inelastic, then this could fall into a traditional bundling case where J&J has bundled its power over existing Remicade patients to break the competitive mechanism and deprive new . . . patients (and their insurers) of the ability to make a meaningful choice between Remicade and its biosimilars." *Pfizer*, 333 F. Supp. 3d at 504.

[79] For example, AbbVie anticipated that its acquisition of Allergan would "provide annual pre-tax synergies and other cost reductions of at least $2 billion in year three while leaving investments in key growth franchises untouched." AbbVie continued: "The synergies and other cost reductions will be a result of optimizing the research and early stage portfolio, and reducing overlapping R&D resources (~50%), driving efficiencies in SG&A, including sales and marketing and central support function costs (~40%), and eliminating redundancies in manufacturing and supply chain, and leveraging procurement spend (~10%)"; this estimate "exclude[d] any potential revenue synergies." Press Release, AbbVie, AbbVie to Acquire Allergan in Transformative Move for Both Companies (June 25, 2019), news.abbvie.com/news/press-releases/abbvie-to-acquire-allergan-in-transformative-move-for-both-companies.htm.

[80] *See, e.g.*, Danzon, Epstein & Nicholson, *supra* note 30.

sumes resources, and may lead to the exit of the most productive individuals who have the best external opportunities.

The evidence presented in Part I shows that sequential large acquisitions have enabled the dominant firms to replenish their product pipelines and survive until the next acquisition becomes necessary and that shareholders of acquired firms have captured abnormal returns in the form of acquisition premiums. However, even if merger announcements have on average generated weakly positive abnormal returns for the merged entities, such merger premiums could reflect increases in market power that are of concern here, rather than efficiency savings. Unfortunately, we cannot observe the counterfactual of what might have happened had these large mergers been blocked, permitting upcoming firms to remain independent and perhaps become market leaders, rather than being absorbed into existing larger entities that have, at best, survived. As a result, we propose that mergers between two large firms be treated as anticompetitive, with the burden of proof shifted to the firms to rebut such a presumption by, for example, showing synergies from cross-national complementarity of assets or better utilization of excess capacity in manufacturing without risk of increased market power in negotiations or sales.

B. MERGERS INVOLVING MID-SIZE FIRMS

When a large pharmaceutical firm merges with a mid-size firm, there also should be heightened scrutiny, albeit not rising to the level of a presumption of harm to competition. Firms that are mid-size by revenue and number of marketed products (roughly, those ranked 11 through 20 in industry rankings by sales) play an important competitive role in the pharmaceutical industry, serving as viable competitors for the largest firms in marketing and as potential acquirors of smaller firms.

These mid-size firms typically have proven competence of their own with in-house drug discovery and development, marketing and sales, and partnerships with or acquisitions of smaller companies. The mid-size firms are attractive acquisition targets for larger firms, as the mid-size firm's marketed products can provide rapid replenishment for gaps in the large firm's pipeline when its patents on lead products approach expiration or internal R&D fails. Mergers involving mid-size firms also remove a potential acquiror for smaller firms and potential competitor for the largest firms. Large firms' acquisition of mid-size firms assures the continued market dominance of the same large firms over time. At the same time, these large/mid-size acquisitions offer no obvious efficiency savings.

The likelihood of the agencies challenging a merger between a large and a mid-size firm should increase based on the combined entity's product portfo-

lio. Concerns would be heightened when the target firm has a must-have or blockbuster product with large sales and few good substitutes that PBMs cannot exclude from their formularies, to which the firm can tie preferential treatment of its other products. Concern is especially heightened if the merger involves a blockbuster biologic that is approaching patent expiry, with the potential for biosimilar entry that the incumbent may seek to block. AbbVie's acquisition of Allergan is a case in point, as AbbVie's Humira is a must-have blockbuster that PBMs cannot exclude and that will soon face potential biosimilar entry. Similarly, Allergan's Botox is a must-have blockbuster facing increased would-be competitors. We suggest that such a merger warrants careful scrutiny for the potential for anticompetitive contracting to obstruct potential competitors for both of these products.

BMS's acquisition of mid-sized Celgene provides a recent example involving a large and mid-size firm. On the positive side, the two firms' complementary portfolios of cancer products could create marketing synergies for the merged firm. But these marketing synergies may be employed to disadvantage competitors, especially new entrants and smaller firms with fewer products that are not able to offer competitive portfolio-wide deals. And as argued earlier, it is highly unlikely that any real efficiency savings in marketing that the merged firm realizes will be passed through to consumers as lower prices.[81]

Mergers between two mid-size firms warrant modestly less scrutiny than those involving a large firm, albeit still more attention than the usual concerns with overlapping products. Such mergers can create yet another relatively large firm, with increased portfolio power compared to the two stand-alone firms. One example is Takeda's acquisition of Shire, with the new firm now ranking ninth industrywide. In particular, if the acquired firm has one or more must-have products with large sales and rebate volume, these may be leveraged over unrelated classes in the acquiror's portfolio. In addition, if the parties' drugs are predominantly in classes with few competitors, especially biologics that are protected from competition by restrictive rules for biosimilars, such classes are more vulnerable to anticompetitive behavior by powerful players.

On the other side, the parties might offer the defense that all the relevant products are in relatively crowded classes, preferably with (or at least subject to) generic entry, which mitigates the risk of anticompetitive contracting. Or they could contend that the mid-size firm has a promising, early-stage product that has the potential to address an unmet need, which the financing and expertise of the other mid-size or larger firm could help develop and bring to

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[81] As described earlier, these physician-dispensed drugs are generally reimbursed at the firm's average selling price + X% (ASP + 6% for Medicare), which creates incentives for firms to compete by setting higher, not lower, prices.

market more quickly. The weighing of potential benefits and risks is context-specific, with risks increasing based on must-have products and decreasing the smaller the merged entity.

C. MERGERS INVOLVING SMALL FIRMS

In general, mergers involving small firms do not require scrutiny beyond the traditional concerns with overlapping products in specific markets.[82] Market-by-market analysis is still important in these settings to determine whether a small company's product could potentially compete with one owned by the large firm or create excessive concentration due to related products.[83] For example, in Roche's acquisition of Spark Therapeutics, Spark's pipeline gene therapy program for hemophilia A could reinforce Roche's existing share of that market based on its Hemlibra treatment. Antitrust agencies in the United States and United Kingdom carefully reviewed this acquisition before authorizing it. Such review reflects appropriate concern that the acquisition might give Roche undue power in that product market or even cause Roche to discontinue the gene therapy. The existence of other companies with competing gene therapy programs mitigated this risk.

Large firms' acquisitions of small firms can provide important efficiencies. As discussed above, large firms generally can provide a lower-cost source of financing for the small firm's R&D, compared to private or public equity, and an exit for early investors. Further, acquisition by a larger firm with established marketing experience eliminates the need for the small firm to develop its own marketing and sales functions. In particular, in contexts in which the large firm already has a licensing agreement with the small firm for either sole or shared development and marketing of the small firm's lead product, the large firm's acquisition of the smaller firm can eliminate costly coordination and duplication of functions.[84] Consistent with this, empirical evidence for merger efficiencies is strongest in cases where a prior licensing relationship already exists between the acquirer and the target, plausibly because this provides both information and the potential for elimination of duplicative, shared functions.

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[82] Review of overlapping products for mergers involving small firms should include pipeline products and "innovation markets," as a merger between the two companies closest to the market with a particular treatment could result in suppression of one of the research paths. *See* Michael A. Carrier, *Two Puzzles Resolved: Of the Schumpeter-Arrow Stalemate and Pharmaceutical Innovation Markets*, 93 IOWA L. REV. 393 (2008).

[83] We assume that, where required as a condition of approval, divested products are sold to companies that are plausible, strong, and committed competitors. This depends on such factors as having related products that can yield synergies in marketing and rebating across categories.

[84] For example, BMS's acquisition of Medarex eliminated potentially duplicative co-marketing of ipilumimab, provided for in BMS's licensing agreement for ipilumimab. *See supra* note 63.

More generally, even without a prior licensing arrangement, acquisition by a larger firm with experience and retained earnings can accelerate the development of the small firm's promising products. For example, Gilead, a mid-size firm with extensive experience in developing and marketing drugs to treat HIV/AIDS, was an effective acquiror for Pharmacyclics, a small firm with early-stage products to treat Hepatitis C. Gilead was able to rapidly develop and launch these acquired compounds to become the first effective treatments for Hepatitis C. Gilead has remained an important competitive player in the Hepatitis C market, which would otherwise be dominated by a few large firms.[85]

In short, absent overlapping products, acquisitions of small firms by large and mid-size firms tend to offer cognizable efficiencies without posing significant anticompetitive threats.[86]

D. Application to Other Industries

We have argued that the pharmaceutical industry warrants special consideration for merger analysis on account of the characteristics related to firm size discussed above. Although these characteristics combine and interact with patents to make pharmaceuticals an extreme case, some similar features in other industries are worth noting, although their full consideration is beyond the scope of this article. We have already noted both differences and similarities to the cross-market effects of hospital mergers, especially those involving dominant hospitals. The potential for the use of bundled contracts to exploit cross-market leverage exists in other industries in which common customers use products from separate but linked markets.

As one example, Amazon Prime gives customers that use Amazon for mail-order book purchases an incentive to also use Amazon for other mail-order products, movies, and grocery deliveries.[87] This is somewhat akin to a large pharmaceutical company using its must-have blockbuster drug for disease X to gain a competitive advantage or restrict competition in diseases Y and Z. Also, the broad scope of Amazon's product offerings enables it to offer one-stop-shopping convenience to customers that could act as a barrier to entry for smaller competitors with a more limited product range.

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[85] AstraZeneca recently proposed acquiring Gilead but abandoned the attempt.

[86] While the framework we propose does not require a heightened scrutiny of mergers involving small firms, for a discussion of potential anticompetitive effects from the acquisitions of small firms with proprietary drug discovery platforms, see Patricia M. Danzon, Comment on Pharmaceutical Mergers to the Multilateral Pharmaceutical Merger Task Force, Project No. P212900, at 13–14, 19 (June 25, 2021), www.regulations.gov/comment/FTC-2021-0025-0037.

[87] *Amazon Prime*, AMAZON.COM, www.amazon.com/gp/help/customer/display.html?nodeId=G6LDPN7YJHYKH2J6.

There are important differences in the non-pharmaceutical space, however. For example, Walmart and other firms can and do offer their own free delivery programs on a broad range of products to compete with Amazon Prime and Amazon's broad product range. In contrast, in pharmaceutical markets, PBMs control access for consumers, and the top three PBMs have roughly 75 percent market share.[88] Similarly, the potential for entry of other large, rival drug firms offering similar products and size advantages is limited by the natural size limits on disease classes, stickiness in switching drugs for treating chronic diseases, high R&D costs, and the role of patents and barriers to post-patent biosimilar entry that limit the market potential for competitor products in any therapeutic class. Further, consumers are largely unaware of new products until they are covered by insurance and prescribed by their physicians. Finally, in most industries there is a reasonable presumption that competition for price-sensitive consumers forces the pass-through of efficiency savings from mergers. By contrast, in the pharmaceutical context, insurance undermines consumer price sensitivity and informational asymmetries make it impossible for consumers to aggressively monitor the insurers, PBMs, and physicians that are supposed to act as consumer agents but in reality have opportunities and incentive to also serve their own interests.

VI. CONCLUSION

In this article, we have described the complex environment and structure of competition in the pharmaceutical industry. The industry is characterized by the persistent dominance of the same large firms, which have maintained their preeminence through acquisitions and size-related advantages in contracting, marketing, and financing, rather than innovation.

This perspective challenges the standard antitrust analysis of mergers, which focuses exclusively on increased concentration leading to higher prices in specific markets with overlapping products and the divestiture of such products as a remedy. Although the agencies have long applied an analysis based on overlapping products in particular markets, we argue that overall size conveys advantages that firms can use across product markets in ways that can harm competition. These advantages arise in negotiations with payers/PBMs and physicians; in marketing and selling to physicians; and in retained earnings financing of all costly functions, especially R&D, marketing, and acquisition of other firms.[89] Each of these advantages increases with a firm's size, as measured by overall sales and number of products, especially blockbuster and must-have products.

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[88] *E.g.*, *Pharmacy Benefit Managers Explained*, ADVISORY BD. (Nov. 13, 2019), www.advisory.com/en/daily-briefing/2019/11/13/pbms.

[89] Further research is needed to quantify these effects but is impeded by data confidentiality.

Any one of these characteristics alone may not provide sufficient grounds for the agencies to bring a case. But we believe that the greatest concerns are the risks arising from size-related advantages in contracting, which can be used to exclude competitors across markets, not just in markets with overlapping products. Size-related advantages in marketing and finance further buttress this contracting advantage, enabling dominant firms to acquire and build dominant products and broad portfolios, with potential harm to smaller firms seeking to enter, as well as to potential consumers of their products.[90]

When two large pharmaceutical firms merge, the presumption should be that the merger harms competition. When mergers involve mid-size pharmaceutical firms, the agencies should carefully scrutinize potential cross-market effects, in addition to any overlapping markets. And when a small pharmaceutical firm is involved in the merger, the agencies should apply the typical market-by-market approach. Such a framework is more consistent with industry realities than the approach applied today and ensures that antitrust merger enforcement can play a vital role in supporting competition in the pharmaceutical industry.

[90] As discussed above, although some of the conduct we consider in the merger context—such as bundled rebates—can be challenged outside the setting of mergers, the difficulty of observing the harms makes it important for the agencies to consider the conduct risks before approving combinations of firms that could exacerbate these competitive concerns. *See supra* note 22 and accompanying text.