



Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue NW
Washington, DC 20580

Re: Pharmaceutical Task Force, Project No. P212900 (Docket No. FTC-2021-0025)

The American Antitrust Institute (AAI) appreciates the opportunity to submit comments in the Federal Trade Commission (FTC) proceeding: *Pharmaceutical Task Force, Project No. P212900 (Docket No. FTC-2021-0025)*. AAI commends Commissioner Slaughter for jumpstarting the task force in her capacity as Acting Chair and encourages Chair Khan to pursue this vitally important initiative with all of its intended vigor and thoroughness. AAI's comments address a key topic posed by the Multilateral Pharmaceutical Task Force request for public comment: effective remedies for anticompetitive mergers of branded and generic pharmaceutical companies.

I. AAI's History of Research, Education, and Advocacy on Competition in the Pharmaceutical Sector

AAI has a more than a 20-year history of research, education, and advocacy on the importance of vigorous antitrust enforcement and constructive competition policy in the pharmaceutical sector.¹ AAI has provided legal, economic, business, and institutional analysis of the adverse effects of consolidation and concentration on competition, consumers, and innovation. AAI is uniquely positioned to provide insight into the structure of pharmaceutical markets, strategic anticompetitive practices, anticompetitive abuse of regulatory processes, remedies that fully restore competition, and policies that promote competition and the protection of consumers and innovation. The integrity and stability of the healthcare system is a matter not only of competition and consumer welfare, but also of national wellness, safety, and security.

In September 2020, AAI issued the widely-cited report: *FROM COMPETITION TO CONSPIRACY: ASSESSING THE FEDERAL TRADE COMMISSION'S MERGER POLICY IN THE PHARMACEUTICAL SECTOR* (AAI Pharma Report).² AAI's comments in this proceeding are based on the empirical analysis and recommendations contained in the report. The analysis highlights the fading promise of competition, in both branded pharmaceutical R&D and generic drug markets, for ensuring the provision of accessible, affordable, essential drugs to U.S. consumers. The AAI Pharma Report reveals evidence that connects rising market concentration and high drug prices. Price gouging for important drugs, conspiracies to fix generic drug prices, and ever more innovative schemes by

¹ The American Antitrust Institute (AAI) is an independent, nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. For more information, please visit antitrustinstitute.org.

² *FROM COMPETITION TO CONSPIRACY: ASSESSING THE FEDERAL TRADE COMMISSION'S MERGER POLICY IN THE PHARMACEUTICAL SECTOR* (AAI PHARMA REPORT), AM. ANTITRUST INST. (Sept. 3, 2020).

branded drug manufacturers to keep generic rivals out of the market therefore put merger control at center stage.

II. The FTC's Pharmaceutical Merger Policy Has Resulted in the "Swapping" of Assets Within a Shrinking Group of Large Drug Manufacturers

The AAI Pharma Report examines a major root of the competition problem in pharmaceutical markets—the FTC's policy of settling virtually all challenged horizontal pharmaceutical mergers with consent orders requiring divestitures. AAI's analysis of the 67 pharmaceutical mergers challenged by the FTC between 1994-2020 reveals that many drug makers engaged in serial mergers and/or repeatedly purchased divestiture assets in other challenged mergers. Many of these firms were subsequently acquired by other pharmaceutical manufacturers, sometimes shortly after purchasing divestiture assets.

The AAI Pharma Report finds that just under 20% of all unique branded and generic firms that engaged in repeated M&A and/or purchases of divestiture assets account for almost 45% of pharmaceutical assets "changing hands" from 1994-2020.³ In other words, a relatively small group of drug manufacturers have been involved in a significant proportion of M&A activity and purchases of divestiture assets. The effect of the FTC's policy therefore has been the swapping of assets within a relatively small group of large and increasingly powerful drug companies.

Moreover, many of the very firms that were the most active in M&A, and as purchasers of divestiture assets, have been named as defendants in private, state, and federal non-merger antitrust litigations and in federal criminal indictments. These accumulating lawsuits are strong evidence that the FTC's policy of settling all challenged mergers with divestitures has created market conditions conducive to the exercise of market power by dominant firms and tight oligopolies. The FTC's role in managing the allocation and ownership of critical pharmaceutical assets through its merger policy has unduly involved it in shaping the industry—an approach that resembles "industrial planning," not law enforcement.

The FTC's merger policy has also deprived the competition community and public of important transparency. Highly concentrative mergers are presumed to be harmful to competition and consumers. However, the FTC's consistent strategy of almost never seeking injunctions to stop harmful deals means that there is no judicial record on how defendants in 67 pharmaceutical mergers would have overcome a presumption of illegality with a showing of merger-specific, cognizable efficiencies. The FTC's policy thus leaves the courts and consumers in the dark on how pharmaceutical mergers have delivered claimed benefits of a sufficient magnitude to allay concerns over adverse effects.

In sum, competition problems in pharmaceutical markets now rise to the level of a public policy concern that requires a coordinated policy response, including stronger antitrust enforcement. The imperative for wholesale change in the FTC's merger policy in the pharmaceutical sector is more pressing than ever. Only robust competition among drug manufacturers will result in the availability and affordability of drugs. The FTC, which has devoted considerable resources and

³ AAI PHARMA REPORT, *supra* note 2, at note 45.

expertise to understanding the pharmaceutical sector, should take the lead in reforming its own policy on merger control.

III. Curing Anticompetitive Pharmaceutical Mergers through Divestitures Has Proved Largely Unsuccessful

In unpacking challenged pharmaceutical mergers over the period 1994-2020, the AAI Pharma Report found that the vast majority were highly concentrative. For example, of the over 350 total relevant markets identified in Commission documents in 67 challenged merger investigations, over 25% involved 4-3 mergers, over 35% involved 3-2 mergers, and almost 25% involved 2-1 mergers. Some generic “mega-mergers” involved a large number of drug-specific relevant markets, including Teva-Barr, Teva-Allergan, and Watson-Actavis. Before any required divestitures, the effect of pharmaceutical mergers in the majority of cases was therefore to increase concentration in *already* highly concentrated markets.⁴ The role of patent protection in branded drugs and the process of generic entry under the Hatch-Waxman Act exacerbate concentration in drug markets—a feature that the FTC’s merger policy has not adequately recognized.

Highly concentrative mergers, and the guaranteed adverse effects they have on competition and consumers, put enormous pressure on a remedy to fully restore competition lost by an anticompetitive merger. This is because the more concentrative a merger, the commensurately higher is the risk that the remedy will fail to restore lost competition.⁵ For example, to the extent a buyer of divested assets cannot quickly reinject pre-merger competitive discipline, the remedy is more likely to fail. And any confidence that the remedy will fully restore competition is eliminated if the purchaser turns around and sells the asset(s) shortly after purchase. This stands in stark contrast to the most effective remedy, a full stop injunction, that would ensure that future anticompetitive conduct is fully deterred.⁶

The performance of divestiture assets exacerbates the foregoing concern. For example, the Commission’s most recent study of divestitures from 2006-2012 highlights systemic problems. For example, the Commission found generally that divestitures of limited packages of assets fared less well than divestitures of ongoing businesses.⁷ Because generic drug merger settlements almost *always* involve discrete packages of assets rather than ongoing businesses, the study shines the light on the ineffectiveness of such remedies.

Second, the FTC study reviewed 24 consent orders involving 60 on-market generic drugs.⁸ It found that only 75% of buyers of divestiture assets actually sold the drug, post-divestiture. For the 25% of buyers that did not, the failure rate on oral solid generics divestitures was 18% and the rate on complex generics divestitures was 36%.⁹ Given the importance of generic competition for consumers’ access to fairly priced, life-saving medications, the failure of divestitures in generic drug mergers signals the need for the FTC to reform its pharmaceutical merger policy.

⁴ AAI Pharma Report, *supra* note 2, at 16.

⁵ [FTC’S MERGER REMEDIES 2006-2012](#), Fed. Trade Comm’n Bureau of Competition and Econ. (2017).

⁶ See, e.g., Diana L. Moss, *Realigning Merger Remedies with the Goals of Antitrust*, in GCR GUIDE TO MERGER REMEDIES 32 (2d ed. 2019).

⁷ *Supra* note 5.

⁸ *Id.*

⁹ *Id.*

IV. AAI's Recommendations for Overhauling the FTC's Policy on Merger Control in the Pharmaceutical Sector

Analysis in the AAI Pharma Report highlight the need for major changes to the FTC's policy on merger control in the pharmaceutical sector. Competitive concerns forced the abandonment of the recent proposed merger of Sandoz and Aurobindo, which would have created the second largest generic firm in the world.¹⁰ This may signal that the FTC's policy is moderating. However, the FTC's policy of settling virtually all concentrative mergers with divestitures has already raised the bar on future merger challenges that the agency should seek to litigate.

For example, the absence of any judicial record on past mergers provides no transparency or ability to predict outcomes in future litigated cases. Courts therefore will be starting from "scratch" in evaluating the burden on the FTC to demonstrate the likelihood of anticompetitive harms, and in considering the burden on defendants to show countervailing efficiencies. Moreover, the FTC's lack of a record of litigation outcomes makes potential future litigation less predictable. In other words, with the FTC's current record of always settling deals, it will be more difficult to assess litigation risk when the agency contemplates going to court to seek an injunction. This could lead the agency to misjudge the risk and to seek weak settlements in cases it could have won and to litigate cases it should have settled.

Even in light of the foregoing challenges, the Commission can take steps now to reduce litigation risk and uncertainty involving pharmaceutical mergers. AAI therefore recommends that the FTC consider the following steps to raise the bar on merging parties and to strengthen enforcement, the combined effect of which will be to slow down consolidation.

- **Abandonment of current merger policy of not seeking injunctions:** The FTC's long-term policy of settling virtually all drug mergers subject to divestitures has resulted in the swapping of assets within a shrinking group of large and increasingly powerful drug companies. The agency should therefore move expeditiously to abandon its policy of settling drug mergers with divestitures and move to enjoin more highly concentrative mergers.
- **Automatically seeking injunctions on generic "mega-mergers":** The FTC has allowed a number of generic mega-mergers, each of which affected competition in numerous relevant drug markets. These mega-mergers should be of particular concern, given rising concentration in pharmaceutical markets and the high rate of failed generic divestitures. The potential adverse effects of mega-mergers are significant and pose unacceptable risk for competition and consumers. The FTC should routinely move to enjoin generic drug mergers that involve a large number of relevant markets, as identified in a Commission complaint.
- **Discouraging further M&A by "serial acquirers":** Serial M&A and acquisitions of divested assets are a major driver of the concentration of pharmaceutical assets in the hands of a shrinking group of large firms. The FTC should discourage companies with a deep record of past M&A and divestiture asset purchases from pursuing additional mergers. This can be accomplished through a higher rate of second requests; routine specification of crown-jewel assets; and consent orders requiring post-consummation reporting on the realization of claimed efficiencies.

¹⁰ Angus Liu, Novartis, *Aurobindo Admit Defeat by FTC in Aborting Their \$1B Generics Deal*, FIERCE PHARMA (Apr. 2, 2020).

- **Banning certain antitrust “violators” from purchasing divested assets:** Violators of both civil and criminal antitrust law have demonstrated “intent” to engage in harmful conduct. As a result, they should be deemed non-viable buyers of divested assets. The FTC should therefore clearly signal that it will not consider companies that are named defendants in a pending federal investigation, or have recently been a named defendant in any civil or criminal cases that was not dismissed on the pleadings.
- **Required reporting on claimed efficiencies:** A complete absence of information in non-litigated merger cases on efficiencies creates unacceptable opacity in how the agencies consider anticompetitive effects in the balance with pro-competitive benefits involving pharmaceutical mergers. For those deals that are allowed to proceed, the FTC should provide detailed, publicly available analysis of claimed merger-specific and cognizable cost-savings or consumer benefits that were considered in coming to a Commission decision.
- **Monitoring “turn-around” sales of divested assets:** Currently, the FTC does not appear to appreciably monitor the disposition of divested assets. The AAI Pharma Report reveals that buyers of divested assets have in a number of cases quickly disposed of the assets after purchase. Such “turn-around” sales of assets that are not reportable fly under the antitrust radar, with material effects on market concentration. To increase the transparency of the effects of M&A on market concentration, the FTC should monitor all sales (reportable and unreportable) of purchased assets for 10 years post-divestiture, and publish an annual report on their disposition and effect on market concentration.

Respectfully submitted,
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FROM COMPETITION TO CONSPIRACY: *ASSESSING THE FEDERAL TRADE COMMISSION'S MERGER POLICY IN THE PHARMACEUTICAL SECTOR*

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“The Commission has developed significant expertise in the pharmaceutical industry and follows a standard approach for evaluating these mergers and designing relief.”

– Federal Trade Commission (2017)¹

I. INTRODUCTION

Prescription drugs safeguard Americans from numerous life-threatening maladies. Penicillin and bronchodilators protect children from infections and asthma. Beta-blockers and antidiabetics protect older Americans from heart disease and adverse symptoms from diabetes. And lipid-lowering drugs and antidepressants prevent heart attacks, strokes, and depression.² Competition in pharmaceutical R&D, and for generic entry, produces essential drugs and ensures that medications are accessible and affordable.³ That promise is fading. There is mounting evidence that connects high market concentration and high drug prices. Price gouging for important drugs, conspiracies to fix generic drug prices, and ever more innovative schemes by branded drug manufacturers to keep generic rivals out of the market put merger control at center stage.

The accretion of market power by drug companies has predictable and concerning outcomes. Some powerful drug manufacturers have tested the mettle of U.S. antitrust enforcers. Teva Pharmaceutical Industries (Teva) reportedly walked away from early settlement talks with the U.S. Department of Justice (DOJ) for its participation in a price-fixing conspiracy for widely used drugs. In providing drugs in response to the COVID-19 pandemic, the powerful generic drug manufacturer wagered that ...the U.S. [wouldn't] dare charge it with crimes.⁴ The government has since obtained charges against the Israel-based drug manufacturer.

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¹ FED. TRADE COMM'N BUREAUS OF COMPETITION AND ECON., FTC'S MERGER REMEDIES 2006-2012, (2017), www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf.

² CRESCENT B. MARTIN ET AL., CTRS. FOR DISEASE CONTROL & PREVENTION, PRESCRIPTION DRUG USE IN THE UNITED STATES, 2015–2016 (2019) <https://www.cdc.gov/nchs/products/databriefs/db334.htm>.

³ William S. Comanor & F.M. Scherer, *Mergers and Innovation in the Pharmaceutical Industry*, 32 J. OF HEALTH ECON., 106, 108 (2013).

⁴ Katie Benner et al., *Drug Maker Wagers U.S. Won't Dare Pursue Case*, N.Y. TIMES, May 16, 2020, at B3.

This White Paper examines a major root of this problem—the Federal Trade Commission’s (FTC’s) policy of settling virtually all challenged horizontal pharmaceutical mergers with consent orders requiring divestitures. This stands in contrast to agency decisions to seek injunctions to stop highly concentrative, harmful mergers—arguably the most effective remedy for fully restoring competition. AAI’s macro-analysis of pharmaceutical mergers challenged by the FTC between 1994-2020 (to date) reveals that many drug makers engaged in serial mergers and/or repeatedly went to the till to purchase divestiture assets in other challenged mergers.⁵ Many of these firms were subsequently acquired by other pharmaceutical manufacturers, sometimes shortly after purchasing divestiture assets.

The effect of the FTC’s policy has been the swapping of assets within a relatively small group of large and increasingly powerful firms. Just under 20% of all unique branded and generic firms that engaged in repeated mergers and acquisitions (M&A) and/or purchases of divestiture assets account for almost 45% of pharmaceutical assets “changing hands” from 1994-2020. Many of the very firms that were the most active in M&A, and as purchasers of divestiture assets, appear as defendants in private, state, and federal non-merger antitrust litigations and in federal criminal indictments. These accumulating lawsuits serve as powerful evidence that something has gone awry with merger policy in the pharmaceutical sector, leading to the exercise of market power by dominant firms and oligopolies.

The FTC’s role in managing the allocation and ownership of important pharmaceutical assets through its extraordinary approach toward merger control has unduly involved it in shaping the industry. This resembles a form of “industrial planning” rather than antitrust law enforcement, which is designed to deter future anticompetitive conduct and relies on market forces to determine market structures.⁶ The FTC’s policy has also deprived the antitrust community and public of important transparency. Because no challenged merger between 1994-2020 was litigated in federal court, there is no judicial record detailing how highly concentrative mergers were likely to have survived a presumption of illegality. There is thus no way to evaluate claims that pharmaceutical mergers were likely to have delivered lower prices through claimed cost savings or consumer benefits due to improved quality and innovation.

This White Paper begins with background on drug pricing and competition in the pharmaceutical supply chain. It then turns to the drug mergers themselves and the asset divestitures required in FTC consent orders. Next is an assessment of private, state, and federal antitrust cases against the companies involved in M&A and as buyers of divestiture assets. It concludes with policy recommendations on reframing competition policy in the pharmaceutical sector. The FTC, which has significant expertise in the pharmaceutical sector, and an admirable record of enforcement in the non-merger area, should take the lead in reforming its own policy on merger control.⁷

⁵ Commission remedies include divestitures; transfers of development, marketing, distribution rights; and licensing of intellectual property. This analysis focuses on remedies that involve the transfer of operational control of economic assets to a different entity.

⁶ Nick Archer, *FTC Comes Down Hard on Cement Industry*, MANHATTAN INST. FOR POL’Y RES. (June 24, 2016) <https://economics21.org/html/ftc-comes-down-hard-cement-industry-1909.html> (“[I]t is important to see the actions of the FTC for what they are: industrial planning, not consumer protection.”).

⁷ Among other major events and efforts, the agency has performed two studies of its historical divestitures, including in pharmaceuticals. It has also held numerous workshops on competition in drug markets, most recently in 2017. See *Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics* (Nov. 8, 2017) <https://www.ftc.gov/news-events/events-calendar/2017/11/understanding-competition-prescription-drug-markets-entry-supply>.

Competition problems in pharmaceuticals now rise to the level a public policy concern, addressable only through a coordinated policy response, of which stronger antitrust enforcement and legislative reform should be central components. The imperative for wholesale change in the FTC's merger policy in the pharmaceutical sector is more pressing than ever. Only robust competition among drug makers will result in the availability and affordability of drugs more generally, but also essential drug therapies and vaccines relating to the COVID-19 pandemic.

II. THE PROBLEM OF HIGH DRUG PRICES

Evidence of the adverse effects of high concentration is a resounding rebuttal to the now defunct claim that consolidation generally produces efficiencies that outweigh harm to competition and consumers. Economic analysis of pharmaceutical markets shows high concentration. Some sources estimate that over 50% of generic molecules are sold in markets with only one or two suppliers, with significant increases in those shares for some oral, injectable, and other formulations for periods between 2004-2016.⁸ Generic entry, which peaked around 2012, has also fallen since around 2010.⁹ Studies also draw a close connection between market concentration and higher prices. For example, a retrospective study of over 1,000 generic drugs, using data on prescription claims from commercial health plans from 2008-2013, shows that the level of market concentration is strongly associated with higher price increases.¹⁰ The study finds that price increases are more pronounced within concentrated product markets and for acquisitions of drugs still in the pipeline.¹¹

“Some sources estimate that over 50% of generic molecules are sold in markets with only one or two suppliers and the level of market concentration is strongly associated with higher price increases.”

The foregoing studies paint a grim picture for evaluating pricing abuses in pharmaceuticals. To better understand the significance of drug prices, we note that the U.S. pharmaceutical market accounts for one-third of the global market.¹² Americans are projected to spend almost \$360 billion on retail pharmaceuticals in 2020.¹³ This is an increase of over 40% from about \$250 billion in 2010. Nearly one in two Americans has

⁸ ERNST R. BERNDT, RENA M. CONTI, & STEPHEN J. MURPHY, THE LANDSCAPE OF US GENERIC PRESCRIPTION DRUG MARKETS, 2004-2016. NBER working paper #w23640, at 53-56 (July 2017) <http://www.nber.org/papers/w23640>.

⁹ Id., at 43.

¹⁰ Dave V. Chintan et al., High Generic Drug Prices and Market Competition: A Retrospective Cohort Study, 167 ANNALS INTERNAL MED. 145 (Aug. 2017), <https://pubmed.ncbi.nlm.nih.gov/28672324/#affiliation-1>.

¹¹ Alice A. Bonaime and Ye Wang, *Mergers, Product Prices, and Innovation: Evidence from the Pharmaceutical Industry* (Mar. 15, 2019), <https://ssrn.com/abstract=3445753>. The analysis shows that prices increased 2.4-3.5% more for drugs in consolidating markets and remained at elevated levels for two years.

¹² INT'L. TRADE ADMIN., BIOPHARMACEUTICAL SPOTLIGHT <https://www.selectusa.gov/pharmaceutical-and-biotech-industries-united-states>. This is despite that fact that Americans make up only 4.3% of the global population, according to <https://www.census.gov/popclock/>.

¹³ Matej Mikulic, *Prescription Drug Expenditure in the United States from 1960 to 2020*, STATISTA (Jun. 12, 2020) <https://www.statista.com/statistics/184914/prescription-drug-expenditures-in-the-us-since-1960/>.

used prescription drugs within the last thirty days¹⁴ and Americans filled nearly 4.5 billion retail prescriptions in 2019, with that number expected to increase to nearly 5 billion in 2025.¹⁵ Prices for prescription drugs are high and rising. Between 2008 and 2016, the consumer price index for prescription drugs increased at a rate more than double that of inflation.¹⁶

Pharmaceutical manufacturers retain the lion's share of the price paid by the consumer. For example, for a \$100 blood pressure medication, the manufacturer keeps \$62, the wholesaler keeps \$.50 cents, the pharmacy benefit manager (PBM) keeps about \$11, and the pharmacy keeps about \$5.¹⁷ Drug manufacturers have strong incentives to protect their cut. Between 2006 and 2015, the 25 largest drug producers had average annual profit margins of 15-20%.¹⁸ These supra-normal returns are often defended as necessary to incentivize significant expenditures on pharmaceutical R&D in an industry where the probability of producing commercialized, blockbuster drugs is low. But they are higher than the average annual profit margins of non-drug companies with R&D expenses comparable to those in the pharmaceutical industry.¹⁹ As discussed later, this period of supra-normal returns corresponds closely with a significant uptick in pharmaceutical M&A activity.

Concerns over high drug prices have intensified as companies have successfully attempted significant price increases for life-saving medications. Mylan increased the price for a pack of two Epi-Pen auto-injectors to over \$600 in 2016, a 400% price increase beginning in 2011 for a 100-year old drug that costs \$1 per dose to manufacture.²⁰ Even with generic entry by Teva in 2017, the price of the EpiPen two-pack remains high, averaging close to \$400.²¹ Another example is insulin, needed to treat diabetes that affects more than 10% of Americans.²² There are only three manufacturers of insulin, with no generic alternatives.²³

“Drug pricing problems have spurred legislative proposals designed to protect competition and consumers, targeting harmful conduct that ranges from agreements to pay generic firms to stay out of the market, to excessive pricing, and other problems.”

¹⁴ CRESCENT B. MARTIN, *supra* note 2 at 1–2.

¹⁵ M. Shahbandeh, *Total Number of Retail Prescriptions Filled Annually in the United States from 2013 to 2025*, STATISTA (Nov. 12, 2019) <https://www.statista.com/statistics/261303/total-number-of-retail-prescriptions-filled-annually-in-the-us/>.

¹⁶ COUNCIL OF ECONOMIC ADVISORS, *MEASURING PRESCRIPTION DRUG PRICES: A PRIMER ON THE CPI PRESCRIPTION DRUG INDEX* at 17 (Oct. 2019) <https://www.whitehouse.gov/wp-content/uploads/2019/10/Measuring-Prescription-Drug-Prices-A-Primer-on-the-CPI-Prescription-Drug-Index.pdf>.

¹⁷ Matej Mikulic, *Flow of Payments for a 100 Dollar Blood Pressure Medication if the Patient Pays a Copayment in the U.S. as of 2017*, STATISTA (May 23, 2018) <https://www.statista.com/statistics/829418/payment-flow-for-100-usd-blood-pressure-medication-with-patient-copayment/>.

¹⁸ *Drug Industry: Profits, Research and Development Spending, and Merger and Acquisition Deals*, Governmental Accountability Office, Report GAO-18-40 (Nov. 2017).

¹⁹ Fred D. Ledley, Sarah Shonka McCoy, and Gregory Vaughan, et al., *Profitability of Large Pharmaceutical Companies Compared With Other Large Public Companies*, 323 JAMA 834 (2020), <https://jamanetwork.com/journals/jama/article-abstract/2762308>.

²⁰ Tori Marsh, *Generic EpiPen Is Still Expensive – Here's How You Can Save*, GoodRx (Oct. 30, 2019) <https://www.goodrx.com/blog/generic-epipen-is-still-expensive-heres-how-you-can-save/>; *Committee on Oversight and Gov't Reform, Hearing on Reviewing the Rising Price of EpiPens*, 114th Cong. 3 (2016) <https://www.govinfo.gov/content/pkg/CHRG-114hhrg24914/pdf/CHRG-114hhrg24914.pdf>.

²¹ Tori Marsh, *supra* note 20.

²² Tara O'Neill Hayes & Margaret Barnhorst, *Understanding the Insulin Market*, AMERICAN ACTION FORUM (Mar. 3, 2020) <https://www.americanactionforum.org/research/understanding-the-insulin-market/>.

²³ *Id.*

Prices for insulin increased, on average, 14% annually between 2012–2018, forcing some patients to ration their supplies—a potentially lethal practice.²⁴ A final example involves Daraprim, used for treating toxoplasmosis and that is over 60 years old. After the drug was acquired by Turing Pharmaceuticals in 2015, the price rose from \$13 to \$750 per tablet, an increase of more than 5,500%.²⁵ Even \$13 per tablet was a large increase from Daraprim’s approximately \$1 per tablet only a few years earlier.²⁶

The foregoing problems have spurred legislative proposals designed to protect competition and consumers. They target harmful conduct that ranges from agreements to pay generic firms to stay out of the market, to excessive pricing, and other problems. Federal legislative efforts on this front include the CREATES Act of 2019, Protecting Consumer Access to Generic Drugs Act of 2019, and Prescription Drug Price Relief Act of 2019.²⁷ The CREATES Act was created to ease the development of affordable generic and biosimilar drugs.²⁸ The Protecting Consumer Access to Generic Drugs Act would make pay-for-delay agreements illegal, in order to address one cause of “the skyrocketing cost of prescription drugs.”²⁹ The Prescription Drug Price Relief Act focuses on taking intellectual property protection away from firms that charge higher median prices for their drugs in the U.S. than in other countries.³⁰ California has also introduced legislation to make pay-for-delay agreements presumptively illegal.³¹ In signing the legislation, California Governor Newsom emphasized that the legislation was based on both competitive and moral concerns: competition in pharmaceuticals is good both for lower prices and maintaining access to life-saving drugs.³²

III: CONCENTRATION IN THE PHARMACEUTICAL SUPPLY CHAIN

The structure of the markets that form the pharmaceutical supply chain is a major determinant of competition and, ultimately, the pricing and availability of branded and generic drugs. But markets in the supply chain cannot be viewed in isolation. Dominant players and oligopolies often have bargaining power over upstream suppliers or downstream distributors.³³ This dynamic affects competition, for example, between PBMs in negotiating with health insurers on prescription drug plans, drug manufacturers in negotiating rebates with PBMs, and distributors in negotiating medical supplies contracts with hospitals. In highly concentrated markets along the supply chain, such bargaining produces prices that are set through negotiations between powerful market players, not by a competitive process.

²⁴ Tara O'Neill Hayes & Josee Farmer, *Insulin Cost and Pricing Trends*, AMERICAN ACTION FORUM (Apr. 2, 2020) <https://www.americanactionforum.org/research/insulin-cost-and-pricing-trends>; Bram Sable-Smith, *Insulin's High Cost Leads To Lethal Rationing*, NAT'L PUB. RADIO, Sept. 1, 2018, www.npr.org/sections/health-shots/2018/09/01/641615877/insulins-high-cost-leads-to-lethal-rationing.

²⁵ Andrew Pollack, *Once a Neglected Treatment, Now an Expensive Specialty Drug*, N.Y. TIMES, Sept. 20, 2015 at B1.

²⁶ *Id.*

²⁷ S. 340, 116th Cong. (2019) (incorporated into H.R. 1865, 116th Cong. (2019), which was enacted on December 20, 2019); H.R. 1499, 116th Cong. (2019); S. 102, 116th Cong. (2019).

²⁸ S. 340, 116th Cong. (2019).

²⁹ Press Release, Bobby L. Rush, United States Congressman, 1st District of Illinois, Rush Introduces the Protecting Consumer Access to Generic Drugs Act (Mar. 5, 2019) <https://rush.house.gov/media-center/press-releases/rush-introduces-the-protecting-consumer-access-to-generic-drugs-act>.

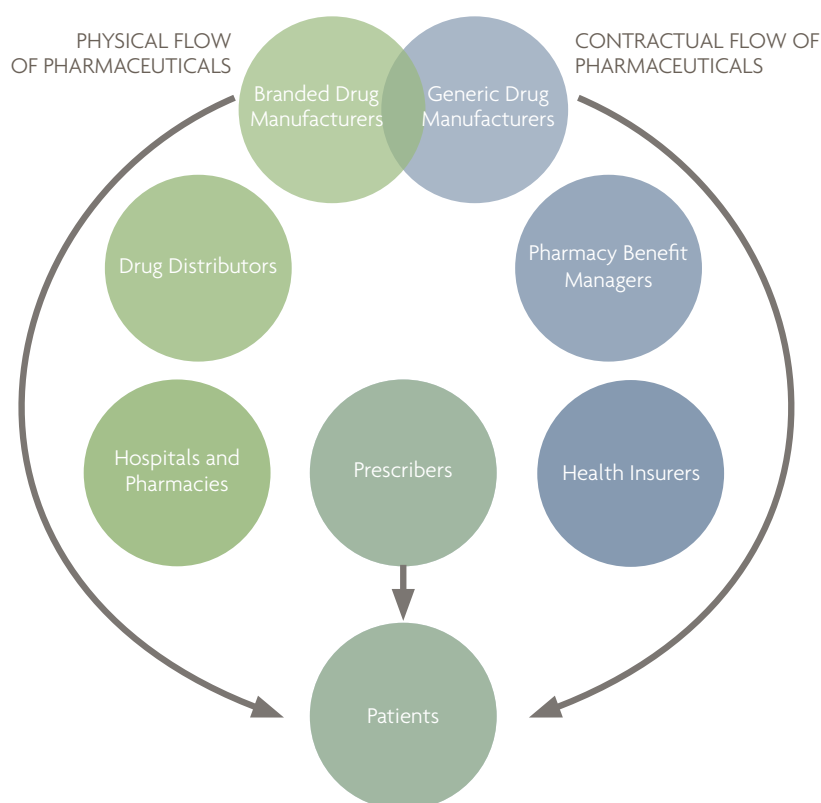
³⁰ S. 102, 116th Cong. (2019).

³¹ A.B. 824, 2019–20 Sess. (Cal. 2019).

³² Press Release, Gavin Newsom, Governor, State of California, Governor Gavin Newsom Signs Legislation Banning “Pay for Delay” to Fight Runaway Prescription Drug Costs (Oct. 7, 2019) <https://www.gov.ca.gov/2019/10/07/governor-gavin-newsom-signs-legislation-banning-pay-for-delay-to-fight-runaway-prescription-drug-costs/>.

³³ Germaine Gaudin, *Vertical Bargaining and Retail Competition: What Drives Countervailing Power?*, 128 ECON. J. 2380, 2380 (2018).

FIGURE 1: THE PHARMACEUTICAL SUPPLY CHAIN



Pharmaceutical markets are positioned in the upstream part of the drug supply chain.³⁴ As shown on the left side of Figure 1, drugs flow physically through the supply chain from pharmaceutical manufacturers, to drug wholesalers, and to pharmacies and hospitals. On the right side of the figure is the contractual flow of drugs, where drug manufacturers negotiate formularies with PBMs as part of prescription drug plans offered to subscribers through health insurers.

Concentration levels in many parts of the pharmaceutical supply chain are high. The top three branded pharmaceutical firms, Johnson & Johnson, Roche, and Pfizer, account for just over 40% of the global market.³⁵ In contrast, the top three generic firms, Mylan, Sandoz (Novartis), and Teva, control over 65% of the generic market.³⁶ The PBM market is dominated by three large players that control over 75% of the national market: CVS Caremark (30%), Express Scripts (23%) and Optum Rx (23%).³⁷ In a sweeping set of recent mergers that have transformed the drug supply chain, the three major PBMs are now integrated with a different major health insurer. The wholesale drug distribution market also features only a few major competitors. Three firms control over 90% of the national

³⁴ *What's the Difference? Biosimilar and Generic Drugs*, CANCER TREATMENT CENTERS OF AMERICA (Dec. 26, 2018) <https://www.cancercenter.com/community/blog/2018/12/whats-the-difference-biosimilar-and-generic-drugs>.

³⁵ Eric Sagonowsky, *The Top 20 Pharma Companies by 2019 Revenue*, FIERCE PHARMA (Apr. 20, 2020) <https://www.fiercepharma.com/special-report/top-20-pharma-companies-by-2019-revenue>.

³⁶ Tiash Saha, *The World's Biggest Generic Pharmaceutical Companies in 2018*, PHARMACEUTICAL TECH. (Apr. 3, 2019) <https://www.pharmaceutical-technology.com/features/biggest-generic-pharmaceutical-companies-2018/>.

³⁷ José Vasquez & Gina Lohr, *Pharmacy Benefit Managers, Explained*, ADVISORY BOARD (Nov. 13, 2019) <https://www.advisory.com/daily-briefing/2019/11/13/pbms>.

market: McKesson Corp. (35%), AmerisourceBergen Corp. (32%), and Cardinal Health Inc. (25%).³⁸ Further downstream, we see high levels of concentration in the health insurance markets. The vast majority of the states are served by three or fewer major health insurers that account for 80% or more of the market.³⁹ The table below summarizes three-firm ratios and the antitrust agency responsible for merger review for key markets along the pharmaceutical supply chain.

3-FIRM RATIOS FOR KEY SEGMENTS OF THE PHARMACEUTICAL SUPPLY CHAIN

Market in the Pharmaceutical Supply Chain	Market Share of Top 3 Firms	Agency Responsible for Merger Review
Branded Pharmaceuticals	~40%	FTC
Generic Pharmaceuticals	~65%	FTC
Pharmacy Benefit Management	~75%	FTC
Drug Distributors	~90%	FTC
Health Insurers	~80%	DOJ

The quest for bargaining power is a major driver of both horizontal and vertical consolidation in the pharmaceutical supply chain. Firms seek to “bulk up” to gain leverage over larger rivals or customers and suppliers. Bargaining power is a poor defense for consolidation, yet it continues to surface in merger proposals. In landmark cases, the Antitrust Division under the Obama administration successfully blocked the mergers of Anthem-Cigna and Aetna-Humana, which would have eliminated important competition in commercial health insurance and the health exchange plan markets.⁴⁰ The Trump administration DOJ, however, gave the green light to the vertical PBM-insurer mergers of CVS Caremark-Aetna, and Express Scripts-Cigna. This was despite highly public concerns over the dominance of CVS in the PBM market and the likelihood that the merger would enhance CVS-Aetna’s incentive to exclude rival insurers, smaller PBMs, and mail order pharmacies.⁴¹

“Markets in the pharmaceutical supply chain cannot be viewed in isolation—dominant players and oligopolies often have bargaining power over upstream suppliers or downstream distributors.”

³⁸ Adam J. Fein, *The Big Three Wholesalers: Revenues and Channel Share Up, Profits Down*, DRUG CHANNELS (Oct. 2, 2019) <https://www.drugchannels.net/2019/10/the-big-three-wholesalers-revenues-and.html>.

³⁹ Kaiser Family Foundation, *Market Share and Enrollment of Largest Three Insurers – Individual Market* (2017) https://www.kff.org/private-insurance/state-indicator/market-share-and-enrollment-of-largest-three-insurers-individual-market/?currentTimeframe=1&selectedRows=%7B%22wrapups%22:%7B%22united-states%22:%7B%7D%7D%22states%22:%7B%22all%22:%7B%7D%7D%7D&sortModel=%7B%22collid%22:%22Total%20Individual%20Market__Enrollment%22:%22sort%22:%22desc%22%7D.

⁴⁰ Complaint at 2, *United States v. Aetna Inc.*, 240 F. Supp. 3d 1 (D.D.C. 2017) (No. 16-1494); Complaint at 3, *United States v. Anthem, Inc.*, 236 F. Supp. 3d 171 (D.D.C. 2017) (No. 16-1493).

⁴¹ Letter from Diana L. Moss, President, Am. Antitrust Inst., to Makan Delrahim, Assistant Atty Gen., U.S. Dep’t of Justice (Mar. 26, 2018) https://www.antitrustinstitute.org/wp-content/uploads/2018/09/CVS-Aetna_AAI-Letter_3.26.18.pdf.

The importance of competition within the pharmaceutical supply chain is also apparent in petitions by major healthcare companies to temporarily coordinate with immunity from the antitrust laws during the COVID-19 pandemic. For example, Eli Lilly & Co., AbCellera Biologics, Amgen, AstraZeneca, Genentech, and GlaxoSmithKline requested permission to share information on potential treatments for COVID-19 involving monoclonal antibodies.⁴² AmerisourceBergen also requested permission to collaborate with distributors to provide medications and healthcare supplies to imperiled communities;⁴³ and McKesson Corp., Owens & Minor, Cardinal Health, Medline Industries, and Henry Schein requested permission to collaborate in an effort to provide personal protective equipment and medications to areas that needed them most.⁴⁴ Such coordination can be beneficial under carefully monitored circumstances and for specific activities and periods of time. However, in markets already characterized by tight oligopolies with only a few major suppliers, these grants of immunity raise issues that could have longer term impacts on the structure of the pharmaceutical supply chain.

IV. SHAPING THE INDUSTRY: PHARMACEUTICAL MERGERS FROM 1994-2020

The FTC has challenged 67 pharmaceutical mergers involving human health since 1994.⁴⁵ The Commission moved to enjoin only one of those transactions between 1994-2020: CSL Limited's proposed \$3.1 billion acquisition of Talecris Biotherapeutics in 2009, which the FTC alleged would substantially reduce competition in markets for plasma-derivative protein therapies.⁴⁶ The parties abandoned the deal.⁴⁷ Given this remarkable series of approvals of mergers valued at over \$900 billion dollars, we gathered more information on the drug manufacturers involved, identifying about 90 "unique" firms as merging parties. Just over one-quarter of these unique firms engaged in multiple mergers over the period and account for about one-half of all parties to mergers between 1994-2020.

Figure 2 shows the count of challenged mergers over the period 1994-2020. Mergers reached an initial peak from 2006-2009, with a second, much larger peak a decade later in 2015—cycles that align more generally with economy-wide merger activity.⁴⁸ The number of mergers approved by the FTC between 2012-2015 was at an all-time high, with eight deals approved in 2015 alone.

⁴² Letter from Makan Delrahim, Assistant Atty Gen., U.S. Dep't of Justice to Thomas O. Barnett, Covington & Burling (July 23, 2020) <https://www.justice.gov/atr/page/file/1297161/download>.

⁴³ Letter from Makan Delrahim, Assistant Atty Gen., U.S. Dep't of Justice to John G. Chou, Exec. Vice President, AmerisourceBergen Corp. (Apr. 20, 2020) <https://www.justice.gov/atr/page/file/1269911/download>.

⁴⁴ Letter from Makan Delrahim, Assistant Atty Gen., U.S. Dep't of Justice to Lori A. Schechter, Exec. Vice President, Chief Legal Officer, & Gen. Counsel, McKesson Corp., et al. (Apr. 4, 2020) <https://www.justice.gov/atr/page/file/1266511/download>.

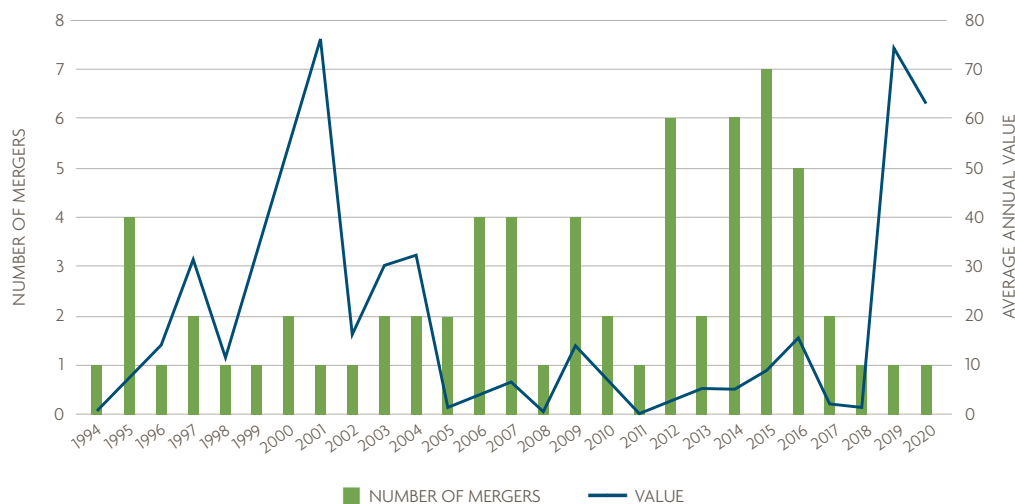
⁴⁵ Data on merger transactions and divestitures was gathered from a number of sources (henceforth, "Merger Data Sources"). These include: (1) the Federal Trade Commission website, using the Cases and Proceedings advanced search tool with identifiers "Industry=Prescription Drugs," "Mission=Competition," and "Competition Topics=Mergers." See <https://www.ftc.gov/enforcement/cases-proceedings>; (2) MARKUS H. MEIER ET AL., OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION (2019) https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_june_2019.pdf; (3) CRUNCHBASE, <https://www.crunchbase.com/home> (last visited Aug. 4, 2020); (4) news sources, including *Watson to Acquire Arrow Group*, FIERCE BIOTECH (June 17, 2009), <https://www.fiercebiotech.com/biotech/watson-to-acquire-arrow-group-0>; *First Horizon Pharmaceutical to Become Sciele Pharma*, ATLANTA BUS. CHRON. (June 15, 2006), <https://www.bizjournals.com/atlanta/stories/2006/06/12/daily29.html>; *Agreement Executed for Amneal Pharmaceuticals to Acquire the Assets of Interpharm Holdings, Inc.*, BIOSPACE (Apr. 25, 2008), <https://www.biospace.com/article/releases/agreement-executed-for-amneal-pharmaceuticals-to-acquire-the-assets-of-interpharm-holdings-inc-/>; and *Actavis Completes Acquisition Of NJ-Based US Generics Company Amide Pharmaceutical, Inc.*, BIOSPACE (July 28, 2005) <https://www.biospace.com/article/releases/actavis-completes-acquisition-of-nj-based-us-generics-company-amide-pharmaceutical-inc-/>; and (4) complaints and consent orders too numerous to list here.

⁴⁶ Complaint at 1, *CSL Limited*, 2009 FTC. LEXIS 105 (2009) (No. 9337).

⁴⁷ The parties also abandoned the proposed merger of Mylan and Perrigo (2016) due to shareholder opposition. See OVERVIEW OF FTC ACTIONS IN PHARMACEUTICAL PRODUCTS AND DISTRIBUTION, *supra* note 45, at 31.

⁴⁸ M&A in the United States, *Institute for Mergers, Acquisitions and Alliances* <https://imaa-institute.org/m-and-a-us-united-states/> (last visited Mar. 8, 2020).

FIGURE 2: NUMBER AND VALUE OF PHARMACEUTICAL MERGERS APPROVED BY THE FTC (1994-2020)



The pace of merger activity is inversely related to the size of drug mergers. For example, as shown by the solid line in Figure 2, the number of mergers challenged in the early part of the period (1994-2004) was low, but the average deal value was relatively high.⁴⁹ Similarly, there are few mergers in the latter part of the period (2018-2020 (to date)) but their average value is also high.⁵⁰ The largest branded mergers that have shaped the pharmaceutical sector occurred early in the period. These include combinations that created some of the now top firms such as AstraZeneca (1999), GlaxoSmithKline (2001), and Sanofi-Aventis (2004). More recent branded transactions have expanded the footprint of top firms such as Bristol Myers Squibb through its acquisition of Celgene (2019), as well as AbbVie Inc. (AbbVie) through its recent acquisition of Allergan (2020).

“Between 1994-2020, the FTC challenged 67 pharmaceutical mergers worth over \$900 billion dollars, moved to block only one, and settled virtually all of the remainder subject to divestitures.”

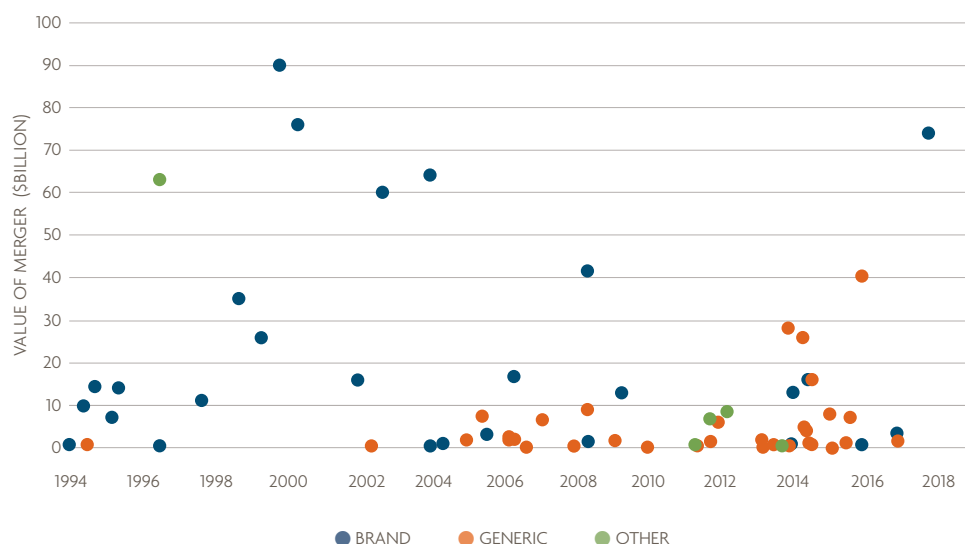
The middle period (2005-2017) shows a large number of lower value generic drug mergers. These deals produced the now behemoth generic firms such as Teva, Sandoz, Mylan, and Sun Pharmaceutical Industries (Sun) that dominate the top generic lineup and are named defendants in numerous generic drug price fixing litigations.⁵¹ Figure 3 illustrates this concentration of generic mergers, particularly between 2013-2016.

⁴⁹ Merger Data Sources, *supra* note 45.

⁵⁰ *Id.*

⁵¹ Tiash Saha, *supra* note 36.

FIGURE 3: VALUE OF CHALLENGED PHARMACEUTICAL MERGERS BY TYPE (1994-2020)



Pharmaceutical mergers challenged by the FTC represent only a fraction of total M&A from 1994-2020. Top branded and generic pharmaceutical companies have grown through hundreds of mergers and acquisitions over this period. Figure 4 shows mergers and acquisitions for which data on deal value is available.⁵² For example, Johnson & Johnson and Roche both made over 40 acquisitions and Pfizer made over 30 acquisitions. The FTC challenged two Johnson & Johnson acquisitions, one Roche acquisition, and four Pfizer acquisitions and settled them with divestitures.⁵³ Mylan and Teva made a total of 11 acquisitions each from 1994-2020.⁵⁴ The FTC challenged three Mylan and four Teva acquisitions, respectively, and settled them with divestitures. As shown in Figure 4, hundreds of transactions contributed to substantial consolidation in both the branded and generic sectors, with a concentration of activity in the period after 2012 that corresponds to the surge of generic consolidation.

Many of the transactions shown in Figure 4 were not reportable to the FTC because their value fell below the Hart Scott Rodino Act merger filing requirement thresholds.⁵⁵ These include acquisitions of smaller and potential rivals. For those transactions that were reportable, over 350 were granted “early termination” by the FTC after a brief initial review.⁵⁶ Others were cleared to the FTC for a further look under the second request process but where the agency concluded its investigations without a challenge.⁵⁷

⁵² CRUNCHBASE <https://www.crunchbase.com/home> (last visited Aug. 4, 2020). Search query based on the following criteria: Industry Group = Healthcare, Industries = Pharmaceutical, keywords = biopharma, biotechnology, pharmaceutical, manufacturing.

⁵³ Merger Data Sources, *supra* note 45.

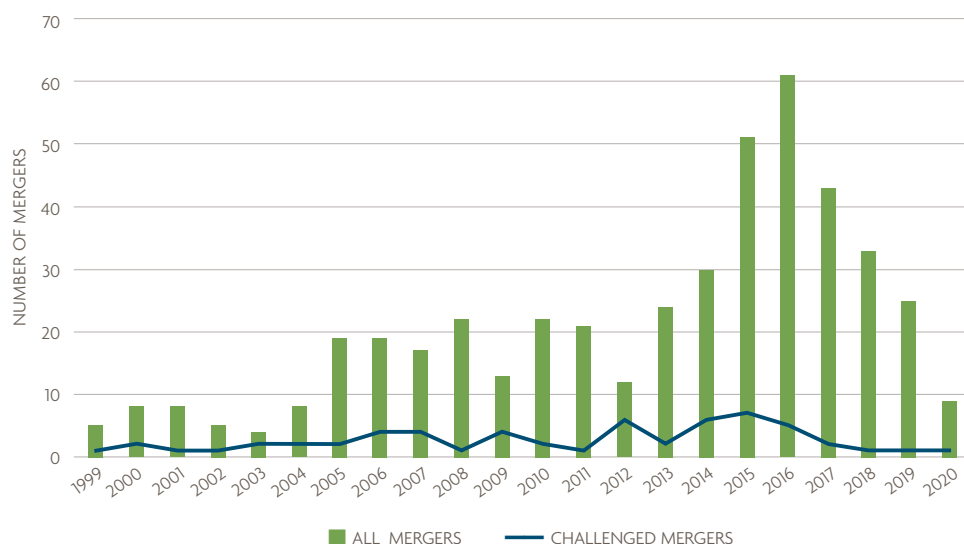
⁵⁴ *Id.*

⁵⁵ 15 U.S.C. § 18a.

⁵⁶ See *Early Termination Notices*, FED. TRADE COMM’N <https://www.ftc.gov/enforcement/premerger-notification-program/early-termination-notices> (last visited Aug. 4, 2020), (Enter “pharmaceutical” in the Keyword search filter).

⁵⁷ Diana L. Moss, *The Record of Weak U.S. Merger Enforcement in Big Tech*, AM. ANTITRUST INST. (Jul. 8, 2019) https://www.antitrustinstitute.org/wp-content/uploads/2019/07/Merger-Enforcement_Big-Tech_7.8.19.pdf.

FIGURE 4: ALL PHARMACEUTICAL M&A V. CHALLENGED MERGERS (1999-2020 to date)



The pattern of consolidation reveals the extent to which many pharmaceutical companies have expanded through M&A, as opposed to through organic growth and innovation. Moreover, the pace of merger activity appears recently to have become disconnected from FTC enforcement. Merger challenges shown by the solid line generally track upward as merger activity increases from 1999-2014. Beginning in 2015, however, challenges fall while M&A activity continues to rise. Overall, there is a low correlation between all merger activity and challenges from 1999-2019, a feature that warrants close scrutiny in light of the FTC's unusual approach to pharmaceutical mergers.

V. LIFTING THE VEIL ON HIGHLY CONCENTRATIVE PHARMACEUTICAL MERGERS

Sweeping consolidation in the branded and generic drug sectors, high drug pricing, antitrust violations, and the role of merger control raise significant questions. To gain more insight into how these issues relate, AAI evaluated competitive concerns raised in FTC complaints in the 67 drug mergers challenged by the agency between 1994-2020. For each relevant market for which information is available, this included: (1) the reduction in number of competitors, (2) the type of competitive harm alleged, and (3) the impact on actual and/or future competition. This process reveals a total of over 350 relevant markets, defined around products sold by the merging companies that are bio-functional equivalents.⁵⁸ This leads to highly segmented markets that often contain only a few, if not

⁵⁸ FTC complaints describe, in detail, the effect of mergers in relevant drug markets in about 25% of the markets identified.

only one or two, actual and/or potential competitors.⁵⁹ Large mergers affect multiple relevant markets, including Teva-Allergan (2016), where the FTC’s complaint defined 90 relevant markets.⁶⁰

“The significant number of relevant drug markets that involve a reduction in number of rivals from 3-2 or 2-1 maps directly to the major concern that pharmaceutical mergers have created dominant firms and oligopolies.”

Of the relevant markets defined in 67 challenged merger investigations, over 25% involved 4-3 mergers, over 35% involved 3-2 mergers, and almost 25% involved 2-1 mergers. Before any required divestitures, the effect of pharmaceutical mergers in the majority of cases has therefore been to increase concentration in already highly concentrated markets.⁶¹ This comes as no surprise given the role of intellectual property and the process of generic entry under the Hatch-Waxman Act. As discussed later, these highly concentrative mergers, and the adverse effects they lead to, put enormous pressure on a remedy to fully restore competition.

Market concentration reveals valuable information about competitive dynamics in post-merger markets. That is, namely, whether a merger is likely to harm competition through unilateral and/or coordinated effects. In about one-third of markets, the FTC’s complaints allege only unilateral effects, or that the merger eliminates a close rival, increasing the merged firm’s ability and incentive to raise price, degrade quality, or stifle innovation. In almost 60% of cases, the FTC alleges both unilateral *and* coordinated effects, and in the small remainder of cases, only coordinated effects.⁶²

The significant number of relevant drug markets in which mergers led to a reduction in number of rivals from 3-2 or 2-1 maps directly to the major concern that pharmaceutical mergers have created dominant firms and oligopolies. The FTC’s concern over both unilateral and coordinated effects are apparent in cases where mergers created a dominant firm *and* left a remaining fringe of smaller actual or potential rivals.⁶³ Finally, in about 75% of merger complaints, the FTC alleges harm to actual and future competition.⁶⁴ This reveals the importance of potential entry in disciplining competition in pharmaceutical markets, included branded rivals anticipating entry with a new drug and generic entry under the Hatch-Waxman Act.⁶⁵ Agreements between branded and generic firms to delay entry are clear evidence that entry by potential rivals would challenge a branded firm’s dominant position.

⁵⁹ See, e.g., *Teva Pharm. Indus. Ltd.*, 2016 F.T.C. LEXIS 121 (2016) (No. C-4589); and Barak D. Richman et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 *LOY. UNIV. CHI. L. J.* 787-819 (2017).

⁶⁰ *In re Teva Pharm. Indus. Ltd.*, 2008 F.T.C. LEXIS 181 (2009) (No. C-4242).

⁶¹ Merger Data Sources, *supra* note 45.

⁶² *Id.*

⁶³ Four-to-three mergers often create or tighten an oligopoly, which enhances incentives to collude. See, e.g., DIANA L. MOSS, WHY THE PROPOSED SPRINT-T-MOBILE MERGER SHOULD BE DOA AT THE DOJ, (2018) https://www.antitrustinstitute.org/wp-content/uploads/2018/08/AAI_Sprint-T-Mobile_Comm_6.5.18.pdf.

⁶⁴ Merger Data Sources, *supra* note 45.

⁶⁵ See *Abbreviated New Drug Application (ANDA)*, U.S. Food and Drug Administration, <https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda>.

“ The absence of litigated pharmaceutical merger cases means there is no judicial record detailing how highly concentrative deals would have survived a presumption of illegality, and thus no way to evaluate claims that pharmaceutical mergers would have delivered efficiencies. ”

The foregoing analysis of competitive effects in challenged pharmaceutical mergers makes clear that the majority of deals were highly concentrative. Despite a presumption of illegality, the FTC’s consistent strategy of not seeking injunctions means that there is no judicial record on how defendants in 67 mergers would have overcome such a presumption with a showing of merger-specific, cognizable efficiencies.⁶⁶ The FTC’s policy thus provides the courts and consumers with no transparency on how pharmaceutical mergers have delivered claimed benefits of a sufficient magnitude to allay concerns over adverse effects. As discussed next, observed problems with numerous pharmaceutical divestitures amplify this concern.

VI. SERIAL DIVESTITURES AND CONCENTRATION OF ASSETS

The FTC’s policy of settling virtually all concentrative mergers with divestitures has significant consequences. Aside from abandoning the structural presumption, the absence of any judicial record could have adverse implications for future mergers that the Commission *does* decide to litigate. Moreover, the FTC’s policy will lead to an almost impossibly high bar for divestiture remedies in the future. This is because the more concentrative a merger, the commensurately higher is the risk that the remedy will fail to restore lost competition.⁶⁷ To the extent the buyer cannot quickly reinject pre-merger competitive discipline, the remedy is more likely to fail. This stands in stark contrast to the most effective remedy, a full stop injunction, that would ensure that future anticompetitive conduct is fully deterred.⁶⁸

To better understand the magnitude and effect of divestitures in pharmaceutical mergers, AAI examined the over 80 buyers of divestiture assets specified in consent orders that settled the FTC’s competitive concerns.⁶⁹ These buyers include drug manufacturers that were party to other challenged mergers and those that were not party to mergers. Our analysis revealed that almost 25% of firms that were parties to challenged mergers also purchased divestiture assets. Some of these firms were particularly active, often engaging in multiple purchases, including Watson Pharmaceuticals (Watson), Sandoz, Impax

⁶⁶ The only FTC complaint that mentions efficiencies is CSL Limited’s proposed acquisition of Talecris Biotherapeutics (2009), the only transaction the agency sought to block in federal court. *See supra* note 45.

⁶⁷ FTC’s MERGER REMEDIES 2006–2012, *supra* note 1.

⁶⁸ Diana L. Moss, *Realigning Merger Remedies with the Goals of Antitrust*, in GCR GUIDE TO MERGER REMEDIES 32 (2d ed. 2019).

⁶⁹ Eight buyers were not specified by name in FTC consent orders.

Laboratories (Impax), Par Pharmaceuticals (Par), Actavis, Pfizer, Perrigo Company (Perrigo), and Barr Pharmaceuticals (Barr).⁷⁰

Moreover, 45% of merging parties that were also divestiture buyers in unrelated deals purchased multiple divestiture assets. These “serial” purchasers of divestiture assets, many of which were also party to multiple mergers, accounted for almost 70% of asset purchases by merging parties. Of the remaining buyers of divestiture assets that were not party to any merger, many are also serial acquirers of divestiture assets. This includes: Alvogen, Renaissance, Dr. Reddy’s Laboratories (Dr. Reddy’s), Sagent Pharmaceuticals, and Torrent Pharmaceuticals.

“*The more concentrative a merger, the commensurately higher is the risk that the remedy will fail, which puts enormous pressure on a remedy to fully restore competition.*”

The performance of divestiture assets exacerbates the foregoing concern. For example, the FTC’s own studies of past pharmaceutical divestitures highlight systemic problems. In its most recent study of divestitures from 2006-2012, the Commission reviewed 24 consent orders involving 60 on-market generic drugs.⁷¹ The study finds that only 75% of buyers of divestiture assets actually sold the drug, post-divestiture. For the 25% of buyers that did not sell the drug post-divestiture, the failure rate on oral solid generics divestitures was 18% and the rate on complex generics divestitures was 36%.⁷² Because the FTC’s assessment of pharmaceutical divestitures in its most recent study is flawed and incomplete, it is likely that the rate of failure of those divestitures is even higher.

More generally, the FTC study found that divestitures of limited packages of assets fared less well than divestitures of ongoing businesses.⁷³ Because generic merger settlements almost always involve discrete packages of assets rather than ongoing businesses, and in light of their high rate of failure, the FTC’s policy to settle virtually all challenged pharmaceutical mergers with remedies warrants close scrutiny. Taking remedies in highly concentrative mergers more generally—and in pharmaceutical mergers specifically—sets a commensurately high bar for restoring competition. Moreover, divestitures of branded drug assets are fundamentally different than generics, which do not involve brands and patents. Buyers are far more likely to place a higher value on generic drug assets that enable an early mover advantage, not a later mover advantage. This feature exacerbates the problem of taking remedies in highly concentrative mergers.⁷⁴

Further amplifying concerns over the FTC’s policy of taking divestitures in essentially all pharmaceutical mergers is that many buyers of divestiture assets were later acquired by other pharmaceutical companies. Indeed, one-third of all buyers were ultimately merged into or acquired by a top pharmaceutical company, or acquired within two years of

⁷⁰ Merger Data Sources, *supra* note 45.

⁷¹ FTC’s MERGER REMEDIES 2006-2012, *supra* note 1.

⁷² *Id.*

⁷³ FTC’s MERGER REMEDIES 2006-2012, *supra* note 1, at 1.

⁷⁴ See, American Antitrust Institute, Letter to Chairwoman Edith Ramirez re: Review of the Teva-Allergan Merger (Jan 28, 2016), available at https://www.antitrustinstitute.org/wp-content/uploads/2018/08/AAI_Teva-Allergan-Ltr-to-FTC.pdf. See also, David Reiffen & Michael R. Ward, *Generic Drug Industry Dynamics*, 87 REV. ECON. & STAT. 37, 38 (2005).

purchasing divestiture assets.⁷⁵ It goes without saying that a buyer's incentive to maintain assets and compete vigorously *at the time* of a settlement are not equivalent to those of a firm—especially a large rival—that later acquires such a buyer. Had the FTC possessed information that a buyer would be acquired shortly after purchasing an asset, that buyer may not have been approved as part of a merger settlement. This has significant implications for the agency's approach to approving viable buyers and placing conditions on the post-divestiture transfer of assets.⁷⁶

VII: DAMAGE CONTROL AND PHARMACEUTICAL MERGER POLICY

In tying together the threads of the foregoing analysis of pharmaceutical mergers and divestitures, it becomes clear just under 20% of all unique branded and generic firms that engaged in repeated M&A and/or purchases of divestiture assets account for almost 45% of pharmaceutical assets “changing hands” from 1994-2020.⁷⁷ In other words, a relatively small group of powerful drug manufacturers have been involved in a significant proportion of M&A activity and purchases of divestiture assets. This is a direct outgrowth of the FTC's policy “industrial planning” approach to approving virtually all mergers subject to divestitures. Now, a substantial number of those manufacturers are defendants in private, state, and federal civil and criminal antitrust conduct cases. This is strong evidence that the FTC's policy of settling all challenged mergers with targeted divestiture remedies has created market conditions that have led to the exercise of market power by dominant firms and oligopolies of firms.

The significance of antitrust violations as evidence of harmful past mergers is apparent in other markets. For example, Live Nation-Ticketmaster's persistent violations of the original consent decree in the company's 2010 merger recently moved the DOJ to amend it.⁷⁸ The government recognized at the time of the merger that Ticketmaster dominated primary ticketing, including primary ticketing for major concert venues, for over two decades. The harmful effects of the merger were thus guaranteed, regardless of the remedy, by combining Live Nation's concert promotion services with Ticketmaster's entrenched monopoly in ticketing.

In drawing the connection between merger policy and the damage control that both the FTC and DOJ have instituted in the pharmaceutical sector, it is helpful to explore the various types of antitrust violations that have surfaced over the past two decades. For example, pay-for-delay agreements between branded and generic drug manufacturers are facilitated by the incentives created under the Hatch-Waxman Act—a problem that has generated numerous proposals for reform.⁷⁹ Outside the pay-for-delay context, branded

⁷⁵ *Id.*

⁷⁶ “Respondents shall not sell, transfer, encumber, or otherwise impair the Divestiture Product Assets (other than in the manner prescribed in this Order), nor take any action that lessens the full economic viability, marketability, or competitiveness of the Businesses related to that Divestiture Product.” *Teva Pharm. Indus. Ltd.*, 2016 F.T.C. LEXIS 176 at 178 (2016) (No. C-4589).

⁷⁷ Merger Data Sources, *supra* note 45.

⁷⁸ Letter from AAI to Makan Delrahim, Assistant Attorney General, U.S. Department of Justice, Antitrust Division Re: Amended Final Judgment: U.S. v. Ticketmaster Entertainment, Inc., and Live Nation Entertainment, Inc. (Feb. 4, 2020), https://www.antitrustinstitute.org/wp-content/uploads/2020/02/AAI_Ltr-to-DOJ_LN-TM_F.pdf.

⁷⁹ See, e.g., *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). See also, *Impax Laboratories, Inc., In the Matter of*, Fed. Trade Comm'n <https://www.ftc.gov/enforcement/cases-proceedings/141-0004/impax-laboratories-inc> (last updated Aug. 2, 2019). In *Watson Pharmaceuticals, Inc., et al. (FTC v. Actavis, 2009)*.

“AAI’s analysis shows that just under 20% of all unique branded and generic firms that engaged in repeated M&A and/or purchases of divestiture assets account for almost 45% of pharmaceutical assets “changing hands” from 1994-2020.”

firms regularly exercise unilateral market power through exclusionary practices to keep out generic competition. In the early landmark case, *FTC v. Mylan Laboratories, Inc., et al.* (1998), the FTC alleged four companies conspired to deny Mylan’s competitors ingredients necessary to manufacture the anti-anxiety drugs lorazepam and clorazepate.⁸⁰ The FTC recently brought suit against Vyera Pharmaceuticals, Inc., et al. in alleging illegal schemes to block generic competition to Daraprim.⁸¹

Branded pharmaceutical manufacturers have turned to ever more innovative schemes to protect their entrenched market positions and foreclose generic competition. This includes “product hopping,” or switching patients to a reformulated version of a drug with little or no additional therapeutic benefit, including in *Mylan v. Warner Chilcott*, *New York v. Actavis*, and *In re Suboxone Antitrust Litigation*.⁸² In *AbbVie Inc., et al* (2014), Abbott Laboratories, Unimed Pharmaceuticals, and Besins Healthcare filed sham patent infringement litigation against potential generic rivals Teva and Perrigo to unlawfully maintain and extend monopoly power on AndroGel. Another anticompetitive tactic was used by Mylan to delay Teva’s generic EpiPen. When Teva was about to enter the market, Mylan filed a citizen petition with the FDA and five months later filed a supplemental study that it had commissioned to make the Teva generic seem inoperable for consumers.⁸³

The FTC’s aggressive record on enforcement involving pay-for-delay and exclusionary conduct in the pharmaceutical industry is admirable. However, burgeoning anticompetitive schemes by branded pharmaceutical companies over the last two decades raise serious questions about pervasive competitive problems in pharmaceutical markets. These problems should but do not yet appear to factor prominently into the FTC’s approach toward pharmaceutical mergers more generally. Of course, the most compelling evidence linking pharmaceutical mergers and the perils of high concentration are the generic price fixing conspiracies that are the focus of numerous antitrust lawsuits. Indeed, consolidation has eliminated competition and increased opportunities for multimarket contact that facilitates interdependent or explicit coordination.

The last few years have ushered in antitrust complaints against generic drug companies alleging conspiracies among generic manufacturers. The DOJ has recently obtained

⁸⁰ *FTC v. Mylan Labs., Inc.*, 62 F. Supp. 2d 25 (1999).

⁸¹ Complaint for Injunctive and Other Equitable Relief, *FTC v. Vyera Pharmaceuticals, Inc., et al.*, No. 20-CV-00706 (S.D.N.Y., Jan. 27, 2020).

⁸² *Mylan Pharms. Inc. v. Warner Chilcott Pub. Ltd. Co.*, 838 F.3d 421 (3d Cir. 2016); *New York v. Actavis*, 787 F.3d 638 (2d Cir. 2015); *In re Suboxone Antitrust Litigation*, 64 F. Supp. 3d 665 (E.D. Pa. 2014). See also Brief for the American Antitrust Institute as Amicus Curiae in Support of Plaintiffs-Appellees, *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, No. 19-3640 (3d Cir. July 28, 2020); *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 919 F.3d 869 (5th Cir. 2019); Consolidated Class Action Complaint, *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Practice, and Antitrust Litig.*, No. 17-md-2785-DDC-TJJ, MDL No: 2785, 2020 U.S. Dist. LEXIS 40788 (D. Kan. Mar. 10, 2020).

⁸³ Michael A. Carrier & Carl Minniti, *Citizen Petitions: Long, Late-Filed, and At-Last Denied*, 66 Am. U.L. Rev. 305, 350–51 (2017); Supplement from Mylan Specialty Tab 1 IAA Handling Study Nonconfidential, Docket No. FDA-2015-P-0181 (posted May 28, 2015).

seven indictments against generic drug companies and executives for price fixing, including Rising Pharmaceuticals, Teva, Taro Pharmaceutical Industries (Taro), Heritage Pharmaceuticals, Glenmark Pharmaceuticals, Sandoz, and Apotex. The conspiracies involve medications designed to treat diseases ranging from diabetes (glyburide), to hypertension (Benazepril HCTZ), high cholesterol (pravastatin), and over the counter medications. Private and state cases have been consolidated into the multi-district litigation (MDL) *In Re Generic Pharmaceuticals Pricing Antitrust Litigation*. Both direct and indirect purchasers brought putative class actions against generic drug manufacturers, alleging conspiracy to fix, maintain, and stabilize prices, rig bids, and engage in market and customer allocation.

“Many of the very firms that were the most active on the M&A front, and as purchasers of divestiture assets, appear as defendants in private, state, and federal non-merger antitrust litigations and in federal criminal indictments.”

Private cases name numerous generic drug makers as defendants and highlight the key role of the Generic Pharmaceutical Association in facilitating coordination. The cases focus on drugs such as Digoxin, used to treat irregular heartbeat and heart failure, where prices increased almost 900% between 2012 and 2014 and remained high even after the entry of competitors. Prices for the antibiotic doxycycline increased by over 8000% between 2012 and 2014.⁸⁴ The state cases, joined by 42 states, allege a horizontal conspiracy to allocate markets and fix prices for generics. The complaints note that collusion was facilitated by “the cozy nature of the industry” through mechanisms such as trade associations, customer conferences, industry dinners, and private meetings.⁸⁵ In schemes extending back to 2009, the industry allegedly divided markets by adopting a “code” where each rival, once achieving a “fair share” of a market, would not compete for more business.⁸⁶ The outcome of these conspiracies rests heavily on consumers. A January 2014 survey found that 75% of pharmacists reported higher prices on many generic drugs, some spiking as high 2000%.⁸⁷

The pervasive nature of antitrust violations in the pharmaceutical industry highlights the connection between non-merger antitrust violations and consolidation. In taking a closer look, we identified the approximately 70 drug companies that are defendants in private, state, and federal non-merger antitrust litigations, many of which are named in multiple actions. About 55% of these companies are parties to mergers and/or purchasers of divestiture assets, and non-merging buyers of assets. Within this group, we identified the set of companies that have been *most* active: Sandoz, Watson, Actavis, Par, Mylan, Teva,

⁸⁴ *In re Generic Pharms. Pricing Antitrust Litig.*, 338 F. Supp. 3d 404, 420 n. 54 (E.D. Pa. 2018).

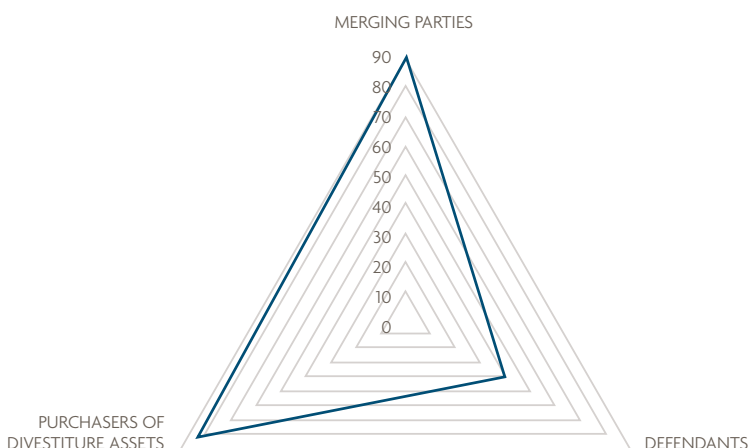
⁸⁵ Complaint at 29, *Connecticut v. Teva Pharms. USA, Inc.*, No. 2:19-cv-02407 (E.D. Pa. May 30, 2019).

⁸⁶ *Id.* at 8.

⁸⁷ Complaint at 51, *Connecticut et al v. Sandoz, Inc.*, No. 2:20-cv-03539 (E.D. Pa. Jul. 20, 2020) (“[M]ore than \$500 million of Medicaid drug reimbursement during the twelve months ending on June 30, 2014 was for generic drugs whose prices had increased by over 100%.”).

Impax, Pfizer, Endo, Valeant Pharmaceuticals, Perrigo, Apotex, Allergan, Barr, Taro, Sun, Dr. Reddy's, Amneal Pharmaceuticals, Inc., and Schering AG.⁸⁸ Figure 5 provides a map of all pharmaceutical firms involved in M&A and as purchasers of divestiture assets that are *also* defendants in non-merger antitrust litigations. It shows a relatively large “footprint” across these three criteria, that again shines the light on the connection between the FTC’s approach toward merger control and the damage control that has resulted from it.

FIGURE 5: DRUG MANUFACTURERS AS MERGING PARTIES, BUYERS OF DIVESTITURE ASSETS, AND DEFENDANTS IN NON-MERGER ANTITRUST LITIGATIONS



VIII: CONCLUSIONS AND POLICY RECOMMENDATIONS

The FTC’s 2017 divestiture study notes that “[t]he Commission has developed significant expertise in the pharmaceutical industry and follows a standard approach for evaluating these mergers and designing relief.”⁸⁹ This description of the agency’s policy toward merger control in pharmaceuticals hints at much of what has gone awry. It is troubling that the FTC considers its approach to be “standard” and that settling mergers—instead of seeking to enjoin them when appropriate—appears integral to essentially all merger challenges. This has resulted in assets trading hands within a group of pharmaceutical firms that account for significant portion of M&A activity and purchases of divestiture assets. Many of these firms were subsequently acquired and a non-trivial number of divestitures have failed. The FTC’s policy has thus transformed the industry from one with a prospect for vigorous competition to its current incarnation of a consolidated group of powerful drug manufacturers. Many of these same companies are now embroiled in private, state, and federal civil and criminal antitrust actions.

⁸⁸ Merger Data Sources, *supra* note 45.

⁸⁹ FTC’s MERGER REMEDIES 2006-2012, *supra* note 1.

“The FTC’s role in merger control has unduly involved it in shaping the pharmaceutical industry through a form of “industrial planning.””

A new policy on pharmaceutical mergers is in order. Competitive concerns forced the abandonment of the recent proposed merger of Sandoz and Aurobindo, which would have created the second largest generic firm in the world.⁹⁰ This may signal that the FTC’s policy is moderating. But much more is needed in the form of a course correction that protects competition and consumers. This imperative raises two major policy questions for the FTC. Aside from agency resource constraints around litigating more merger cases, a major issue is likely to be whether a proposed “fix” will have a significant effect on the outcome of a litigated case. For example, the FTC may extract stronger remedies up front if its strategy is to litigate *without* considering a fix. In contrast, perceived higher litigation risk may motivate the agency to settle with weaker remedies if it litigates a restructured merger in court. This dynamic will affect outcomes of litigated cases, incentives to abandon harmful mergers, and the effectiveness of remedies when cases are settled.

In light of the macro-analysis of pharmaceutical mergers presented in this White Paper, the AAI recommends the following:

- **The FTC should abandon its stated “standard” policy of settling highly concentrative drug mergers with divestitures. It should signal a move away from this policy by seeking to enjoin more mergers in obtaining the most effective remedy to restore competition lost by the merger.**
- **The FTC should discourage companies with a deep record of past M&A, divestiture asset purchases, and as named defendants in non-merger antitrust litigation from pursuing additional mergers. Agency leadership should clearly signal this policy to “worst offenders.”**
- **For pharmaceutical mergers that are allowed to proceed, the FTC should publish a detailed analysis of claimed merger-specific and cognizable efficiencies (i.e., cost-savings or consumer benefits) that were considered in coming to a Commission decision.**
- **The FTC’s own analysis of divestiture remedies indicates a too-high failure rate of generic pharmaceutical divestitures. Rather than attempt to correct this approach by creating more complex remedies, the agency should move to enjoin more problematic mergers.**
- **In cases where the agency takes remedies, divestitures should be carefully conditioned to ensure that they are not transferred, post-divestiture, to other firms with competitive incentives that are different from the original buyer’s.**

⁹⁰ Angus Liu, *Novartis, Aurobindo Admit Defeat by FTC in Aborting Their \$1B Generics Deal*, FIERCE PHARMA (Apr. 2, 2020) <https://www.fiercepharma.com/pharma/novartis-aurobindo-admit-defeat-by-ftc-aborting-1b-sandoz-u-s-generics-deal>.