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ABSTRACT

Standard merger analysis, which focuses on the proposed merger's potential to raise prices or reduce innovation in individual product markets, ignores the potential for horizontal mergers to increase size-related leverage and anticompetitive cross-market effects that can arise out of the multiproduct portfolios of large firms. These advantages of firm size depend on the structure and institutional details of price/reimbursement, marketing and selling pharmaceuticals, which differ across countries and between originator and generic drugs within countries. This paper examines this potential for anticompetitive leverage and cross-market effects in mergers of originator firms and generic firms in the US and Europe, respectively. It concludes that the risk of anti-competitive cross-market effects is of greatest concern for mergers of large originator firms in the US and, to lesser extent, for generics mergers in the US, because firm size conveys advantages in contracting, marketing and selling in the market-driven US healthcare system. By contrast, the various regulatory features of European pharmaceutical markets substantially mitigate the potential for size-related leverage and anticompetitive cross-market effects in both originator and generics mergers in Europe.

L'analyse standard des fusions, qui se concentre sur le potentiel de la fusion proposée à augmenter les prix ou à réduire l'innovation sur les marchés de produits individuels, ignore le potentiel des fusions horizontales à augmenter l'effet de levier lié à la taille et les effets anticoncurrentiels sur les marchés croisés qui peuvent résulter des portefeuilles multiproduits des grandes entreprises. Ces avantages liés à la taille de l'entreprise dépendent de la structure et des détails institutionnels relatifs au prix/remboursement, à la commercialisation et à la vente des produits pharmaceutiques, qui diffèrent d'un pays à l'autre et entre les médicaments princeps et les médicaments génériques au sein d'un même pays. Ce document examine ce potentiel d'effet de levier anticoncurrentiel et d'effets croisés sur le marché dans les fusions de laboratoires de princeps et de fabricants de génériques aux États-Unis et en Europe, respectivement. Il conclut que le risque d'effets anticoncurrentiels croisés est le plus préoccupant pour les fusions de grands laboratoires de princeps aux États-Unis et, dans une moindre mesure, pour les fusions de génériques aux États-Unis, car la taille des entreprises confère des avantages en matière de contrats, de marketing et de vente dans le système de soins de santé américain, axé sur le marché. En revanche, les diverses caractéristiques réglementaires des marchés pharmaceutiques européens atténuent considérablement le potentiel d'effet de levier lié à la taille et d'effets croisés anticoncurrentiels dans les fusions de laboratoires de princeps et de génériques en Europe.

I. Introduction

1. A new working group has recently been formed by the European Commission, the US Federal Trade Commission (FTC) and Department of Justice (DOJ), Canada's Competition Bureau and Britain's Competition and Markets Authority, to address pharmaceutical mergers. "*The number of mergers in the pharmaceutical sector has grown in recent years, and there is the need to scrutinise closely to detect those that could lead to higher drug prices, lower innovation or anticompetitive conduct.* (. . .) *The goal of the working group is to identify concrete and actionable steps to update the analysis of pharmaceutical mergers.*"[1] In the words of FTC Acting Chair Rebecca Slaughter, "*Given the high volume of pharmaceutical mergers in recent years, amid skyrocketing drug prices and ongoing concerns about anti-competitive conduct in the industry, it is imperative that we rethink our approach toward pharmaceutical merger review.*"[2]

2. Mergers in the pharmaceutical sector warrant special scrutiny not only because of concerns over the affordability of medicines but also because the institutional details of pharmaceutical markets complicate the economic analysis of merger effects, as has been recognized: "*For competition policy and its enforcement activities in the pharmaceutical sector to be effective, they need to take account of the particularities and the resulting competitive dynamics of this sector* [including] (. . .) *the specific structure of demand and supply involving a variety of stakeholders* (. . .) *and the comprehensive legislative and regulatory framework in the different Member States*."[3] However, there has been little formal analysis of how these complexities, in particular, the structure of insurance and reimbursement arrangements and the agency roles of doctors and pharmacies, affect competition

1 European Commission, Press release IP/21/1203 of March 16, 2021, Competition: The European Commission forms a Multilateral Working Group with leading competition authorities to exchange best practices on pharmaceutical mergers, https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1203.

2 F.Y. Chee, EU regulators team up with U.S. and UK on pharmaceutical mergers, Reuters, March 16, 2021. https://www.reuters.com/article/us-eu-antitrust-pharmaceuticals/eu-regulators-team-up-with-u-s-and-uk-on-pharmaceutical-mergers-idUSKBN-2B823R (last accessed 5.17.21).

3 European Commission, Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009–2017), COM(2019) 17 final, at 16.

between pharmaceutical firms, and how these factors differ between originator[4] and generic sectors markets and across countries.

3. Standard antitrust analysis of mergers, in pharmaceuticals as in other industries, focuses on the proposed merger's potential to raise prices or reduce innovation by eliminating potential competitors in individual product markets defined by substitutability and geography. For pharmaceuticals, product markets are typically defined by indication (rheumatoid arthritis) and formulation (oral vs. injectable). Geographic market is the nation, because healthcare markets are regulated and structured by national laws. In this standard merger analysis, multi-product portfolios of large pharmaceutical firms are treated as a series of independent product markets, without concern for possible cross-market effects. Mergers are permitted subject to divestiture of overlapping products in specific markets or overlapping pipeline compounds that might be discontinued, adversely affecting innovation.[5] A recent report by the American Antitrust Institute (AAI) found that between 1994 and 2020, the US FTC "*challenged 67 pharmaceutical mergers worth over $900 billion* (. . .), *moved to block only one, and settled virtually all of the remainder subject to divestitures.*"[6] AAI concluded that this narrow focus on drug-specific markets has resulted in "*the swapping of assets within a relatively small group of large and increasingly powerful firms*."[7] Similarly, the European Commission analyzed over 80 mergers in the pharmaceutical sector between 2009 and 2017. Of these, 19 were problematic from a competition standpoint, due to the risk of higher prices or reduced availability or diminished innovation for some products in some Member States. "*The Commission considers structural remedies, in particular divestitures, to be the preferred way to resolve competition issues in merger cases. Accordingly, the remedies in the pharmaceutical sector often consist of a divestiture of marketing authorisations for problematic molecules in the relevant Member State.* (. . .) *Taking into account the remedies offered by the merging companies, the Commission was able to clear all* (. . .) *the mergers that raised these targeted concerns, allowing the merger to go ahead and protecting competition and consumers in Europe.*"[8]

4. This focus in horizontal merger review on overlapping products in individual product markets is fundamental and often sufficient. However, concern is growing that this approach may be too narrow, as expressed in dissenting statements by former FTC Commissioner Rohit Chopra in AbbVie's acquisition of Allergan,[9] and Acting FTC Chair Rebecca Slaughter's dissent in Bristol-Myers' acquisition of Celgene.[10] Ignored by this exclusive focus on individual markets is the potential for horizontal mergers to increase market power through cross-market effects enabled by large portfolios that span individual markets.

5. The thesis of this paper is that cross-market effects can arise in pharmaceutical mergers because larger firms gain bargaining leverage and other advantages in dealing with reimbursement, marketing and selling in pharmaceutical markets. The relevant institutional details—and the potential risks to competition—differ across countries and between originator and generic drugs. An earlier paper outlined these potential cross-market effects in mergers of originator pharmaceutical firms in the US.[11] This paper extends the analysis to examine how far similar cross-market effects are also a concern in mergers of originator firms in Europe and for generic firms in the US and Europe. More generally, this paper examines how far the analysis of pharmaceutical mergers can be standardized across countries and sectors or whether countries' differing regulatory regimes for originator and generic sectors imply different competitive concerns in reviewing mergers.

6. Although the focus here is on pharmaceutical mergers, related cross-market effects have been documented in the US for mergers of hospitals that operate in separate geographic markets, and in markets for physician services.[12] These cross-market issues in healthcare also bear some analogy to those in digital markets, where large firms operate gateways through which other firms provide their services to consumers. Large health insurers or their pharmacy benefit managers (PBMs) in the US effectively operate as gateways through which suppliers offer their drugs to consumers. Conversely, large pharmaceutical firms with broad portfolios that include essential drugs have portfolio-based market power in bargaining with PBMs that they can use to their competitive advantage. Thus detailed analysis of cross-market effects in pharmaceuticals may offer insights for other sectors with similar features.

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4 "Originator" is used to refer to patented, research-based drugs. They are sometimes called "brand name" drugs, but this is confusing because generics may also be branded in some contexts.

5 In vertical or conglomerate mergers, involving both horizontal and vertical functions, the potential for foreclosure of competitors through restrictive distribution contracts would also be considered, but such issues have generally not been raised in pharmaceutical mergers.

6 D. L. Moss, From Competition to Conspiracy: Assessing the Federal TradeCommission's Merger Policy in the Pharmaceutical Sector, American Antitrust Institute Report, at 10, Sept. 3, 2020,

7 Ibid. at 3.

8 *Supra* note 3, at 14.

9 Dissenting Statement of Commissioner Rohit Chopra, *In the Matter of AbbVie, Inc. / Allergan plc*, Comm. File No. 1910169, at 3, May 5, 2020.

10 Dissenting Statement of Commissioner Rebecca Kelly Slaughter, *In the Matter of Bristol-Myers Squibb and Celgene*, Comm. File No. 191-0061, at 1, Nov. 15, 2019. But *see* Statement of Commissioner Noah Joshua Phillips, *In the Matter of Bristol-Myers Squibb and Celgene*, Comm. File No. 191-0061, at 2, Nov. 15, 2019 ("*we need to articulate a viable theory of harm to competition posed by the merger and produce evidence to supporthat theory*" and "*must convince a judge that* [a merger] *violates the law*").

11 P. M. Danzon & M. A Carrier, The Neglected Concern of Firm Size in Pharmaceutical Mergers, 84 *Antitrust L.J.* (forthcoming 2021).

12 G. S. Vistnes & Y. Sarafidis, Cross-Market Hospital Mergers: A Holistic Approach, 79 *Antitrust L. J*253 (2013); L. Dafny, K. Ho & R. S. Lee, The Price Effects of Cross-Market Mergers: Theory and Evidence from the Hospital Industry, 50 *RAND J. Econ.* 286 (2019), at 286–87; Testimony of Leemore S. Dafny, Ph.D., Before the US House Cmte on the Judiciary, Subcmte on Antitrust, Commercial and Administrative Law, April 29, 2021. https://docs.house.gov/meetings/JU/JU05/20210429/112518/HHRG-117-JU05-Wstate-DafnyL-20210429.pdf.

7. In this paper, section II first reviews potential cross-market effects in mergers of large originator pharmaceutical firms in the US and then applies the analysis to mergers of originator firms in Europe. It concludes that size-related cross-market effects are a significant concern in the US but are largely mitigated in Europe through its regulatory structure for price/reimbursement, promotion and drug dispensing. Section III examines mergers in generic markets in the US and Europe. In the pharmacy-driven generic markets of the US and UK, mergers that enhance a firm's portfolio breadth and bargaining power may convey competitive advantage but also create potential efficiency savings that must be weighed. In the physician-driven generic markets of several large European countries, size-increasing mergers offer less competitive advantage but also less efficiency savings. Section IV concludes that cross-market effects are potentially of greatest concern in originator pharmaceutical mergers in the US and, to a lesser extent, for generic mergers in the US. While these concerns warrant assessment in Europe, they are generally mitigated by various regulatory features of European pharmaceutical markets.

II. Originator pharmaceutical markets

8. In all high-income countries, healthcare services, including pharmaceuticals, are covered by insurance—national, social or private—that assures access for patients while protecting them from high costs. Because insured patients pay at most a modest copayment at point of service, they are typically uninformed and insensitive to the full prices paid by payers. Patient price insensitivity creates incentives for pharmaceutical firms to raise prices beyond the levels enabled by patents[13] unless insurers set limits. In practice, insurers as customers for pharmaceuticals play a key role in setting price and other reimbursement conditions. Physicians and pharmacies who, respectively, prescribe and dispense drugs for patients, are also important customers of pharmaceutical firms. Country-specific reimbursement and other regulations significantly influence these customer roles and competitive dynamics for originator and generic sectors, with implications for mergers.[14] We focus first on originator drugs, in the US and then Europe.

13 A. Garber, C. Jones & P. Romer, Insurance and Incentives for Medical Innovation, 9 *Forum Health Econ. Pol.* 1 (2006).

14 Biosimilar copies of biologic drugs are produced by firms in both categories. Competition dynamics are more similar to those of originator drugs.

1. Originator drugs in the United States

9. As the largest market (by sales value) and the most profitable, the US has a disproportionate influence on pharmaceutical firm structure and on global markets.[15] The US is also often the country of first launch of new originator drugs, and US prices become the benchmark that firms seek to achieve in other high-income countries. In the US market, firm size offers potential competitive advantages through cross-market effects in four contexts: reimbursement, marketing, selling to physicians, and financing.

1.1 Reimbursement

10. In the US, pharmaceutical firms can freely set a drug's list price (wholesale acquisition cost or WAC) at launch and throughout the drug's economic life. Annual price increases of 5–10% are common.[16] Few customers pay list prices, but they are an important benchmark from which discounts and rebates are calculated.

11. For drugs sold through retail pharmacies, most payers (insurers, self-insured employers, unions) employ PBMs as agents to negotiate rebates from pharmaceutical firms and reimburse pharmacies for the drugs that they dispense.[17] PBMs structure formularies of preferred vs. non-preferred drugs, using tiered cost-sharing and administrative rules to steer patients to preferred drugs. PBMs negotiate rebates with firms in return for preferred positioning, lower cost-sharing and increased market share for their drugs.[18] PBMs compete for the business of the payers/employers who represent patients. These ultimate customers prefer formularies with broad coverage and low cost, but they lack the detailed information needed to compare the price-access trade-offs on hundreds of drugs offered by competing PBMs.

15 North America (USA and Canada) and Europe account for 48.9% and 23.2%, respectively, of global pharmaceutical sales in 2018. European Federation of Pharmaceutical Industries and Associations, The Pharmaceutical Industry in Figures, Key Data 2019, https://www.efpia.eu/media/412931/the-pharmaceutical-industry-in-figures-2019.pdf.

16 "*In 2018, retail prices for 267 widely used brand name prescription drugs increased by 5.8 percent, contrasting with the general inflation rate of 2.4 percent over the same period. Despite being more than twice as high as inflation, this was the slowest average annual price increase for widely used brand name prescription drugs since at least 2006.*" S. W. Schondelmeyer and L. Purvis, Brand Name Drug Prices Increase More than Twice as Fast as Inflation in 2018, *Rx Price Watch*, Nov. 2019, AARP Public Policy Institute, https://www.aarp.org/content/dam/aarp/ppi/2019/11/brand-name-drug-prices-increase-more-than-twice-as-fast-as-inflation.doi.10.26419-2Fppi.00073.005.pdf.

17 For details and evidence on effects of US reimbursement and PBMs, *see* P. M. Danzon, Differential Pricing of Pharmaceuticals: Theory, Evidence and Emerging Issues, 36 *Pharmacoeconomics* 1395 (2018); P. M. Danzon, Pharmacy Benefit Management: Are Reporting Requirements Pro- or Anticompetitive?, 22 *International J. Econ. Bus.* 245 (2015); P. M. Danzon, Pricing and Reimbursement of Biopharmaceuticals and Medical Devices in the USA, 3 *Encyclopedia of Health Econ.* 127 (A. J. Culyer, ed., Elsevier, 2014).

18 In 2021, median standard cost-sharing among all Medicare PDPs is $0 for preferred generics and $5 for generics, $40 for preferred brands, 40% coinsurance for non-preferred drugs (the maximum allowed is 50%), and 25% coinsurance for specialty drugs (the maximum is 33%). J. Cubanski & A. Damico, Medicare Part D: A First Look at Medicare Prescription Drug Plans in 2021, https://www.kff.org/medicare/issue-brief/medicare-part-d-a-first-look-at-medicare-prescription-drug-plans-in-2021/#:~:text=Among%20all%20PDPs%2C%20median%20standard,%25)%2C%20and%2025%25%20coinsurance%20for.

12. Although PBM contracts with payers generally stipulate the pass-through of most rebates on drug prices, rebate confidentiality makes this hard to enforce and some contracts specifically allow PBMs to retain some rebates—indeed, this may be necessary to motivate PBMs to negotiate. If PBMs retain a share of rebates, an important implication is that both pharmaceutical firms and PBMs may prefer a scenario with high list prices and large rebates over an alternative with lower list prices and lower rebates, even with the same net price. However, patients are worse off in the high price, high rebate scenario because patient cost-sharing may be linked to list prices.[19]

13. In this context, a large pharmaceutical firm with a multi-product portfolio spanning several individual markets and including one or more "must have" products can gain bargaining leverage with PBMs by bundling its products across its portfolio, compared to smaller firms selling separate competing products in each class. Bargaining leverage increases with the number, sales value and criticality of the firm's products, because the loss that the firm can impose on the PBM by refusing to contract increases with the value of its products to the PBM's employer/patient customers.[20]

14. Large pharmaceutical firms could in theory use their bargaining leverage to raise list prices. This would be consistent with evidence from hospital markets that mergers are associated with higher prices, even when the merging hospitals are in separate geographic markets, because the larger hospital network can impose a larger loss on the insurer if it refuses to contract.[21] However, for pharmaceutical firms, raising list prices may not be the optimal way to use their leverage because a drug's list prices apply to all payers and indications, whereas the firm's bargaining leverage varies across payers and indications. Moreover, drug price increases that exceed general inflation may incur an "excess inflation" rebate payable to Medicaid. A second way the firm could use its leverage is to reduce the rebates it pays to the PBM, but this would imply revenue loss to the PBM. A third, potentially win-win use of the large firm's bargaining leverage is to negotiate that its drugs be sole (or one of only two) preferred drugs in each class, which effectively excludes or severely disadvantages competitor products. PBMs may incur no loss and even gain from the exclusion of new drugs, which typically have slow market uptake and generate minimal rebate revenue for PBMs, at least initially. Indeed, entry of a new, lower-priced competitor imposes loss on the PBM and the incumbent firm, if class-wide average prices fall and demand is price-inelastic, because of insurance and disease-related limits on medical need. This negative effect of entry on the potential surplus to be split between the PBM and the incumbent firm is particularly likely if the entrant is a biosimilar, hence exclusionary PBM-incumbent contracting to bar biosimilar entry is a significant risk.[22]

15. Developing empirical evidence of these hypothesized anticompetitive, cross-market effects of firm size in originator-PBM contracting is hampered by the confidentiality of rebates and other contractual terms. However, cases alleging exclusionary conduct have been filed by competitors[23] and customers,[24] and provide evidence supporting this concern that large pharmaceutical firms can implement exclusionary strategies through their PBM contracts. Similar exclusionary contracts have been used by dominant hospital systems, with tying arrangements that require insurers to include all the system's providers in a network or prevent steering patients to competitor hospitals.[25,26] This evidence from allegations and from hospital markets supports the anticompetitive risks of portfolio-wide bargaining leverage outlined here.

1.2 Marketing

16. Large firms have scale advantages in pharmaceutical detailing. Detailing involves sending representatives to physician offices to: inform/remind doctors about a drug's characteristics and uses; establish personal relationships with doctors; and, in the US, to leave free drug samples that doctors can give to patients to avoid cost-sharing. A multi-product firm can detail several drugs on one visit and deepen brand loyalty and relationships through more frequent visits. Although such scale economies entail efficiencies for the firm, any savings for firms or physicians are unlikely to be passed through as lower prices, due to the price insensitivity

19 The fact that both pharmaceutical firms and PBMs may benefit from a high-price, high-rebate regime does not mean that high rebate demands by PBMs "cause" high prices, as the pharmaceutical industry sometimes argues. PBMs, wholesalers and others in the distribution chain may also benefit from high list prices to the extent that their reimbursement is proportional to list prices. *See* https://portal.ct.gov/-/media/AG/Press_Releases/2019/FINAL-Unredacted-Derm-Complaint-CV-002.pdf, at 106–107.

20 Each self-insured employer selects one PBM to offer its patients/employees each year. Employees express their dissatisfaction to employers if the selected PBM's formulary excludes or places high cost-sharing on widely used or critical drugs.

21 *See supra* note 12. Also M. S. Lewis & K. E. Pflum, Diagnosing Hospital System Bargaining Power in Managed Care Networks, 7 *Am. Econ. J. Econ. Policy* 243 (2015); M. S. Lewis & K. E. Pflum, Hospital Systems and Bargaining Power: Evidence from Out-of-Market Acquisitions, 48 *RAND J. Econ.* 579 (2017).

22 Such contracting to exclude biosimilar entry is alleged in *Pfizer Inc. v. Johnson & Johnson*, 333 F. Supp. 3d 494 (E.D. Pa. 2018).

23 In *Shire v. Allergan*, 375 F. Supp. 3d 538 (D.N.J. 2019), 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, thereby allegedly blocking the adoption by these plans of Shire's superior drug for dry eyes, Xiidra. Shire argued that it would have to offer its drug below average cost in order to compensate the PBM for its loss of rebate revenue from Allergan which was conditional on preferred tier exclusivity for Restasis. This is not 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 is a sustainable strategy for the incumbent.

24 Letter from Families USA et al. to The Honorable Joseph J. Simons, Sept. 12, 2019, https://www.fdanews.com/ext/resources/files/2019/09-16-19-LetteronMerger.pdf?1568653634.

25 The 2019 settlement of antitrust lawsuits against Sutter Health requires Sutter to discontinue all-or-nothing contracting deals; stop anticompetitive bundling and offer a stand-alone price for each service that is lower than any bundled package price; increase transparency; and limit charges for out-of-network services. E. Mitchell, Seizing on the Sutter Health Settlement to Create Competitive Health Care Markets Nationwide, Jan. 24, 2020, https://www.milbank.org/2020/01/seizing-on-the-sutter-health-settlement-to-create-competitive-health-care-markets-nationwide.

26 *See supra* note 12. Also M. S. Lewis & K. E. Pflum, Diagnosing Hospital System Bargaining Power in Managed Care Networks, 7 *Am. Econ. J. Econ. Policy* 243 (2015); M. S. Lewis & K. E. Pflum, Hospital Systems and Bargaining Power: Evidence from Out-of-Market Acquisitions, 48 *RAND J. Econ.* 579 (2017). XXX Same as note 21 XXX

of insured demand.[27] Rather, cost savings that increase price-cost margins may simply reinforce firms' incentives for promotion of brand loyalty for on-patent drugs.[28] More generally, since originator drugs compete heavily on promotion,[29] antitrust analysis of a merger's potential competitive effects should include effects on promotion.

1.3 Selling to physician and hospital customers

17. Physician-administered drugs, which are primarily biologics that require infusion or injection, are administered through physician offices or hospital outpatient departments that "buy-and-bill" for the drugs.[30] This is the fastest-growing segment of drug spending, it includes the most expensive drugs and is not subject to savings from generics. Similar to PBM contracting, if these customers' choice of preferred drugs is influenced by manufacturer rebates and/or convenience of one-stop contracting, large pharmaceutical firms that offer a portfolio of drugs to meet multiple needs have a bargaining advantage compared to smaller firms that each can supply only one or two products. Again, there could be real efficiency savings. But these are likely to accrue to the pharmaceutical firms and providers as higher income, due to lack of competitive pressures to pass through savings to patients as lower prices. Indeed, because Medicare reimburses the dispensing physicians at the drug's average sales price (ASP) plus 6%, pharmaceutical firms can increase the profit margin for providers on their drugs by raising rather than lowering drug price.[31]

18. By contrast, for drugs for inpatient use, hospital pharmacies are highly price-conscious customers, because inpatient drugs are generally not reimbursed separately but are included in bundled payments for hospital stays paid by Medicare or private payers. Although large pharmaceutical firms may have portfolio advantages in contracting for inpatient drugs, any potential for cross-market bundling is mitigated because hospital buyers are well informed and price sensitive, and the sector is relatively small. Thus for mergers involving only inpatient drugs, anticompetitive conduct is primarily a concern in individual product markets, where shortages and some egregious price increases have occurred.[32]

27 Studies of insurer markets show that large insurers are able to negotiate greater provider discounts, but there is no evidence that these discounts are passed through to consumers as lower insurance premiums. *See* Dafny Testimony *supra* note 12.

28 *See infra* note 40.

29 Large firms spend similar amounts on promotion and R&D, though precise estimates vary depending on sources. M.-A. Gagnon & J. Lexchin, The Cost of Pushing Pills: A New Estimate of Pharmaceutical Promotion Expenditures in the United States, 5 *PLoS Med.* e.1 (2008), doi:10.1371/journal.pmed.0050001.

30 Dispensing physicians—mostly oncologists and other specialists—buy the drugs through specialty distributors and are reimbursed by payers. Any margin between acquisition cost and reimbursement accrues as profit to the physician or outpatient department, in addition to their dispensing fee.

31 ASP is average sales price to all customers, net of rebates, which creates disincentives for rebating in this sector. Most private payers use Medicare's reimbursement approach, sometimes with a higher percentage margin.

32 American Hospital Association, Federation of American Hospitals & American Society of Health-System Pharmacists, Recent Trends in Hospital Drug Spending and Manufacturer Shortages, Final Report, 2019, https://www.aha.org/system/files/2019-01/aha-drug-pricing-study-report-01152019.pdf.

1.4 Financing

19. Large firms that own a portfolio of marketed products typically enjoy a cash flow and retained earnings that enable them to finance promotion, acquisitions and other activities at a lower cost of capital than smaller firms that must raise their capital in external capital markets.[33] The lower cost of internal capital may partly reflect real size-related efficiencies. But to the extent that such low-cost capital is used for promotion or to acquire other firms, in order to perpetuate or increase a firm's size and market power, which in turn generate additional revenue and perpetuate the cycle, the social value of size-related low-cost financing and its role in mergers is questionable.

20. Several important implications flow from this analysis of the US originator pharmaceutical market, in which firms can set list prices and compete through rebates offered to PBMs. First, the number of competitors is not sufficient to assure competition on list prices. This is illustrated by evidence from the tumor necrosis factor (TNF) inhibitor class between 2009 and 2016, where list prices increased following the entry of each of three new competitors.[34] Second, although a merger may increase the bargaining leverage of the merged firm, this may not manifest as higher list prices. A more likely alternative is barriers to competitors through confidential formulary terms that exclude or restrict competitor products to non-preferred tiers and hence increase the incumbent's sales volume. Such exclusionary contracts can significantly reduce consumer welfare, through reduced choice and/or higher cost-sharing. But they are unlikely to be observed or prosecuted by agencies or patients, because PBM rebate contracts are confidential and it is challenging to prove what the uptake of the new product would have been, had there been no anticompetitive contracting by the dominant firm. These obstacles to detecting and prosecuting anticompetitive contracting conduct argue for assessing such risks as part of the analysis of proposed mergers, especially those involving large pharmaceutical firms, where potential anticompetitive risks are greatest and efficiency gains are at most minor.

2. Originator pharmaceutical markets in Europe

21. In contrast to the US, all European countries use centralized mechanisms to constrain prices of pharmaceuticals covered by insurance; pharmaceutical promotion is more regulated; and physicians generally have no financial stake in drugs they dispense. These and other institutional differences reduce the advantages

33 S. C. Myers & N. S. Majluf, Corporate financing and investment decisions when firms have information that investors do not have, 13 *J. Fin. Econ.* 187 (1984).

34 Based on WAC data, annual treatment cost increased 144% between April 2009 and December 2016 after entry of three new drugs, compared with a 34% increase expected in the absence of new drugs' entry. These increases were born solely by Medicare, while patient out-of-pocket spending and manufacturer discounts remained relatively constant. A. San-Juan-Rodriguez, M. V. Prokopovich, W. H. Shrank et al., Assessment of Price Changes of Existing Tumor Necrosis Factor Inhibitors After the Market Entry of Competitors, 179 *JAMA Intern. Med.* 713 (2019).

of firm size through leveraging portfolio breadth, with implications for merger analysis in Europe compared to the US.[35]

2.1 Reimbursement

22. After a new drug receives market authorization through the European Medicines Agency or national competent authorities, its price and other conditions of reimbursement (covered indications, age groups, etc.) must be approved by the national payer or payer agent in each country where reimbursement is sought. Although each country's approach to drug pricing is different, certain common features eliminate opportunities for pharmaceutical firms to leverage portfolio breadth through cross-market bargaining.

– Drug-by-drug pricing at launch: A drug's price and other reimbursement conditions are negotiated between the firm and the payer at launch and remain unchanged unless new circumstances require revisions.[36] This drug-specific negotiation of national price/coverage conditions, at launch and for the product's life, eliminates the potential for large firms to gain advantage from portfolio-wide bargaining, with renegotiation of formulary positioning, pricing and rebates annually, as occurs in the US.

– Benchmarks for pricing: Countries that regulate drug prices use two basic benchmarks to determine a reasonable price:

(i) Internal referencing compares the price of the new drug to prices of other, already-marketed drugs in the same country, paying a premium over established prices only if the new drug offers superior benefits or cost savings, as measured by cost-effectiveness or similar metrics;

(ii) External referencing bases the price of the new drug in country X on the mean, median or minimum price of the same drug in specified comparator countries, e.g., an EU-wide median or minimum price.

By focusing solely on the characteristics of the new drug, relative to therapeutic substitutes or its price in other countries, these pricing benchmarks preclude the pharmaceutical firm from gaining pricing advantage by leveraging across its portfolio of drugs.

– Confidential rebates: Rebates off list prices paid by firms to payers are a growing share of gross drug spending in European markets.[37] However, in contrast to the US, these rebates do not arise out of firm bargaining for preferred position. Rather, they arise from three main sources:

(i) Mandatory discounts, as required by the German statutory health insurance (SHI) system, for all drugs sold in retail settings;

(ii) Confidential rebates that firms negotiate with payers as part of initial price/reimbursement negotiations, rather than accept a reduction in a drug's list price that could affect its price in other countries through external referencing (so-called patient access schemes);

(iii) Discounts or paybacks required by some countries (e.g., France) if aggregate drug spending exceeds targets.[38]

23. Although confidential rebates in aggregate are a significant component of net pricing in some European countries, none of these rebate mechanisms are subject to influence by firm-level size or cross-market leverage. They therefore do not raise concerns that size-increasing mergers would enhance a firm's leverage or market power, or result in higher prices or exclusion of competitors.

2.2 Marketing

24. Promotion in general and size-related advantages in marketing for large firms are generally less important in Europe than in the US for several reasons: detailing to physicians is more heavily regulated; universal insurance coverage and low patient cost-sharing reduce the value of free drug samples to physicians and patients in Europe; all European countries ban product-specific, direct-to-consumer (DTC) advertising,[39] which also reduces firms' incentives to continually detail physicians with information to address patients' questions; DTC bans also plausibly reduce brand loyalty of consumers and reduce market power of "must have" drugs; finally, regulation of drug prices reduces profit margins, which reduces the expected return (ROI) and incentives to invest in all forms of marketing in Europe.[40]

2.3 Selling to providers

25. In Europe, physician-administered drugs are typically dispensed in hospital outpatient departments and drug prices are regulated. Unlike the US, dispensing physicians have no financial stake in drug dispensing, beyond possibly a fee for their services.

35 Healthcare, including pharmaceuticals, is a Member State prerogative in the EU and details differ across countries, but with common features. The focus here is on the five largest markets, Germany, France, Italy, Spain and the UK. Canada has features of both European and US pharmaceutical markets, with centralized drug price regulation but provincial public and private pharma plans that bargain with pharmaceutical firms, offering confidential rebates in return for preferred formulary placement and market share.

36 Even countries with multiple competing insurance plans, as in Germany, use a national agency to set drug reimbursement. Germany's AMNOG process allows free pricing at launch but requires a negotiated price based on added therapeutic benefit within 12 months of launch, https://www.oecd.org/health/health-systems/Pharmaceutical-Reimbursement-and-Pricing-in-Germany.pdf.

37 J. Espin et al., Projecting Pharmaceutical Expenditures in EU5 to 2021: Adjusting for the Impact of Discounts and Rebates, 16 *Applied Health Econ. Health Policy*, 803 (2018).

38 S. G. Morgan, S. Vogler & A. K. Wagner, Payers' Experiences with Confidential Pharmaceutical Price Discounts: A Survey of Public and Statutory Health Systems in North America, Europe, and Australasia, 121 *Health Policy* 354 (2017).

39 So-called informative or help-seeking advertisements are permitted, if they simply inform patients of the existence of a treatment for a particular health condition, and advise them to ask their doctor for information.

40 The Dorfman–Steiner theorem states that the optimal level of advertising (as a share of revenue) is equal to the ratio of the advertising elasticity and price elasticity. More price-inelastic demand thus increases the optimal level of advertising, other things equal. R. Dorfman and P. O. Steiner, Optimal Advertising and Optimal Quality, 44 *American Economic Review* 826 (1954).

26. European hospitals typically develop formularies of drugs for use in their outpatient and inpatient settings, and contract with pharmaceutical firms or distributors for these drugs. The limited evidence indicates significant variation across countries in the details of such contracting,[41] with no specific evidence on whether size or portfolio-related advantages exist for larger pharmaceutical firms. However, since hospital pharmacies are well-informed purchasers and are incentivized by reimbursement rules to be cost-conscious, any size-related bargaining advantage enjoyed by large firms in selling drugs to hospitals is likely immaterial for merger analysis in Europe.

2.4 Financing

27. Larger firms in Europe, as in the US, enjoy a relatively low-cost source of capital from sales of marketed products, compared to smaller firms that must raise capital from external capital markets. Such retained earnings enable large firms to acquire other firms at relatively low cost. While this financing advantage could be considered a real efficiency of size, to the extent that it enables large firms to perpetuate their size advantage through mergers, the welfare effects may be questionable.

28. Overall, this review implies that for originator firms, size-related advantages due to leveraging portfolio strength across drugs for reimbursement, marketing and selling, are significantly less in Europe than in the US. The structure of Europe's drug price reimbursement and other regulations pre-empt opportunities to use bargaining leverage across a firm's product portfolio. By implication, the potential for cross-market anticompetitive effects in mergers of originator firms is of less concern in Europe than in the US.

29. We turn next to the generic sector, where mergers are also common and potential cross-market advantages of large firms may be significant, depending on country-specific reimbursement and regulatory structures.

III. Generics

30. Generics are copies of patent-expired, chemically synthesized drugs. To obtain market authorization, generics must demonstrate bioequivalence to the originator drug, but new clinical trials to demonstrate safety and efficacy are not required.[42,43] The policy goal is to reduce the cost and facilitate the entry of generics that are cheaper and can compete on price. Even countries that regulate prices of originator drugs seek to rely more on competition to constrain generic prices, although some set upper limits on generic prices.[44] Competition law thus plays a potentially critical role in promoting generic entry, uptake and price competition.

31. Competition law related to generics in the US and Europe has dealt primarily with countering anticompetitive attempts by originator firms to delay or obstruct generic entry, through pay-for-delay deals and product hopping. These strategies are more likely to be adopted for high-value drugs, but they appear to be unaffected by firm size or mergers, and are not discussed here. More recently, the 51 US state attorneys general charged the generic industry with wide-ranging price-fixing spanning many years, many drugs and several large generic manufacturers.[45] The evidence from these cases is relevant for merger analysis because it suggests that collusion across individual drug markets is facilitated when a small number of firms dominate the set of drug markets, even if concentration in each market individually is low.

32. More generally, this section examines ways in which firm size and therefore mergers may affect competition in generic markets through cross-market effects that are generally neglected in standard merger analysis which focuses on individual markets. The potential for cross-market effects depends on each country's regulatory and distribution system for generics. Generic markets follow three basic models, based on the locus of decision-making: pharmacy-driven markets in the US, UK and Canada; physician-driven markets in Spain, Italy and France; and payers/sick funds in Germany and Italy.[46]

1. Generic markets in the US: Pharmacy-driven

33. Compared to other countries, the US has relatively high generic uptake and low generic prices. In 2019, 90% of prescriptions were dispensed generically but these generics accounted for 20% of prescription sales by value.[47] This US success at driving high generic uptake and low prices reflects several structural features of US markets. In the US, the default rule is that pharmacies may substitute any bioequivalent generic of the same

41 Pharmaceutical procurement and pricing in European hospitals, *The Pharma Letter*, 12-11-99, https://www.thepharmaletter.com/article/pharmaceutical-procurement-and-pricing-in-european-hospitals (last accessed 5.15.2021).

42 In the US, the 1984 Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman" Act), enables a generic company to file an "abbreviated new drug application" (ANDA) that references the safety and efficacy evidence of the originator drug manufacturer, without conducting costly and duplicative clinical trials.

43 Follow-on versions of biologic drugs (biosimilars) have more complex regulatory requirements, due to the difficulty of establishing equivalence to originators and more complex manufacturing processes for biologics. Biosimilars usually are not interchangeable by pharmacists for the originator versions and they are marketed and sold more like on-patent drugs than generics. This discussion therefore only refers to generics for small-molecule, chemically synthesized drugs, not to biosimilars.

44 For example, some Canadian provinces cap generic prices at some percentage of the originator price, where the allowed percentage declines with the number of generic producers in the market.

45 The first complaint was filed in 2016 and now includes 18 corporate defendants and 15 generic drugs. The second complaint was filed in 2019 against 20 of the largest generic drug manufacturers. The third complaint was filed in 2020 against producers of topical generics, https://portal.ct.gov/AG/Press-Releases/2021-Press-Releases/Court-Unseals-Latest-Generic-Drug-Complaint (last accessed 5.23.21).

46 P. M. Danzon & M. F. Furukawa Cross-National Evidence on Generic Pharmaceuticals: Pharmacy vs. Physician-Driven Markets, *NBER Working Paper* 17226 (2011), https://www.nber.org/papers/w17226.

47 https://www.statista.com/statistics/205036/proportion-of-brand-to-generic-prescription-sales (last accessed 5.28.21).

molecule/formulation/strength for the originator drug unless the prescribing physician explicitly requires the originator brand.[48] This authorization for pharmacy substitution makes pharmacies the ultimate customers for generic firms. In the US, most pharmacies are owned by large retail or supermarket chains, such as Walgreens or Walmart. The largest generic producers negotiate nationwide, portfolio-wide contracts directly with chain headquarters. The mail-order pharmacies of the large PBMs are also large generic customers. Smaller generic producers sell through wholesalers/distributors who supply the smaller pharmacy chains.

34. In the US, generic manufacturers can freely set their list prices, such as WAC, which serves as a benchmark from which firms offer rebates to pharmacy or wholesaler customers. WAC is also a benchmark for setting proportional payments to successive parties along the distribution chain, who all benefit from higher prices.[49] Generic firms compete on rebates off their list prices given to pharmacy and wholesaler customers. As noted in the June 2020 collusion complaint:

"*105. Some of the largest downstream buyers that purchase from generic manufacturers benefit when prices are higher. For example, in McKesson's 2014 10-K filing, the company reported: 'A significant portion of our distribution arrangements with the manufacturers provides us compensation based on a percentage of our purchases. In addition, we have certain distribution arrangements with pharmaceutical manufacturers that include an inflation-based compensation component whereby we benefit when the manufacturers increase their prices as we sell our existing inventory at the new higher prices. For these manufacturers, a reduction in the frequency and magnitude of price increases* (. . .) *could have a material adverse impact on our gross profit margin.'* (. . .)

106. Similarly, in Cardinal's 2014 10-K filing, the company reported that: '(. . .) *Prices for generic pharmaceuticals generally decline over time. But at times, some generic products experience price appreciation, which positively impacts our margins.'*"[50]

35. Insurance payers structure their reimbursement to pharmacies to encourage generic substitution and generic price competition, capturing the savings with a lag. Specifically, most payers pay the pharmacy a MAC (maximum allowable cost) for all interchangeable versions of a particular drug. Since pharmacies capture any margin between the MAC and their acquisition cost as profit, pharmacies seek low-priced generics and generic firms compete on rebated price. Over time, payers reduce their MACs to capture the savings from generic price competition. Payers also encourage patients to accept generic substitution, by setting low copayments on generics and high copayments on off-patent originator drugs.[51]

36. In addition to rebates, generic firms gain competitive advantage with pharmacy customers by offering a broad product portfolio (one-stop shopping); early access to new generics (which have the highest prices and profit margins); reliable quality; and, for the largest firms, direct delivery to pharmacies. In this pharmacy-driven environment, generics are generally unbranded and unpromoted, because branding and promotion incur costs and are irrelevant to the pharmacy decision maker focused on price. The empirical evidence confirms that the pharmacy-driven generic markets in the US generally have aggressive price competition once at least 3–4 competitors enter an individual market. The US also has relatively low generic prices, compared to most European countries, despite the US having the highest prices for on-patent drugs.[52]

37. In this pharmacy-driven environment, with pharmacy customers who value large rebates, one-stop shopping, reliable delivery, and early access to new products, large generic firms have significant size advantage and opportunity to leverage cross-market bargaining across broad product portfolios, including "must have" products. In particular, if a large generic firm has a Paragraph IV sole entrant[53] on a blockbuster drug or the only generic version for several, important specialty products, it may bundle these high-value products with its other, competitively supplied products, requiring pharmacy customers to take their entire product line, effectively excluding smaller competitors even if they offer slightly cheaper versions of some products. Size may also increase risks of collusion among firms to raise price and allocate market shares if a few large players dominate a set of generic drug markets.

38. The leading generic firms in the US have grown rapidly, primarily through mergers to acquire new capabilities, products and global reach.[54] Successful top-tier entrants to the US generic market have been large foreign generic companies, notably from India, with low-cost structures and broad product lines.[55] Being a top-tier player also requires having significant expertise and capital needed to successfully challenge patents (PIV

48 Substitutable generics are designated by an "AB rating" from the FDA. Individual states set pharmacy substitution rules, so details vary across states.

49 For example, if a wholesaler buys drugs at WAC-2% and is reimbursed by pharmacies at WAC, the 2% spread is part of the wholesaler's compensation. If payments are proportional to WAC, all tiers of the distribution chain benefit when firms raise WAC prices.

50 https://portal.ct.gov/-/media/AG/Press_Releases/2019/FINAL-Unredacted-Derm-Complaint-CV-002.pdf.

51 Median Medicare copayments in 2021 are $5 for generics and 40% coinsurance for non-preferred brands. *Supra* at 9.

52 *Infra* note 56.

53 Under the 1984 Hatch-Waxman Act, the first generic firm to file a substantially complete ANDA with the FDA and successfully challenge originator patents (PIV) gets six months of market exclusivity as the sole ANDA-approved generic. It may compete with an authorized generic version of the originator, but in this duopoly period, generic prices generally remain at 70–80% of the originator brand, compared to 20–30% once four or more generics enter.

54 For example, market leader Teva has acquired 23 companies, including from 8 countries, https://mergr.com/teva-pharmaceutical-industries-acquisitions#cma-tab.

55 Three of the top 10 US generic drug companies in 2021 originated in India (Sun Pharmaceuticals, Lupin Pharmaceuticals and Dr. Reddy's Laboratories). http://www.imarcgroup.com/top-10-largest-us-generic-drug-companies.

filings) and to develop higher-margin, specialty generics. Thus, when mergers occur among the top 10 firms, it takes time before effective new competitors emerge. Review of mergers involving large generic firms should therefore not only include the traditional analysis of overlapping products in specific drug markets but also assess the potential for leveraging increased power in contracting with pharmacy customers, as well as the increased risk of collusion among dominant firms in specific market segments.

2. Generic markets in Europe: Pharmacy-driven; physician-driven; tenders

39. Generic uptake and prices vary widely across European markets, reflecting differences in regulation and prescribing norms. Generics account for around 50% of the overall European market by volume, ranging from 80% in Germany to 20% in Italy.[56] In contrast to the US, pharmacy substitution is generally not permitted unless the physician prescribes by the drug's international non-proprietary name (INN). Chain pharmacies are also not permitted in some European countries. Differences in INN-prescribing, chain pharmacies and other factors drive differences in generic market structures and competitive dynamics.

2.1 Pharmacy-driven markets

40. In the UK, INN prescribing and pharmacy substitution are widespread, and chain pharmacies are permitted. Similar to the US, UK generic markets are pharmacy-driven, most generics are unbranded, generic prices are low and uptake is high. Generics accounted for 75% of prescriptions in 2017, but only 28% of NHS drugs spending at reimbursement prices. Generic prices in the UK are generally lower than in other large European markets.[57] Similar to the US, large generic firms have size-related advantages in contracting with pharmacy and wholesaler customers, through portfolio breadth, low cost and delivery efficiencies. Payer reimbursement strategies encourage price competition and capture savings with a lag.

2.2 Physician-driven markets

41. In countries such as Spain and Italy, where physicians generally prescribe either the originator or a specific generic by brand name, physicians are the key customers for generics. In such physician-driven generic markets, generics are branded and promoted to physicians like originator drugs, resulting in higher generic prices, lower generic uptake and less savings for payers. Generic firms that have local brand recognition and effective sales force can thrive in such markets, and size may be important mainly if it enhances branding and promotion, which have minimal information value when generics are bioequivalent. Payers have attempted to stimulate price competition by adopting generic reference pricing[58] and creating incentives for physicians to adopt INN prescribing, with limited success.

2.3 Tendering

42. Some payers, notably some German sickness funds and some Italian provincial payers, have adopted tendering to drive price competition and capture savings on retail generics.[59] Tendering is also used by hospital pharmacies in many countries.[60] Large firms with broad portfolios may have competitive advantage if tenders on multiple products are bundled together, with suppliers required or permitted to compete on all products. However, if payers run tenders frequently and separately, with low barriers to entry and avoiding winner-take-all strategies, smaller firms should be able to compete if they can offer lower prices and meet quantity and quality requirements. In general, tendering offers a pro-competitive mechanism to stimulate price competition that is otherwise weak in physician-driven, branded generic markets.

43. This review of generic markets concludes that mergers that enhance generic firm size (number, volume and criticality of products) can create both competitive advantage and anticompetitive risks. In pharmacy-driven markets, size brings real efficiencies but also bargaining leverage for generic firms in contracting with large pharmacy or wholesaler customers. Because large pharmacy customers are well informed and motivated by their reimbursement to be price conscious, the ability of dominant incumbent generic firms to exclude lower-cost competitors is limited. In contrast to originator markets, payers reimburse pharmacies for generics using forms of reference pricing (MAC reimbursement in the US) that can be designed to stimulate generic price competition and capture savings for payers. Similar conclusions apply to generic markets with tendering. However, large firm size also increases the risks of collusion among generic firms to raise prices and allocate markets in pharmacy-driven or tendering contexts.

44. In physician-driven markets, firm size and mergers may convey some advantage in brand recognition, but smaller firms with niche portfolios can survive. In general, competition is on brand, not price, and branded generic prices are high, relative to unbranded generics in pharmacy-driven markets. Increasing price competition in physician-driven generic markets requires changes in regulation, for example, authorizing pharmacies to

56 Deloitte, European market-entry strategies for generics companies (2016), https://www2.deloitte.com/us/en/pages/life-sciences-and-health-care/articles/european-market-entry-strategies-for-generics-companies.html. O. J. Wouters, P. G. Kanavos & M. McKee, Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes and, Spending, 95 *Milbank Quarterly* 554 (2017).

57 Selling prices (net of rebates) are significantly lower than reimbursement prices. Oxera, The Supply of Generic Medicines in the UK, June 2019, www.oxera.com.

58 Under generic reference pricing, the payer reimburses all generics at a single "reference price" based on the price of a relatively low-priced generic.

59 Deloitte, *supra* note 56.

60 *Supra* note 39.

substitute any bioequivalent generic, regardless of brand or INN prescribing, and allowing chain pharmacies. Without such regulatory changes, competition on brand rather than price is likely to remain.

IV. Conclusions

45. This review concludes that, while standard analysis of concentration in individual product markets remains the essential core of antitrust review of pharmaceutical mergers, consideration of cross-market effects is potentially important in mergers involving large firms, whose broad portfolios, especially those with must-have products, create bargaining leverage that can be used to exclude competitors, including those with superior products or lower prices. However, these concerns over potential cross-market merger effects depend on institutional details that differ across countries and between originator and generic segments.

46. Concerns are greatest for large originator firm mergers in the US, where the reimbursement, marketing and selling environments create advantages for large firms that can be exploited through anticompetitive cross-market contracting. Any size-related savings are unlikely to benefit consumers, because insurance blunts competition on price.

47. By contrast, concerns over cross-market effects in mergers involving large originator firms are minimal in Europe, where the structure of drug price reimbursement and other regulations pre-empt opportunities for anticompetitive use of bargaining leverage across a firm's product portfolio. Although large firms may have advantages of repeat-game experience in negotiating with regulators, the process of setting each drug's price and reimbursement criteria at launch, by reference only to therapeutic substitute products, eliminates opportunities for large firms to exploit portfolio bargaining. Thus, the concerns over anticompetitive effects of originator pharmaceutical mergers are minimal in Europe but significant in the US.

48. In reviewing mergers of generic firms, the potential for real efficiency savings from increased scale and scope must be weighed against large firms' potential anticompetitive use of their portfolio bargaining leverage when contracting with pharmacies or wholesalers. The potential for efficiency savings that are passed on to consumers is greater in pharmacy-driven generic markets such as the US and UK than in physician-driven markets. However, recent US experience shows that when the same generic firms dominate multiple drug markets, collusion spanning markets becomes possible. Nevertheless, the persistent fact of relatively low generic prices and broad generic uptake in the pharmacy-driven generic markets of the US and UK indicates that efficiencies have dominated anticompetitive effects overall, at least so far. Significant savings are possible if physician-driven markets adopt regulatory changes needed to evolve to become pharmacy-driven markets, and mergers may be a necessary part of this evolution. Overall, the potential in generic markets for competitive structure and price-competitive reimbursement implies that, absent collusion, cross-market effects are a lesser concern in mergers of generics than originator firms. ■

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