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PHARMACEUTICAL MERGERS: DO WE HAVE THE RIGHT CURE?

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Few federal agencies wield tools more powerful than the Federal Trade Commission's authority to review—and deny—proposed mergers between companies. This authority is powerful for a reason: Large mergers can be uniquely harmful to the United States economy, potentially reducing competition, undercutting consumer choice, and inflating prices.

The pharmaceutical industry is particularly sensitive to merger harms, given the limited number of competitors and the inelasticity of demand for prescription drugs. As a result, when pharmaceutical companies seek to merge, the FTC often requires that one of the companies divest ownership of certain drugs not yet on the market—so-called "pipeline" drugs—to a third party.

FTC evaluations deem the pipeline divestiture program a complete success. But does it really work? As a client once said when asked this question, "It depends on what you mean by 'it' and 'work.'" In prior research, the FTC determined the

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success of a divestiture based solely on whether it occurred—rather than whether it meaningfully preserved competition post-merger. Our first-of-its-kind study reveals that pipeline divestitures have not in fact worked. Using conservative measures, our analysis shows that 81% of divested pipeline products fail to attain even a 1% share of their relevant markets.

But all is not lost: With a few key changes, drug divestiture can indeed achieve its intended effects. We recommend that the FTC require either a "crown jewel divestiture" (selling the on-market product, not the pipeline product) or a "skin in the game divestiture" (if the pipeline product fails, the company divests its on-market product).

I. INTRODUCTION

The U.S. pharmaceutical industry has experienced a significant increase in mergers and consolidation over the last four decades.[1] Specifically, there have been several successive waves of consolidation since the late 1980s, each increasing the market share of the largest companies.[2] The first wave commenced in 1989 and led to the creation of two of the biggest U.S. pharmaceutical companies, Bristol-Myers Squibb and Smith-Kline Beecham.[3] A second wave started in the mid-1990s and

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[1] David Alvaro, Emilie Branch & Cynthia A. Challener, *M&A: Fundamental to Pharma Industry Growth*, PHARMA'S ALMANAC (Mar. 20, 2020), https://www.pharmasalmanac.com/articles/manda-fundamental-to-pharma-industry-growth [https://perma.cc/BQJ2-GWFK] ("Over the last few decades, waves of M&A have led to significant consolidation. . . . Nearly 50 biopharma industry M&A deals with a value (the highest transaction dollar value, not the inflation-adjusted value) greater than $10 billion were completed between 1995 and 2015. Nearly 1,350 M&A transactions with disclosed values totaling nearly $700 billion that involved pharmaceutical assets companies were announced during the first 10 years of this century. . . . All told, 60 of the pharmaceutical companies that existed in 1999 have been consolidated into 10 big pharma firms." (footnote omitted)); *see* Jaimy Lee, *Drug Manufacturers Have Spent a Record $342 Billion on M&A in 2019,* MARKET WATCH (Dec. 10, 2019), http://marketwatch.com/story/drugmakers-have-spent-a-record-342-billion-on-ma-in-2019-2019-12-09 [https://perma.cc/VG4G-H93X]; Andrew Ward, *No End in Sight to Wave of Pharma Deal Making,* FINANCIAL TIMES (Apr. 26, 2015), https://www.ft.com/content/6aad8ebe-e9c0-11e4-b863-00144feab7de [https://perma.cc/56C4-ELZM] ("Since the start of [2014], pharmaceuticals companies have agreed $462bn of mergers and acquisitions — greater than the gross domestic product of Austria.").

[2] Barak Richman et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 LOY. U. CHI. L.J. 787, 790–92 (2017) ("[T]he number of annual deals grew from approximately one hundred deals in the late 1980s, to almost 800 deals in 2015."); Henry Grabowski & Margaret Kyle, *Mergers, Acquisitions, and Alliances, in* THE OXFORD HANDBOOK OF THE ECONOMICS OF THE PHARMACEUTICAL INDUSTRY 552, 552-53 (Patricia M. Danzon & Sean Nicholson eds., 2012) (explaining three major merger waves, the first occurring in 1989, the second lasting from the mid-1990s into the 2000s, and the third consisting of two major mergers in 2009). *See also* David J. Ravenscroft & William F. Long, *Paths to Creating Value in Pharmaceutical Mergers*, *in* MERGERS AND PRODUCTIVITY 287 (Steven Kaplan ed., 2000) (discussing merger trends in the 1990s); Grabowski & Kyle, *supra*, at 554-55 (noting that between 1989 and 2009, the top 10 pharmaceutical companies went from controlling 28.3% of the global market to controlling 45.2% of that market).

[3] Grabowski & Kyle, *supra* note 2, at 553 ("The first merger wave began in the 1989-1990 period."); Michael E. D. Koenig & Elizabeth M. Mezick, *Impact of Mergers & Acquisitions on Research Productivity within the Pharmaceutical Industry*, 59 SCIENTOMETRICS 157, 159 (2004) (noting that the first wave of pharmaceutical mergers started in 1989 and included the Bristol-Myers Squibb and Smith-Kline Beecham mergers). *See* Steve Lohr, *SmithKline, Beecham to Merge*, N.Y. TIMES (Apr. 13, 1989), https://www.nytimes.com/1989/04/13/business/smithkline-beecham-to-merge.html [https://perma.cc/KK77-JAD2] ("[Smith-Kline Beecham] would rank second in worldwide prescription drug sales behind Merck and second worldwide in nonprescription, or over-the-counter, medicines."); Nancy Rivera Brooks, *Bristol-Myers, Squibb Agree to Merge: $12-Billion Stock Swap Would Form 2nd-Largest Drug Firm*, L.A. TIMES (July 28, 1989), https://www.latimes.com/archives/la-xpm-1989-07-28-fi-295-story.html [https://perma.cc/2DRV-4LPB] ("[This merger] would create the world's second-largest drug company.").

continued into the early 2000s.[4] This wave was even larger than the first as the mergers consummated between 1994 and 1996 alone accounted for more assets than all the mergers that took place in the preceding decade.[5] A third wave consisted of two major mergers that took place in 2009.[6] In 1995, there were no mergers between companies that produced generic drugs; in 2016, there were 17 such mergers.[7]

These waves of mergers resulted in substantial consolidation within the U.S. pharmaceutical industry. In 1987, the largest eight pharmaceutical companies owned 36% of the U.S. market, but by 2017, the market share controlled by the largest eight companies rose to 58.3%.[8] All told, the growing number of mergers poses a risk to competition[9] and, as a result, to the availability of lower-priced medicines.[10]

Moreover, consolidation has brought signs of declining innovation.[11] The

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[4] Grabowski & Kyle, *supra* note 2, at 552-53 ("[The merger wave of 1989-90] was followed by an even larger merger wave that began in mid-1990s and continued into the 2000s."). *See also* Koenig & Mezick, *supra* note 3, at 159 (noting the waves of pharmaceutical mergers during the mid-1990s and again in the early 2000s).

[5] Ravenscroft & Long, *supra* note 2, at 288-89 (noting that more than $250 billion worth of assets were acquired in pharmaceutical mergers between 1985 and 1996 and more than half of these assets were acquired in mergers that took place between 1994 and 1996).

[6] Grabowski & Kyle, *supra* note 2, at 553; Bill Berkrot et al., *Merck, Schering-Plough Set to Complete Merger*, REUTERS (Nov. 3, 2009), https://www.reuters.com/article/business/healthcare-pharmaceuticals/merck-schering-plough-set-to-complete-merger-idUSTRE5A23YZ/ [https://perma.cc/G95R-FAJZ] (noting that Merck and Schering-Plough were set to complete their $41.1 billion merger and that Pfizer had completed its $67 billion acquisition of Wyeth).

[7] Marc-André Gagnon & Karena D. Volesky, *Merger Mania: Mergers and Acquisitions in the Generic Drug Sector from 1995-2016*, 13 GLOBALIZATION & HEALTH 1, 4 (2017) (analyzing the surge in mergers involving generic drug companies using data from Bloomberg Finance L.P.).

[8] Robin Feldman et al., *Challenges with Defining Pharmaceutical Markets and Potential Remedies to Screen for Industry Consolidation*, 47 J. HEALTH POL. POL'Y. & L. 583, 585-87 (2022).

[9] Justus Haucap & Joel Stiebale, *Research: Innovation Suffers When Drug Companies Merge*, HARV. BUS. REV. (2016), https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge [https://web.archive.org/web/20250206232441/https://hbr.org/2016/08/research-innovation-suffers-when-drug-companies-merge] (arguing that competition and innovation decline for both the merging and non-merging entities in the relevant drug market); *see infra* Part II.A.

[10] *See infra* Part IV; Haucap & Stiebale, *supra* note 9 ("Since generic drugs are priced lower than their branded counterparts, they generate cost savings for individuals and drug plans."); RYAN CONRAD & RANDALL LUTTER, GENERIC COMPETITION AND DRUG PRICES: NEW EVIDENCE LINKING GREATER GENERIC COMPETITION AND LOWER GENERIC DRUG PRICES, U.S. FOOD & DRUG ADMIN. 2–3 (2019), https://www.fda.gov/media/133509/download [https://perma.cc/Y9A9-ZC69] (finding that when there is only one generic in the market, the generic, on average, sells at a price 39% lower than the price of its brand-name counterparts; when there are two generics in the market, they sell at a price 54% lower than the price of the brand, on average; when there are 4 generics, the average discount is 79%; when there are 6 or more generics, the average discount is more than 95%); David Armstrong, *The Price of Remission,* PROPUBLICA (May 8, 2025), https://www.propublica.org/article/revlimid-price-cancer-celgene-drugs-fda-multiple-myeloma [https://perma.cc/G5KP-KPDA] (describing price increases and alluding to the $19,660 monthly cost of a multiple myeloma medication).

[11] *See infra* text accompanying notes 137-48.

merger waves between roughly 1990 and 2010 preceded a sharp drop-off in new molecular entities, new patents, and research and development (R&D) spending.[12] Where innovation does occur, pharmaceutical companies tend to prioritize drugs that treat small numbers of patients at tremendously high prices[13] or modifications of drugs that extend existing patent rights.[14]

In the United States, the Federal Trade Commission (FTC) serves as a bulwark against the anti-competitive effects of large mergers and acquisitions ("M&A"). In theory, the FTC's role is to block the M&A behaviors most likely to suppress competition and raise prices,[15] but recent trends in pricing, consolidation, and

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[12] Henry Grabowski & Margaret Kyle, *Mergers and Alliances in Pharmaceuticals: Effects on Innovation and R&D Productivity*, *in* THE ECONOMICS OF CORPORATE GOVERNANCE AND MERGERS 263 (Klaus Gugler & B. Burcin Yurtoglu, eds., 2008) (describing the "productivity crisis" in the age of pharmaceutical mergers); Carmine Ornaghi, *Mergers and Innovation: The Case of the Pharmaceutical Industry* 4-5 (Univ. of Southampton Econ. Div. Discussion Papers in Econ. and Econometrics No. 0605, 2006) ("[H]igher levels of technological relatedness are associated with poorer performances. . . . [C]onsolidations between large pharmaceutical companies seem to have a detrimental impact on the incentives of competitors to undertake research in those therapeutic areas where both acquirer and target are active players."); *see also* Iain M. Cockburn, *Is the Pharmaceutical Industry in a Productivity Crisis?*, *in* 7 INNOVATION POL'Y & ECON. 1, 22 (2006) (describing potential R&D inefficiencies that may result from large mergers while acknowledging that there isn't sufficient data to reach a conclusion); *see generally* Feldman et al., *supra* note 8 (discussing these sources and evaluating the full landscape).

[13] Matthew Herder, *When Everyone is an Orphan: Against Adopting a U.S.-Styled Orphan Drug Policy in Canada*, 20 ACCOUNTABILITY RSCH. 227, 227-28 (2013); *see* Kao-Ping Chua et al., *Spending for Orphan Indications Among Top-Selling Orphan Drugs Approved to Treat Common Diseases*, 40 HEALTH AFF., 453, 453 (2021) (describing the monopolistic benefits afforded to orphan drug sponsors); Sarah Jane Tribble & Sarah Lupkin, *Drugs for Rare Diseases Have Become Uncommonly Rich Monopolies*, NPR (Jan. 17, 2017), https://www.npr.org/sections/health-shots/2017/01/17/509506836/drugs-for-rare-diseases-have-become-uncommonly-rich-monopolies [https://perma.cc/R7YL-A9F4] ("[T]he system intended to help desperate patients is being manipulated by drugmakers to maximize profits and to protect niche markets for medicines already being taken by millions."); Joshua P. Cohen, *Are Orphan Drugs Getting Too Much Attention by Payers and Policymakers?*, FORBES (June 25, 2018), https://www.forbes.com/sites/joshuacohen/2018/06/25/are-orphan-drugs-getting-too-much-attention-by-payers-and-policymakers/ [https://perma.cc/JC7T-RVPC] ("The high prices of many rare disease drugs—first and next-in-class—have raised payer concerns. On average, the top 100 selling orphan drugs in the U.S. are priced at $140,442 per patient on an annual basis, according to EvaluatePharma.").

[14] *See* Tahir Amin & Aaron S. Kesselheim, *Secondary Patenting of Branded Pharmaceuticals: A Case Study of How Patents on Two HIV Drugs Could be Extended for Decades*, 31 HEALTH AFFAIRS 2286, 2286 (2012) (explaining how companies make minor modifications to aspects of the drug other than the API in order to obtain secondary patents); Amy Kapczynski, Chan Park & Bhaven Sampat, *Polymorphs and* Prodrugs *and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents*, PLOS ONE, Dec. 2012 at 1, 6-7 (analyzing data showing that companies use secondary patents to extend their monopolies); Robin Feldman, *May Your Drug Price Be Evergreen*, 5 J.L. & BIOSCIENCES 590, 595-96, 601 & n.56 (2018) (establishing evidence of "evergreening"—i.e., artificially extending patent lifespan by obtaining additional protections—through FDA data as well as identifying the incentives for evergreening and its constituent behaviors).

[15] FED. TRADE COMM'N, MISSION, https://www.ftc.gov/about-ftc/mission [https://perma.cc/VVM3-5SWN]; *see* Eleanor Tyler & Grace Maral Burnett, *ANALYSIS: FTC Rethinks Pharma M&A*

innovation indicate that something is clearly amiss.

We ought now to ask: What cures have been administered? Divestiture is a key FTC strategy to prevent anticompetitive harms resulting from pharmaceutical mergers or acquisitions. If the merging parties have overlapping drug products, one party must divest its version, selling the rights to the product to a third party. If one version of the product has not yet reached the market—in other words, if one version is a "pipeline" product—then the FTC will select it for divestiture, and the third party who buys it can finish bringing it to market. This approach ostensibly prevents loss of competition. The two entities may merge into one, but a third-party buyer can now introduce competition that would have naturally arisen had the merger not taken place.

But does it work? As a client once said to a lawyer when asked this question, "It depends on what you mean by 'it' and 'work.'" To assess the efficacy of divestiture as an anticompetitive remedy, the FTC conducted two studies—one in 1999[16] and another in 2017.[17] The two studies, described in detail in Part II, deemed the pipeline divestitures during each relevant study period to be successful.[18] The FTC concluded that divestiture, in its current form, is one of the most successful remedies for anticompetitive mergers, especially when it comes to pipeline products in the pharmaceutical industry.[19] We strongly disagree with that conclusion.

In our own first-of-its-kind analysis, we challenge the way in which the FTC measures success, and we suggest more appropriate criteria. We analyzed 26 merger cases from 2006 and 2018, in each of which the FTC issued a consent order requiring divestiture of at least one pipeline product. Because the principal goal of these remedy orders is to maintain competition,[20] we define a successful pipeline divestiture as one where the third-party buyer received FDA approval for the pipeline product, if needed, and created a significant level of competition. Our

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After a Decade of Mega Deals, BLOOMBERG LAW (Apr. 15, 2021, 2:00 AM), https://news.bloomberglaw.com/bloomberg-law-analysis/analysis-ftc-rethinks-pharma-m-a-after-a-decade-of-mega-deals [https://perma.cc/6LN8-4WT9] (describing role of FTC in regulating potentially harmful pharmaceutical mergers).

[16] BUREAU OF COMPETITION, FED. TRADE COMM'N, A STUDY OF THE COMMISSION'S DIVESTITURE PROCESS (1999) [hereinafter 1999 STUDY], https://www.ftc.gov/sites/default/files/attachments/merger-review/divestiture.pdf [https://perma.cc/3KZX-D6G3].

[17] BUREAUS OF COMPETITION AND ECONOMICS, FED. TRADE COMM'N, THE FTC'S MERGER REMEDIES 2006-2012 (2017) [hereinafter 2017 STUDY], https://www.ftc.gov/system/files/documents/reports/ftcs-merger-remedies-2006-2012-report-bureaus-competition-economics/p143100_ftc_merger_remedies_2006-2012.pdf [https://perma.cc/GN5U-BZ9V].

[18] *See* 1999 STUDY, *supra* note 16, at 8-10*; see id.* at 30-31.

[19] *See* 1999 STUDY, *supra* note 16, at 8-10; 2017 STUDY*, supra* note 17, at 30-31.

[20] The FTC issues remedy orders such as divestiture orders out of concern that, absent any remedy, the proposed merger would reduce the number of current or potential participants in the relevant market. *See, e.g.*, Teva Pharmaceutical Industries Ltd., 81 Fed. Reg. 51892, 51893-4 (Fed. Trade Comm'n Aug. 5, 2016); Mylan N.V., 81 Fed. Reg. 51899, 51901 (Aug. 5, 2016); Lupin Ltd., 81 Fed. Reg. 9467, 9468-69 (Fed. Trade Comm'n Feb. 25, 2016); Watson Pharmaceuticals, Inc., 77 Fed. Reg. 64515, 64516-17 (Fed. Trade Comm'n Oct. 22, 2012).

requirement for this "significant level of competition" was that a divested drug attain a market share greater than 1% for all drugs containing the same active pharmaceutical ingredient(s) ("API(s)").[21] The 1% threshold was selected because, in determining the relevant market for a divested pipeline drug, we relied only on API(s) without accounting for dosage form and strength; in case this approach led to an overstatement of the market size and thus an understatement of the divested pipeline product's market share, we chose a low figure of 1% for our market-share threshold. Only if a divested pipeline drug created significant competition did we deem the divestiture successful.

Using these criteria, our study contradicts the FTC's alleged success story. We found that:

- Out of 75 divested pipeline drugs, 61, or roughly 81%, did not achieve a significant level of competition, while only 14, or 19%, did.
- Of the 61 failed divestitures, 29, or roughly 50%, never received FDA approval. Another 18 drugs (roughly 30%) received FDA approval but were discontinued for reasons other than safety or efficacy.[22] The final 14 drugs (roughly 20%) received approval and remained on the market but had a market share of less than 1%.
- For those with a market share below 1%, their shares ranged from 0% to roughly 0.5%.

We also looked at different factors that might influence the success rate.

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[21] A drug's Active Pharmaceutical Ingredient(s) or Active Ingredient(s) is the drug's core ingredient(s) that is responsible for producing the drug's intended therapeutic effect. 21 C.F.R. § 207.1 ("Active pharmaceutical ingredient means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body."); FED. TRADE COMM'N, DRUGS@FDA GLOSSARY OF TERMS, https://www.fda.gov/drugs/drug-approvals-and-databases/drugsfda-glossary-terms [https://perma.cc/TJ8L-9WYZ] (last visited Sept. 24, 2025) ("An active ingredient is any component that provides pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body of man or animals.").

[22] The owner(s) of an FDA-approved drug who wishes to withdraw the product from sale must provide the FDA with advance notice of the withdrawal. There can be a multitude of reasons behind the decision to withdraw, such as lack of demand, supply chain issues, production difficulties, or undesirable price levels. FED. TRADE COMM'N, MARKETING STATUS NOTIFICATIONS UNDER SECTION 506I OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT; CONTENT AND FORMAT: GUID ANCE FOR INDUSTRY 6 (Aug. 2020), https://www.fda.gov/media/120095/download [https://perma.cc/6333-6VYJ]. Once a drug has been withdrawn, the FDA moves that drug to the discontinued section of the Orange Book. The FDA, however, may conduct a review to determine if the drug has been discontinued for safety or efficacy reasons. If the FDA concludes that the drug was withdrawn for safety or efficacy reasons, the drug is removed from the Orange Book. The FDA also publishes the results of such reviews in the Federal Register. 21 U.S.C. § 356i(e) ("The Secretary shall [move] drugs that are not available for sale from the active section to the discontinued section of the [Orange Book], except that drugs the Secretary determines have been withdrawn from sale for reasons of safety or effectiveness shall be removed from the [Orange Book]."); 21 C.F.R. § 314.161.

Surprisingly, within the category of divested pipeline drugs, generic drugs have a much lower chance of creating significant competition than brand-name drugs. Since generic drug applicants do not need to conduct preclinical and clinical studies for FDA approval, we expected pipeline generics to have a higher chance of receiving FDA approval and subsequently making it to the market. Nevertheless, it was startling to find that only 14% of generic drugs managed to create significant competition in their relevant markets, while 80% of brand-name drugs managed to do the same.

Moreover, the chance of creating significant competition plummets if a single drug is divested more than once. Following the second divestiture, the drug's chance of survival in the market is effectively zero.

Our study suggests that, in its current form, divestiture of pipeline pharmaceutical products fails as an anticompetitive remedy. Every time a divested pipeline drug fails to get a foothold in the market, an opportunity for cost-lowering competition disappears. The effects of this loss are significant: 70 out of the 75 divested pipeline drugs included in our study were generic, and the price of generics usually drops substantially with every new entrant.[23] On the other hand, as competition diminishes in the market for the divested pipeline drugs, the price of essential therapies increases, and consumers suffer.

This article proposes two alternatives to pipeline divestiture remedies. The first is what we call "crown jewel divestiture." In this alternative, if one of the merger parties has an on-market version of the overlapping drug while the other party has a pipeline version of the same drug, then the consent order would require divestiture of the on-market version. Granted, merger parties may be reluctant to part with their "crown jewel," in which case our second alternative, which we call "skin in the game divestiture," may be preferable. In this remedy, the merging parties are still allowed to divest the pipeline product, but if that product fails to gain a significant market share by a certain deadline, the pipeline drug will return to its original owner, and the merged entity will be required to divest the on-market version.

This article proceeds as follows. Part II describes the legal foundation of the FTC's antitrust authority and analyzes the two studies of merger remedies commissioned by the FTC, along with scholarly critiques of those studies. Part III describes our study's methodology and results. Part IV describes the financial impact on consumers of failed merger remedies. Part V proposes solutions that can improve the efficacy of divestiture as an anticompetitive remedy. Part VI concludes our analysis.

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[23] CONRAD & LUTTER, *supra* note 10 (finding that generic prices drop sharply as new firms enter the market. Using AMP and invoice pricing data, they show that the first generic entrant reduces price by roughly forty percent relative to the brand price before generic entry. With two competitors, the reduction is over fifty percent, with four it approaches eighty percent, and with six or more competitors prices fall by more than ninety five percent).

II. BACKGROUND

This Part outlines the statutory basis for the FTC's merger authority and reviews both the agency's empirical studies of divestiture remedies and the critiques of those studies.

A. Legal Framework

1. The Clayton Act

While the Sherman Act of 1890 ("Sherman Act") bars monopolies, the Clayton Act of 1914 ("Clayton Act") bars activity that can lead to monopolies. Sweeping far more broadly than the Sherman Act, the Clayton Act bars mergers and acquisitions that have a tendency to create monopolies or substantially lessen competition, regardless of the intent of the parties involved:

> No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, *the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly*. 15 U.S.C. § 18 (emphasis added).

The purpose of the phrase "may be" was to prohibit mergers that had a "reasonable probability" of substantially lessening competition or creating a monopoly, without any requirement that competitive injury be certain and actual.[24] In short, the Clayton Act concerns "probabilities, not certainties."[25]

2. The History of the FTC and Its Exercise of Merger Authority

The FTC, established in 1914 through the Federal Trade Commission Act[26]

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[24] Brown Shoe Co. v. United States, 370 U.S. 294, 323 n.39 (1962) ("The words 'may be' have been in section 7 of the Clayton Act since 1914. The concept of reasonable probability conveyed by these words is a necessary element in any statute which seeks to arrest restraints of trade *in their incipiency and before they develop into full-fledged restraints violative of the Sherman Act*. A requirement of *certainty and actuality of injury to competition* is incompatible with any effort to supplement the Sherman Act by reaching *incipient restraints*.") (emphasis added) (quoting S. Rep. No. 1775, at 4298(1950)); Chicago Bridge & Iron Co. N.V. v. Federal Trade Comm'n, 534 F.3d 410, 423 (5th Cir. 2008); Fort Worth Nat'l Corp. v. Fed. Sav. & Loan Corp. 469 F.2d 47, 60 (5th Cir. 1972) ("Congress provided [the FTC] 'authority for arresting mergers at a time when the trend to a lessening of competition was still in its incipiency.'" (quoting *Brown*, *supra*, at 317)).

[25] Gregory J. Werden, *New Merger Guidelines Treat a Proposed Merger Like Schrödinger's Cat*, MERCATUS CTR., 2, 2 (2024) https://www.mercatus.org/research/policy-briefs/new-merger-guidelines-treat-proposed-merger-schrodingers-cat [https://perma.cc/LP7U-BGRH].

[26] FED. TRADE COMM'N, OUR HISTORY, https://www.ftc.gov/about-ftc/history [https://perma.cc/S88E-NGKJ] (last visited Sept. 24, 2025).

("FTC Act"), is tasked with protecting American consumers from unfair and deceptive trade practices and with promoting competition in the marketplace.[27] To that end, Congress has granted the FTC broad investigative[28] and enforcement[29] authority over alleged anticompetitive behaviors. The FTC may launch an investigation into any entity engaging in commerce in the United States,[30] and, upon finding that an anticompetitive action has occurred, the agency can pursue a broad range of administrative and judicial remedies.[31]

The responsibilities of the FTC include enforcing the federal prohibition on mergers that can lead to diminished competition.[32] The FTC has "wide discretion" to fashion a remedy for a violation of the Clayton Act,[33] and the courts "will not interfere except where the remedy selected has no reasonable relation to the unlawful practices found to exist."[34]

Unfortunately, until 1978, the FTC had no mechanisms to identify problematic mergers in advance.[35] As a result, the agency and other antitrust enforcers were often unsuccessful in fully restoring competition in a market after an

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[27] MISSION, *supra* note 15.

[28] 15 U.S.C. § 43 ("The Commission may . . . prosecute any inquiry necessary to its duties in any part of the United States"); 15 U.S.C. § 46(a); FED. TRADE COMM'N, A BRIEF OVERVIEW OF THE FEDERAL TRADE COMMISSION'S INVESTIGATIVE, LAW ENFORCEMENT, AND RULEMAKING AUTHORITY (July 2025), https://www.ftc.gov/about-ftc/mission/enforcement-authority [https://perma.cc/A9EL-ET8C] [hereinafter A BRIEF OVERVIEW].

[29] The FTC is explicitly authorized to enforce the Clayton Act of 1914 and is the only entity that can bring cases under the FTC Act. Although the FTC is not authorized to enforce the Sherman Act of 1890, the U.S. Supreme Court has held that any violation of the Sherman Act necessarily violates Section 5 of the FTC Act. A BRIEF OVERVIEW, *supra* note 28; Herbert Hovenkamp, *The Federal Trade Commission and the Sherman Act*, 62 FLA. L. REV. 871, 873 (2010); *FTC v. Cement Institute*, 333 U.S. 683, 695-707 (1948).

[30] 15 U.S.C. § 46(a) ("[The FTC may] investigate from time to time the organization, business, conduct, practices, and management of any person, partnership, or corporation engaged in or whose business affects commerce . . . ."). There are, however, certain exceptions to the FTC's broad investigative powers: The FTC Act explicitly prohibits the FTC from investigating, *inter alia*, banks, loan institutions, Federal credit unions, and common carriers. *Id.*

[31] A BRIEF OVERVIEW, *supra* note 28.

[32] Section 7 of the Clayton Act prohibits such mergers. Clayton Act, ch. 323, § 7, 38 Stat. 730, 731–32 (1914) (codified as amended at 15 U.S.C. § 18) ("[N]o corporation engaged in commerce shall [participate in a merger], where the effect of such [merger] may be to substantially lessen competition . . . to restrain [commerce], or tend to create a monopoly . . . ."). For a more detailed discussion of the Clayton Act, see *supra* Part II.A.1. Note that section 7 of the Clayton Act is enforced not only by the FTC but also by the DOJ.

[33] Chicago Bridge & Iron Co. N.V. v. FTC, 534 F.3d 410, 441 (5th Cir. 2008); *see also* Polypore International, Inc. v. FTC, 686 F.23d 1208, 1218 ("The Commission has broad discretion in the formulating of a remedy for unlawful practices."); Ekco Prod Co. v. FTC., 347 F.2d 745, 753 (7th Cir. 1965) ("[T]he order appears to fashion relief within the broad scope allowed the Commission in such cases.").

[34] FTC v. Nat'l Lead Co., 352 U.S. 419, 428 (1957).

[35] 1999 STUDY, *supra* note 16, at 1.

anticompetitive merger took place.[36] Even when the FTC managed to remedy the effects of anticompetitive mergers, its actions often took a substantial amount of time to come into effect.[37] During that period, consumers suffered from reduced competition in the market.

To rectify this problem, Congress passed the Hart-Scott-Rodino Antitrust Improvements Act of 1976 ("HSR Act"),[38] which enables the FTC to review sufficiently large mergers[39] in advance. Title II of the Act requires that parties to a proposed merger notify the FTC and the U.S. Department of Justice ("DOJ") about the intended merger and provide both with any relevant business information.[40] The FTC reviews the proposed merger to evaluate whether it would affect competition in the relevant U.S. market(s).[41] During this preliminary review, the merging

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[36] *See* 1999 STUDY, *supra* note 16, at 1 n.3 (summarizing two studies of the FTC's pre-1980s remedy orders, both of which found that the orders made before the HSR Act overwhelmingly failed to "establish an independent competitor in a timely fashion"); H.R. REP. NO. 94-1373, at 9 (1976) (observing, as explanation for the purpose of the HSR Act, that divestitures are rarely successful in restoring competition to the target market and that an average divestiture case lasts more than five years, allowing the merged parties to reap illegal profits while the consumers sustain injuries).

[37] *See* 1999 STUDY, *supra* note 16, at 1 n.3; H.R. REP. NO. 94-1373, *supra* note 36, at 9.

[38] 1999 STUDY, *supra* note 16, at 1-2. The HSR Act was adopted expressly to address concerns that (1) absent a premerger notification program, the FTC was unable to identify and stop anticompetitive mergers before consummation and (2) the lengthy process of implementing a remedial divestiture order can allow anticompetitive harm during the implementation period. H.R. REP. NO. 94-1373, *supra* note 36, at 8 ("[T]he bill is based on two fundamental propositions: First, the weight of [the government's] burden of proof [in premerger injunction proceedings], together with the present lack of any premerger notification and waiting requirements, has meant that many large and illegal mergers have been successfully consummated in recent years, before the government had any realistic chance to challenge them. Second, experience has shown that after consummation occurs, many large mergers become almost unchallengeable. The government may well file suit and ultimately win the subsequent litigation on the merits of its Clayton Act case, by gaining a final judicial declaration of the merger's illegality. Yet by the time it wins the victory—and the government is successful in the vast majority of its litigated merger cases—it is often too late to enforce effectively the Clayton Act, by gaining meaningful relief. During the course of the post-merger litigation, the acquired firm's assets, technology, marketing systems, and trademarks are replaced, transferred, sold off, or combined with those of the acquiring firm. Similarly, its personnel and management are shifted, retrained, or simply discharged.").

[39] The FTC annually updates the jurisdictional threshold for the premerger notification provisions of the HSR Act. For the jurisdictional thresholds for 2024, *See* Revised Jurisdictional Thresholds for Section 7A of the Clayton Act, 89 Fed. Reg. 7708, 7708 (Feb. 5, 2024).

[40] 15 U.S.C. § 18a. *See also* 1999 STUDY, *supra* note 16, at 1-2; A BRIEF OVERVIEW, *supra* note 28; FED. TRADE COMM'N, MERGERS, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/mergers [https://perma.cc/PD9F-UXTU] (last visited Nov. 6, 2025).

[41] While the merging entities notify both the FTC and the DOJ about the contemplated merger, only one of those two antitrust enforcers reviews the merger. The FTC and the DOJ have a joint internal "clearance process" that assigns a merger case to one of those two authorities based on industry experience. Mergers in the pharmaceutical markets are typically assigned to the FTC while mergers in the health insurance markets are usually handled by the DOJ. This article is concerned only with merger review and remedial orders issued by the FTC. FED. TRADE COMM'N, PREMERGER NOTIFICATION AND THE MERGER REVIEW PROCESS, https://www.ftc.gov/advice-guidance/competition-guidance/guide-antitrust-laws/mergers/premerger-notification-merger-review-process

parties must wait at least 30 days before consummating the merger.[42] The consummation must be pushed back another 30 days if the FTC issues a request for additional information, called a "Second Request."[43]

Once the review is complete, the FTC can take a broad range of remedial actions. If the review indicates that the proposed merger would raise significant competitive issues, the FTC may propose solutions or block the merger outright, using its authority to enforce Section 7 of the Clayton Act. In many cases, however, the potential for anticompetitive harm is not a result of the transaction as a whole but rather occurs only in a subset of the relevant markets.[44] When the merging entities own similar or interchangeable drug products, the FTC may order one of those entities to sell off—i.e., divest—its overlapping assets, and thus to enable a third party to obtain those assets and compete with the merged entity "on an equal footing."[45] The goal of such a divestiture is that the third party replace the competition that would have been lost by the merger of two previously competing entities.[46] In theory, the FTC's consent orders mitigate potential anticompetitive harms with minimal effect on the procompetitive benefits of the merger.

Mergers in the U.S. pharmaceutical industry—one of the largest industries in the United States[47]—fall within the Clayton Act's purview, and premerger reviews are usually assigned to the FTC.[48] Given that each therapeutic class of drugs constitutes its own independent market, any anticompetitive harm arising from a

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[https://perma.cc/RUH7-ELT4] (last visited Sept. 26, 2025); Scott Hulver & Zachary Levinson, *Understanding the Role of the FTC, DOJ, and States in Challenging Anticompetitive Practices Of Hospitals and Other Health Care Providers*, KFF (Aug. 7, 2023), https://www.kff.org/health-costs/issue-brief/understanding-the-role-of-the-ftc-doj-and-states-in-challenging-anticompetitive-practices-of-hospitals-and-other-health-care-providers/ [https://perma.cc/A2KG-Y8LQ].

[42] 15 U.S.C. § 18a. *See also* PREMERGER NOTIFICATION AND THE MERGER REVIEW PROCESS, *supra* note 41.

[43] 16 C.F.R. § 803.20; PREMERGER NOTIFICATION AND THE MERGER REVIEW PROCESS, *supra* note 41.

[44] 2017 STUDY, *supra* note 17, at 1.

[45] Chicago Bridge & Iron Co. N.V. v. FTC, 534 F.3d 410, 441 (5th Cir. 2008).

[46] Even divestiture of assets other than those to which the antitrust violation relates can be appropriate if such divestiture is deemed necessary to create a viable competitor. *Id.*

[47] Marie Salter, *Reference Pricing: An Effective Model for the U.S. Pharmaceutical Industry?*, 35 NW. J. INT'L L. & BUS. 413, 415 (2015). *See also* PHARM. RSCH. & MFRS. OF AM., ECONOMIC IMPACT OF THE U.S. BIOPHARMACEUTICAL INDUSTRY: 2017 NATIONAL AND STATE ESTIMATES 11 (2019) (finding that the pharmaceutical industry accounted for 3.2% of U.S. GDP in 2017).

[48] *See, e.g.*, Teva Pharmaceutical Industries Ltd. and Allergan plc, 81 Fed. Reg. 15892 (Aug. 5, 2016) (summarizing a proposed consent agreement between FTC and Teva Pharmaceutical Industries Ltd.); Mylan N.V., 81 Fed. Reg. 51899 (Aug. 5, 2016) (summarizing a proposed consent agreement between FTC and Teva Pharmaceutical Industries Ltd.); Lupin Ltd., Gavis Pharmaceuticals LLC, and Novel Laboratories, Inc., 81 Fed. Reg. 9467 (Feb. 25, 2016) (summarizing a proposed consent agreement between FTC and Teva Pharmaceutical Industries Ltd.). *See also* FED. TRADE COMM'N & U.S. DEPT. OF JUST., MEMORANDUM OF AGREEMENT BETWEEN THE FEDERAL TRADE COMMISSION AND THE ANTITRUST DIVISION OF THE UNITED STATES DEPARTMENT OF JUSTICE CONCERNING CLEARANCE PROCEDURES FOR INVESTIGATIONS 9 (2002), https://www.justice.gov/sites/default/files/atr/legacy/2007/07/17/10170.pdf [https://perma.cc/K785-HMND].

pharmaceutical merger typically relates to only a subset of the markets in which the merging entities operate. Consequently, in proposed pharmaceutical mergers, the FTC often resorts to issuing consent orders whereby the agency requires the divestiture of the overlapping drug products to third-party buyers. As noted above, in some pharmaceutical mergers, the drugs that are to be divested are pipeline products, meaning that, at the time of divestiture, they are still in the product pipeline and are not yet on the market. In other mergers, the drugs to be divested are already on the market (i.e., "on-market products").

B. The FTC's 2017 Study

The FTC conducted studies in 1999[49] and 2017[50] to assess the success of its divestiture orders. The 1999 Study was the first effort by any government agency to evaluate its merger remedy orders.[51] Using a case study method, the FTC evaluated 35 remedy orders issued from 1990 to 1994 in horizontal mergers,[52] concluding that "most divestitures appear to have created viable competitors in the market."[53]

Although the 1999 Study was criticized for not having assessed post-merger competition, the study itself stated that its goal was simply to determine "whether the buyer of the divested assets was able to enter the market and maintain operations."[54] In other words, the goal was to determine whether the remedy orders created competitors and not to what extent those competitors created competition. Changes implemented in the wake of the 1999 Study included: requiring an "upfront buyer"[55] where less than an ongoing business was divested or where assets risked deterioration pending divestiture; shortening the deadline by which assets must be divested to a "post-order buyer";[56] and more frequently appointing independent third-party monitors to oversee particularly complicated remedies.[57] The changes were evidently designed to ensure that, post-divestiture, the buyer of the divested assets would be in a stronger position to compete, that the divested assets would be put to use promptly and would not lie fallow, and that the risk of evasion or neglect by the buyer would be minimized by disinterested oversight.

In 2015, the FTC decided to assess the success of these changes and more

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[49] 1999 STUDY, *supra* note 16.

[50] 2017 STUDY, *supra* note 17.

[51] *Id.* at 3.

[52] *Id.*

[53] 1999 STUDY, *supra* note 16, at 8.

[54] *Id.* at 9. The term "buyer" refers to the entity approved by the FTC to acquire the assets whose divestiture is required by the FTC's remedy order. 2017 STUDY, *supra* note 17, at 3 n.7.

[55] The term "upfront buyer" refers to a buyer that is named in the remedy order itself, after the buyer has negotiated an acquisition agreement with the divesting party and the FTC has approved the buyer and the terms of the acquisition. *See* 2017 STUDY, *supra* note 17, at 3 n.7.

[56] The term "post-order buyer" refers to a buyer approved by the FTC after issuance of the FTC's remedy order. *See id.* at 4 n.9.

[57] *Id.* at 4.

generally to conduct a second study of merger remedies.[58] Completed in January 2017,[59] the new study expanded on the 1999 Study in several respects. The 2017 Study evaluated all 89 of the FTC's merger remedy orders issued from 2006 to 2012[60] and divided those orders into three groups: (1) a group of 50 orders, issued in a wide variety of industries, where the FTC's analysis was based on a case study method; (2) a group of 15 orders issued in industries of which the FTC already had significant knowledge—funeral homes, supermarkets, drug stores, and health care entities such as dialysis clinics—where the FTC's analysis relied on responses to questionnaires completed by the buyers; and (3) a group of 24 orders issued to the pharmaceutical industry, where the FTC's analysis was based on information already in the FTC's possession combined with information from sources available to the public.[61]

At issue here is the third group. These 24 orders involved divestiture of 60 on-market products and 32 pipeline products.[62] The 2017 Study determined the success of on-market divestitures based on whether the buyers of the divested products continued to sell those products.[63] Meanwhile, the criterion for successful pipeline-product divestitures was whether the assets relating to the pipeline products were transferred to the approved buyers.[64] Under such criteria, the 2017 Study declared that three-quarters of the on-market divestitures and *all* of the pipeline-product divestitures were successful.[65]

As discussed more fully below, the 2017 Study failed to consider the market viability of the pipeline products after divestiture.[66] Specifically, the criterion for successful divestitures failed to account for whether the pipeline product received FDA approval, [67] was actively marketed, and achieved sufficient market penetration. If divestitures are intended to maintain competition, then our analysis of them ought to consider whether the relevant products actually made it to market

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[58] *Id.*

[59] *Id.* at Title Page.

[60] *Id.* at 4.

[61] *Id.* at 4-5.

[62] *Id.* at 30-31.

[63] *Id.* at 2, 30.

[64] *Id.*

[65] *Id.* at 2, 30-31.

[66] *See id.* at 30 n.44 ("[N]or did [FTC] staff measure success by determining if the buyer succeeded in launching a product.").

[67] The criterion's indifference to whether the pipeline product received FDA approval is conspicuous. According to the 2017 Study, the FTC—which has "developed significant expertise in the pharmaceutical industry"—appoints monitors who oversee compliance with divestiture orders and who receive "updates on the buyers' progress securing FDA approval with the divested assets." *Id.* at 10. FTC staff also "monitor[s] FDA approval of buyers' drug products post-divestiture." *Id.* Since the FTC therefore had concrete information on FDA approval, the criterion's failure to consider FDA approval is puzzling, especially when the relevant literature commonly uses FDA approval as a key criterion for determining whether divestiture has succeeded or not. *See infra* notes 124, 141 and accompanying text.

and obtained a meaningful market share.

C. Criticism of the 2017 Study

The 2017 Study has received pointed criticism from a variety of sources. Most critics cite the FTC's remedy order issued in the merger of AbbVie and Allergan as particularly problematic.[68]

1. California Attorney General's Criticism

On June 11, 2020, then-California Attorney General Xavier Becerra wrote a letter to the FTC concerning the AbbVie-Allergan merger.[69] The California Letter criticized not only the narrowness of the FTC's remedy orders but also the FTC's 2017 Study. The California Letter is particularly significant because state attorneys general are partners with the FTC in antitrust enforcement,[70] and because California constitutes the largest state economy in the U.S. and the fourth largest economy in the world.[71]

Regarding pipeline-product divestitures, the California Letter faulted the 2017 Study for failing to determine whether each divested pipeline drug "was actually developed and successfully launched and marketed."[72] In support, the California Letter noted that, although the 2017 Study declared the pipeline divestiture orders to be a total success,[73] an apparently contradictory announcement was made in 2018 by Bruce Hoffman, then the Director of the FTC's Bureau of Competition.[74] Specifically, Hoffman announced that, in complex pharmaceutical mergers, the FTC will require the divestiture of on-market products instead of pipeline

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[68] *See, e.g.*, OFF. OF COMM'R ROHIT CHOPRA, FED. TRADE COMM'N, DISSENTING STATEMENT OF COMMISSIONER ROHIT CHOPRA IN THE MATTER OF ABBVIE, INC. / ALLERGAN PLC COMMISSION FILE NO. 1910169, at 19 (May 5, 2020) [hereinafter CHOPRA DISSENT], https://www.ftc.gov/system/files/documents/public_statements/1574583/191-0169_dissenting_statement_of_commissioner_rohit_chopra_in_the_matter_of_abbvie-allergan_redacted.pdf [https://perma.cc/P9QZ-35VC]; Letter from Xavier Becerra, California Att'y Gen., to Acting Sec'y April Tabor, Fed. Trade Comm'n (June 11, 2020) [hereinafter California Letter or CAL. LTR.], https://www.regulations.gov/comment/FTC-2020-0042-0042 [https://perma.cc/T8QB-89LD]; *see also AbbVie Inc. and Allergan plc,* 170 F.T.C 190 (2020).

[69] CAL. LTR., *supra* note 68.

[70] *See* CHOPRA DISSENT, *supra* note 68, at 7.

[71] *See* U.S. BUREAU OF ECON. ANALYSIS, *Economic Profile for California: Gross Domestic Product (GDP) by State*, (Sep. 26, 2025), https://apps.bea.gov/regional/bearfacts/?f=06000&a=3 (showing that, in 2024, California had highest GDP of any state in U.S.); OFFICE OF GOV. GAVIN NEWSOM, *ICYMI: California Poised to Become World's 4th Biggest Economy* (Oct. 24, 2022), https://www.gov.ca.gov/2022/10/24/icymi-california-poised-to-become-worlds-4th-biggest-economy/ [https://perma.cc/N77A-HG29] ("According to Bloomberg, California is poised to overtake Germany as the world's 4th largest economy, continuing to outperform the nation and other countries in GDP growth, companies' market value, renewable energy and more.").

[72] CAL. LTR., *supra* note 68, at 6, 6 n.12.

[73] 2017 STUDY, *supra* note 17, at 2, 30.

[74] *See infra* Part II.C.2 for a more thorough discussion of Hoffman's announcement.

products,[75] because pipeline-product divestitures "have a high rate of failure."[76] However, the FTC ignored this requirement in the Allergan-AbbVie merger, when it approved the divestiture of Allergan's pipeline drug brazikumab.[77]

Becerra's letter also criticized the 2017 Study's definition of success for pipeline-product divestitures: "[E]xisting FTC studies have simply defined a successful divestiture as one that . . . , [] in the case of a pipeline drug, simply determined if the paperwork for the drug purchase was transferred[.]"[78] The

[75] CAL. LTR., *supra* note 68, at 3 & n.5; Bruce Hoffman, Acting Director, Bureau of Competition, Federal Trade Commission, It Only Takes Two to Tango: Reflections on Six Months at the FTC, Speech at the GCR Live 7th Annual Antitrust Law Leaders Forum 6–7 (Feb. 2, 2018), [hereinafter Hoffman 2018] https://www.ftc.gov/system/files/documents/public_statements/1318363/hoffman_gcr_live_feb_2018_final.pdf [https://perma.cc/PKW9-5KBJ] ("[W]e are trying to learn from experience, particularly the recent remedies study [i.e., the 2017 Study]. One important example of that learning is that parties should expect that in transactions where complex pharmaceutical products such as inhalants or injectables need to be divested, *we will require the divestiture of contract manufacturing capabilities rather than other assets, such as pipeline products*. Based on a history of problems with divestitures in this area, our view is that divesting ongoing manufacturing rather than products that haven't yet come to market places the greater risk of failure on the merging firms, rather than the American public. Since, in the context of merger remedies, we are considering divestitures or other remedies as a fix to an otherwise anticompetitive merger, it is entirely proper that the risk of failure be placed on the parties to the merger." (emphasis added)); OFF. OF COMM'R REBECCA KELLY SLAUGHTER, FED. TRADE COMM'N, DISSENTING STATEMENT OF COMMISSIONER REBECCA KELLY SLAUGHTER IN THE MATTER OF BRISTOLMYERS SQUIBB AND CELGENE COMMISSION FILE NO. 191-0061, at 1 n.1 (Nov. 15, 2019) [hereinafter SLAUGHTER BRISTOLMEYERS DISSENT], https://www.ftc.gov/system/files/documents/public_statements/1554283/17_-_final_rks_bms-celgene_statement.pdf [https://perma.cc/U7CJ-X62E] (stating that, when reviewing a proposed merger between two entities with overlapping products, the FTC "has taken seriously the lesson that *divestitures of on-market, rather than pipeline products, are often more likely to succeed in preserving competition* among the overlapping products" (emphasis added)).

[76] CAL. LTR., *supra* note 68, at 3 n.5 (citing Hoffman 2018, *supra* note 75, at 6-7).

[77] *See id.* By letter dated September 3, 2020, the FTC responded to the California Letter's charge that the order requiring divestiture of Allergan's pipeline drug brazikumab ignored the FTC's own "require[ment]" that on-market products—rather than pipeline products—be divested. Letter from Acting Sec'y April Tabor, Fed. Trade Comm'n, to Xavier Becerra, Cal. Att'y Gen (September 3, 2020) [hereinafter FTC RESP. TO CAL. LTR.], https://www.ftc.gov/system/files/documents/cases/letter_to_californias_attorney_general_becerra.pdf [https://perma.cc/WJ88-ZQRE]. The FTC's response asserted that its order to divest brazikumab did not violate that requirement (now re-characterized by the FTC as simply a "preference") because "Skyrizi … remains a product in development for the indications that raise antitrust concerns." *Id.* But this assertion ignores the facts that (i) Skyrizi was already an on-market product by May 2019, *see* CAL. LTR., *supra* note 68, at 3 n.4 (noting that Skyrizi was launched in 2019 and is an "on-market product"); Michael Christel, *Succession Plan: Skyrizi*, 40 PHARMACEUTICAL EXECUTIVE 22, 22 (2020) (noting that Skyrizi was launched in May 2019), and (ii) that the FTC's requirement (as articulated in Commissioner Hoffman's statement of 2018) mandated divestiture of on-market products *with no exception for on-market products that might in the future be marketed for new indications*. In other words, once a product is on-market, there is no reason why potential new indications should cause the FTC to depict it as a pipeline product for purposes of divestiture orders: That the product is on-market still makes it far more likely than a true pipeline product to survive a divestiture.

[78] CAL. LTR., *supra* note 68, at 5-6 (citing 2017 STUDY, *supra* note 17, at 30). The FTC's response to Attorney General Becerra's letter did not address this criticism of the 2017 Study's definition of success. *See* FTC RESP. TO CAL. LTR, *supra* note 77.

California Letter also faulted the FTC for failing to impose ancillary remedies in pharmaceutical mergers (as it does in other mergers). Becerra noted in particular that the FTC ought to evaluate the role of pharmacy benefit managers and their tiered formularies in limiting competition, as the tiering process might prevent divested pipeline products from being able to compete with established products.[79]

Regarding both on-market and pipeline-product divestitures, the California Letter charged that the FTC does not pay adequate attention to whether the merging parties and other competitors are engaging in less R&D and patenting post-merger.[80] The California Letter further charged that, overall, the FTC's definition of success in its 2017 Study is "extremely broad and generous"—and that, even so, there is a 35% chance of failure, meaning that, with a more reasonable definition of success, the chance of failure is likely much higher than 35%.[81] And when divestiture is of assets rather than ongoing business, only 28% succeeded without difficulty.[82] In support, the California Letter cited a study indicating that divestiture orders are not effective in limiting price rises post-merger and that a "significant fraction" of FTC divestiture orders "fail[] to preserve competition."[83]

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[79] CAL. LTR., *supra* note 68, at 7. The FTC's response to the California Letter (*see* FTC RESP. TO CAL. LTR, *supra* note 77) did not address the failure to impose ancillary remedies to prevent manipulation by pharmacy benefit managers. Though non-statutory, the term "ancillary remedies" refers generally to non-monetary equitable remedies that are additional to the injunction that the FTC may obtain to bar the offending party from engaging in prohibited anticompetitive activity. *See, e.g.*, Fed. Trade Comm'n v. AMG Servs., Inc., 558 F. Supp. 3d 946, 965 (D. Nev. 2021) ("This provision [Section 13(b) of the FTC Act] gives the federal courts broad authority to fashion appropriate remedies for violations of the Act, including any ancillary relief necessary to accomplish complete justice." (citations and internal quotation marks omitted)).

[80] CAL. LTR., *supra* note 68, at 2 n.3 (quoting sources); SLAUGHTER BRISTOLMEYERS DISSENT, *supra* note 75, at 1-2 (expressing concern that the FTC's historical approach of requiring one of two merging parties to divest itself of an overlapping product "is too narrow," stating that the FTC "should more broadly consider whether any pharmaceutical merger is likely to exacerbate anticompetitive conduct by the merged firm *or to hinder innovation*," and noting that "recent studies suggest *mergers may inhibit research, development, or approval*." (footnote omitted) (emphasis added)) The FTC's response to the California Letter asserted that, other than the competitive harm allegedly remedied by the order to divest brazikumab, the FTC found no evidence "that other ongoing product development efforts would likely be altered due to diminished competition." FTC RESP. TO CAL. LTR., *supra* note 77, at 1. For that matter, the FTC's response found no evidence of any other competitive harm identified by the California Letter.

[81] CAL. LTR., *supra* note 68, at 4-5, 4 n.8. The FTC's response to the California Letter did not address this criticism of the 2017 Study's definition of success. FTC RESP. TO CAL. LTR., *supra* note 77.

[82] CAL. LTR., *supra* note 68, at 4-5, 4 n.8.

[83] *Id.* at 4-5, 5 n.9. Regarding on-market products specifically, the California Letter faulted the 2017 Study for not using sales data to evaluate the 24 pharmaceutical orders—as it did to evaluate the 50 orders analyzed in the case study method—and thus for being unable to determine the competitors' market share post-order. *Id.* at 4 n.7, 5-6 n.10. The California Letter charged that, without determining market share post-order, the FTC could not determine whether there was actual competition, as opposed to simply competitors, in the market post-order. *Id.* (citing case saying that what must be restored is not competitors but "competitive intensity"); SLAUGHTER BRISTOLMEYERS DISSENT, *supra* note 75, at 1 (expressing concern that FTC's traditional approach of merely

2. Director Hoffman's Announcement

The announcement by Bruce Hoffman, Director of the FTC's Bureau of Competition, contains a stark albeit implicit criticism of the 2017 Study.[84] The announcement comes as part of a speech given by Director Hoffman on February 2, 2018, entitled, "*It Only Takes Two to Tango: Reflections on Six Months at the FTC.*"[85] As many sources attest, Hoffman stated that divestitures of complex pharmaceutical products (like inhalants and injectables) faced a "startlingly high" rate of failure.[86] The Hoffman statement tells a vastly different story than the 2017

identifying product overlaps and requiring divestiture of one of the overlapping products "does not fully capture all of the competitive consequences of these transactions." (footnotes omitted)). The California Letter also criticized the FTC's failure to prevent parties from choosing a weak buyer, whose limitations would prevent it from fully competing post-merger; as an example, the California Letter cited the FTC's approval of Nestle's purchase of Allergan's ZenPep drug, as Nestle was a food conglomerate with little experience in the pharmaceutical industry. CAL. LTR., *supra* note 68, at 4 n.6, 6-7, 6 n.13. The 2017 Study's definition of success came in for particular criticism, on the ground that it was overly broad: "[E]xisting FTC studies have simply defined a successful divestiture as one that was consummated and resulted in at least a single sale post-merger . . . : 'The divestiture of products marketed by both parties to the merger at the time of the divestiture—on-market-products—was considered successful if the buyer sold the product in the market post-divestiture.'" *Id.* at 5-6, 6 n.11 (quoting 2017 STUDY*, supra* note 17, at 30).

This criticism was echoed by Professor Chris Sagers: "While bold claims are made [in the 2017 Study] in abstract terms, 'success' appears to mean nothing more than that a given divestiture was actually carried out and that the divested assets stayed in the market. How the commission would howl if defendants could prove their markets were 'competitive' just because none of their competitors went bankrupt." Chris Sagers, *The Limits of Divestiture as an Antitrust Remedy*, N.Y. TIMES (Feb. 14, 2017), https://www.nytimes.com/2017/02/14/business/dealbook/the-limits-of-divestiture-as-an-antitrust-remedy.html [https://perma.cc/M7CC-8G7Y]. Professor Sagers further criticized the divestiture remedy itself when unaccompanied by econometric analysis that can definitively determine whether post-remedy the market has not only competitors but also meaningful competition: "Ultimately, an overstated defense of the divestiture remedy may reflect the single oldest criticism of antitrust law. Preserving a remedy that allows the agencies to show that they are doing something, without actually taking meaningfully aggressive action, maintains a political compromise both sides can live with." *Id.*

[84] CAL. LTR., *supra* note 68, at 3 n.5.

[85] Hoffman 2018*, supra* note 75.

[86] *See, e.g.*, Jonathan Ende & Will Diaz, *THE LATEST: Divestitures of Complex Pharmaceutical Products off the Table at the FTC*, MCDERMOTT WILL & SCHULTE: ANTITRUST ALERT (Feb. 9, 2018), https://www.antitrustalert.com/2018/02/the-latest-divestitures-of-complex-pipeline-pharmaceutical-products-off-the-table-at-the-ftc/ [https://perma.cc/Z4NS-MC7Z] ("Bruce Hoffman, acting director of the Bureau of Competition at the Federal Trade Commission (FTC), . . . speaking at the Global Competition Review Seventh Annual Antitrust Law Leaders Forum on February 2, 2018, explained that divestitures of pipeline products were not working well for complex pharmaceuticals, such as inhalants and injectables. . . . *An internal study at the FTC revealed that the rate of failure was 'startlingly high' for divestitures of certain complex pharmaceutical products*. Hoffman blamed the high failure rate on the difficulty in actually getting the complex pipeline pharmaceutical to market by a divestiture buyer. (emphasis added) (bullet points omitted)); C. Scott Hataway, Michael S. Wise, Noah B. Pinegar & Sabin Chung, *US Merger Control in the High-Technology Sector, in* THE MERGER CONTROL REVIEW 46, 52 (Ilene Knable Gotts, ed., 2018) ("Explaining the [FTC's] decision [to renounce reliance on divestiture of certain pipeline products], Hoffman said that *the failure rate of divestitures of these pipeline products [was]*

Study, which declared that *all* of the examined pipeline divestitures were successful.[87] At least one source indicates that Director Hoffman based his comment on an "internal study" by the FTC,[88] which suggests that, at or shortly after the time the 2017 Study was published, the FTC may have possessed data demonstrating failure rather than success.[89]

This contradiction between the Study and Hoffman's remarks raises questions: Did any of the pharmaceutical products addressed in the 2017 Study fall into the category of pipeline products whose divestitures fail at a "startlingly high" rate—namely "complex pharmaceutical products such as inhalants or injectables"?[90] If yes, then there appears to be a direct contradiction between the Hoffman statement and the 2017 Study. If no, then why did the 2017 Study—which was intended to give an accurate assessment of pipeline divestiture orders—exclude pipeline divestitures associated with this "startlingly high" failure rate?

Whatever the answers to these questions, two things are clear. Contrary to the 2017 Study's declaration of success, a significant subset of pipeline divestiture orders were failures. And the FTC may have been aware of those failures either at the time of or soon after the publication of the 2017 Study.

3. Professor Kwoka's Critique

No discussion of divestiture remedies would be complete without mentioning Professor John Kwoka and his book, *Mergers, Merger Control, and Remedies: A Retrospective Analysis of U.S. Policy*.[91] Though predating the 2017 Study and addressing divestitures generally (rather than pipeline divestitures specifically), Kwoka's book contends that the FTC's divestiture remedies have largely been ineffective.[92] Predictably, the published response by FTC personnel was fiercely

'startlingly high' and contrasted them with the FTC's 'overall "pretty good" rate of merger remedies succeeding'." (citing Hoffman 2018) (emphasis added)); Letter from Families USA et al. to April Tabor, Secretary of Fed. Trade Comm'n, at 2 (June 11, 2020) ("[I]n 2018, the former Director of the Bureau of Competition, Bruce Hoffman, noted that *pipeline drug divestitures face a 'start[l]ingly high' rate of failure*." (citing Hoffman 2018) (emphasis added)).

[87] 2017 STUDY, *supra* note 17, at 2, 30–31.

[88] *See* Ende & Diaz, *supra* note 86.

[89] At least one source, in quoting Hoffman's comment about the "startlingly high" failure rate, cites the text of the Hoffman speech available on the FTC's website, complete with the URL. *See, e.g.*, Hataway et al., *supra* note 86, at 52 n.23. Yet the text of the speech currently available on the FTC's website—*at the identical URL*—omits that very same comment. *See* Hoffman 2018.

[90] *See, e.g.*, Ende & Diaz, *supra* note 86 (quoting Hoffman); Hataway et al., *supra* note 86, at 52 (same).

[91] *See* JOHN KWOKA, MERGERS, MERGER CONTROL, AND REMEDIES: A RETROSPECTIVE ANALYSIS OF U.S. POLICY (2014).

[92] *See id.* at 156.

critical,[93] and Kwoka's reply then prompted two rejoinders.[94]

In his reply, Kwoka cited his own biting critique of the 2017 Study,[95] where he noted the 2017 Study's varying definitions of success.[96] The assessment of pipeline-product divestitures took into account only whether pipeline assets were transferred to the divestiture buyer.[97] Thus, consistent with other critiques, Kwoka faulted the 2017 Study for ignoring the "survivorship of the assets" and "restoration of competition."[98] These goals necessarily depend upon additional outcomes beyond the initial divestiture, including FDA approval of the pipeline product, market entry of that product, and the ability for the third-party buyer to achieve significant market penetration.[99]

4. Dissenting Commissioner Chopra's Criticism

In his dissenting statement in the AbbVie-Allergan merger, Commissioner Rohit Chopra made several general criticisms of the FTC's approach and specifically targeted the portion of the AbbVie-Allergan order involving a pipeline-

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[93] *See* Edith Ramirez, Chairwoman, Fed. Trade Comm'n, Keynote Remarks at 10th Annual Global Antitrust Enforcement Symposium 8-9 (Sept. 20, 2016), https://www.ftc.gov/system/files/documents/public_statements/985423/ramirez_-_global_antitrust_enforcement_symposium_keynote_remarks_9-20-16.pdf [https://perma.cc/9VNQ-38ZG].

[94] *See* Michael Vita & F. David Osinski, *John Kwoka's Mergers, Merger Control, and Remedies: A Critical Review*, 82 ANTITRUST L.J. 361, 361-64 (2018); John Kwoka, *Mergers, Merger Control, and Remedies: A Response to the Vita-Osinski Critique*, 82 ANTITRUST L.J. 741 (2019); Michael Vita, *Kwoka's Mergers, Merger Control, and Remedies: Rejoinder to Kwoka*, *in* 28 HEALTHCARE ANTITRUST, SETTLEMENTS, AND THE FEDERAL TRADE COMMISSION 433 (Langenfeld & Galeanno eds., 2018); F. David Osinski, A Rejoinder to Kwoka's Response to Vita/Osinski's Review of Kwoka's Book (Jan. 8, 2018) (unpublished manuscript), https://ssrn.com/abstract=3098871 [https://perma.cc/R3H2-4F62].

[95] Kwoka, *supra* note 94, at 760 n.63 (2019) (citing John Kwoka, Jr., One-and-a-Half Cheers for the FTC's New Remedies Study (Feb. 1, 2017) (unpublished manuscript) [hereinafter Kwoka, 1½ Cheers], https://ssrn.com/abstract=3112689 [https://perma.cc/M75C-Q3EM]).

[96] KWOKA, 1½ CHEERS, *supra* note 95, at 3, 5. ("For the remaining 24 orders arising in the pharmaceutical industry, the criteria for 'success' vary even further. For orders addressing cases where both merging parties sold the product, success is again defined as continued production of the product. But for cases of divestiture of 'pipeline products,'—those in the development stage—the divestiture was viewed as successful simply if the assets designated for transfer were in fact transferred. This does not even purport to measure survivorship of the assets for any period of time, much less their competitive effects. . . . Finally, all of the 32 cases involving divestiture of product development assets were declared 'successes' by virtue of the fact that the transfers in fact occurred, regardless of what ensued. For none of these do we learn anything about the fraction of orders that resulted in the preservation or restoration of competition.").

[97] *Id.* at 3.

[98] *Id.* at 5.

[99] *See supra* text accompanying and following notes 20-21; *infra* text following and accompanying notes 161-65.

product divestiture.[100]

Chopra argued that the FTC's "default strategy" of ordering divestiture of overlapping drug products is too narrow.[101] It leaves merging parties' market dominance undisturbed, a lapse that blocks new entry and increases consolidation.[102] That increase results in a market where a small number of pharmaceutical companies spend their resources more on preserving patent monopolies and less on innovation.[103] Patent monopolies inhibit competition, and large, consolidated firms may use their abundance of products as "leverage in negotiations with health insurers and pharmacy benefit managers," allowing them to secure preferred listings on insurance formularies.[104] By contrast, smaller pharmaceutical companies typically have smaller lists of drugs and thus less bargaining power to obtain preferential placement on formularies.[105]

Much of the Chopra dissent highlights the FTC's tendency to approve weak buyers for divested products. In the case of the AbbVie-Allergan merger, Chopra criticized the divestiture of Allergan's pipeline drug brazikumab to AstraZeneca—a company that paid nothing for it, and therefore likely lacked the incentive to bring the drug to market.[106] In fact, AstraZeneca already owned the intellectual property for brazikumab and had previously licensed it to Allergan, so not only did it pay nothing, but it also got to keep Allergan's $250 million license payment.[107] Additionally, AstraZeneca was permitted to re-license brazikumab to another third party.[108] Given these circumstances, AstraZeneca's commitment to developing brazikumab was questionable;[109] the company had an "option," rather than a

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[100] *See generally* CHOPRA DISSENT, *supra* note 68. In the same matter, Commissioner Rebecca Kelly Slaughter wrote a brief dissenting statement adopting the substance of the Chopra dissent. *See* OFF. OF COMM'R REBECCA KELLY SLAUGHTER, FED. TRADE COMM'N, DISSENTING STATEMENT OF COMMISSIONER REBECCA KELLY SLAUGHTER IN THE MATTER OF ABBVIE/ALLERGAN, COMMISSION FILE NO. 191-0169, at 1 (May 5, 2020), https://www.ftc.gov/system/files/documents/public_statements/1574577/191_0169_dissenting_statement_of_commissioner_rebecca_kelly_slaughter_in_the_matter_of_abbvie_and_0.pdf [https://perma.cc/P8R2-2SLQ] ("I share the concerns Commissioner Chopra has articulated in detail about the proposed divestitures and the absence of meaningful benefits to consumers, and I write separately only to add a few additional thoughts on the question of innovation harms.").

[101] CHOPRA DISSENT, *supra* note 68, at 2.

[102] *Id.* at 2.

[103] *Id.* at 3.

[104] *Id.* at 2-3, 9-11; *see id.* at 3 n.1 (observing that the pharmaceutical industry is "fraught with competitive problems not easily resolved by one-off divestitures").

[105] *Id.* at 11.

[106] *Id.* at 2, 4. The Chopra dissent similarly noted (as did the California Letter) that Allergan's on-market drug ZenPep was being divested to Nestle, which is not a pharmaceutical company and thus is an unworthy buyer. *Id.* at 2-4; CAL. LTR., *supra* note 68, at 4 n.6, 7.

[107] CHOPRA DISSENT, *supra* note 68, at 13.

[108] *Id.*

[109] *Id.* at 14.

"commitment," to compete.[110]

Concerns related to weak buyers have arisen with on-market divestitures as well as pipeline divestitures. In particular, both Chopra and the California letter objected that Allergan's on-market product ZenPep was being divested to Nestle, a food conglomerate with little experience in pharmaceuticals.

The Chopra dissent also charged that the FTC failed to add terms that would have increased the chance of AstraZeneca bringing brazikumab to market.[111] For example, the FTC order did not require AstraZeneca to give higher priority to brazikumab than it gives to other projects.[112] Nor did the FTC restrict the merged company's "contracting and rebating practices."[113] That omission left the merged company free to engage in "portfolio contracting" and "bundled rebates," practices that enable the merged party to obtain formulary preference for its own drugs.[114] The omission also left the merged company free to engage in practices that require its purchasers to give (sometimes exclusive) preference to its own products over

[110] *Id.* at 13-15. In its statement dated May 5, 2020, the FTC's three-commissioner majority that approved the AbbVie-Allergan merger and the order to divest brazikumab addressed the Chopra dissent's critique of that divestiture order and of the 2017 Study. *See* Statement of Chairman Joseph J. Simons, Commissioner Noah Joshua Phillips, and Commissioner Christine S. Wilson, *Concerning the Proposed Acquisition of Allergan plc by AbbVie Inc.* (May 5, 2020) [hereinafter Majority Statement], https://www.ftc.gov/system/files/documents/public_statements/1574619/abbvie-allergan_majority_statement_5-5-20.pdf [https://perma.cc/TP3Z-JQKF]. Regarding the divestiture order, the majority asserted, dubiously, that AstraZeneca's incentive to develop and market brazikumab will depend not on how much it paid Allergan but on how much money it could make from brazikumab going forward. *Id.* at 3. That is, dismissing any suggestion that AstraZeneca has no skin in the game, the majority simply ignored the fact that AstraZeneca suffers no actual out-of-pocket loss if it decides to abandon brazikumab. While dismissing as well the Chopra dissent's statement that AstraZeneca has an *option* rather than a *commitment* to develop and market brazikumab, the majority did not actually disagree with that statement, but simply noted that other divestiture orders using the same model as that used for AstraZeneca have succeeded in bringing drugs to market. *Id.* As to the fact that AstraZeneca previously declined to develop brazikumab (instead licensing it to Allergan), the majority refused to view this history as a strike against Allergan, noting merely that company documents indicate no "current or future plans to relicense or flip" brazikumab. *See id.* at 4 n.3. In response to the fact that AstraZeneca previously "sold off rights to" a number of other immunology products rather than develop them itself, the majority noted that AstraZeneca recently made public statements vaunting its pipeline immunology products. *See id.* at 4. Because the majority thus focused on AstraZeneca's statements rather than AstraZeneca's repeated history of jettisoning its immunology products, it appears that the majority believed words speak louder than actions. Finally, the majority found no evidence that AbbVie would use bundling and rebating schemes to weaken brazikumab's ability to compete in the market, though what exactly would constitute evidence sufficient for the majority was left unaddressed. *See id.* at 5. Regarding the 2017 Study's determination whether the FTC's divestiture orders were successful, the majority cited with approval the study's claims of success but did not address the study's questionable criteria for determining success. *See supra* text accompanying and following notes 20-21; *infra* text following and accompanying notes 161-65. *See* Majority Statement, *supra*, at 8.

[111] CHOPRA DISSENT, *supra* note 68, at 15-17.

[112] *Id.* at 15.

[113] *Id.*

[114] *Id.* at 16.

competitors' products.[115]

The Chopra dissent stressed that approving risky buyers is no solution:

> FTC merger settlements are supposed to restore competition killed off from a transaction. Looking for product overlaps and then accepting risky or questionable buyers to eliminate them is not sound competition policy. . . . Accepting risky buyers that are unlikely to fully restore competition does a disservice to patients and worsens the out-of-control drug costs in our country.[116]

Divestitures work only "if the buyer fully restores the competition that existed prior to the merger."[117] Yet merging parties have incentives to use anticompetitive strategies that cause the buyer of divested assets and products to fail:

> The pharmaceutical industry has long been the focus of anticompetitive conduct enforcement by the FTC, state attorneys general, and private litigants. Challenged conduct includes pay-for-delay settlements, anticompetitive product hopping, fraudulent orange book listings, and sham litigation.[118]

Merging parties also have an incentive not only to sell to the weakest buyer (as noted above),[119] but also to sell quickly, and therefore to lower the price to the point where a buyer (a) does not have sufficient skin in the game, (b) buys as an option, without concrete plans to make the product a success presently, and (c) buys the divested asset solely for the purpose of having it take out sizable loans, and thus incur significant debt.[120] A buyer is sub-optimal when the purchased asset is not key to the buyer's business.[121] To make matters worse, when the buyer's acquisition fails, the buyer sometimes sells the divested asset back to the merged entity for pennies on the dollar, making the merged entity even more powerful.[122]

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[115] *Id.* at 15-16.

[116] *Id.* at 4.

[117] *Id.*

[118] *Id.* at 4 n.3.

[119] *Id.* at 5.

[120] *See id.*

[121] *See id.* at 6.

[122] *See id.* In reviewing divestitures of on-market non-pharmaceutical businesses, the Chopra dissent criticized the 2017 Study directly, insofar as the Study declared those divestitures to be successful. Citing several instances where divestiture buyers went bankrupt or quickly resold the divested assets, the Chopra dissent concluded that a divestiture cannot be called successful if it did not restore competition post-divestiture: "Despite these outcomes, the FTC published a study in 2017 and declared that its merger remedies were effective. It is important that we learn from these and other divestitures that did not fully restore competition." *Id.* at 6-7. To ensure genuinely successful divestitures, the Chopra dissent urged the FTC to make sure that the divested asset is central to the divestiture buyer's long-term business, that the buyer will not quickly resell or repurpose the asset, and that the buyer is not using the purchase "as a branding strategy to increase sales of its other products." *Id.* at 7.

5. Other Relevant Literature

As discussed more fully below, several scholars have made contributions relevant to this discussion. Barak Richman et al. explain what the most important determinant of success is for a pipeline product and why pipeline product divestitures frequently fail. Colleen Cunningham et al. describe "killer acquisitions," in which one company acquires a pipeline product in order to terminate it. The team of William S. Comanor and F.M. Scherer, like John LaMattina, find that the tendency of post-merger entities to cut supposedly duplicative departments ends up destroying the parallel research tracks necessary for pipeline products to succeed. Emphasizing how problematic mergers are, Justus Haucap and Joel Stiebale note that, following a merger, innovation diminishes not only within the merged entity but also within non-merging competitors. Ilene Knable Gotts and Richard T. Rapp conclude that the merged entity might have a better chance of success at marketing a pipeline product than a divestiture buyer might, but that chance dies with divestiture.

Barak Richman et al.[123] state first that, in any assessment of the health of a drug product pipeline, the most important factor is whether the pipeline drug receives FDA approval,[124] which, as discussed, the FTC's 2017 Study does not take into consideration.[125] Second, Richman et al. suggest an explanation for why pipeline divestitures frequently fail.[126] Significant capital and specialized expertise are needed to ensure that any pipeline product succeeds in clinical trials and obtains FDA approval.[127] Yet that capital and expertise tend to reside in large, traditional pharmaceutical companies,[128] many of which are the products of mergers. Thus, ordering the merged entity to divest itself of a pipeline product ensures that the pipeline product will be separated from a sure source of capital and expertise, only to face an uncertain future with a divestiture buyer of unproved suitability. This

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[123] *See* Richman et al., *supra* note 2, at 789, 792, 799, 801-02, 804-05, 809, 811, 818 (2017). The article by Richman et al., while cited in the text for two specific points, offers the following general conclusions. Finding that M&A activity is positively correlated with increased FDA approvals and increased new molecular entities, Richman at al. infer that pharmaceutical M&A does not necessarily harm innovation. *Id.* at 788-89, 818. Richman et al. also observe that that there is nothing inherently lamentable about the shift of the source of innovation from large pharmaceutical companies to startups. *Id.* at 792-93. Richman et al. explain that those startups are then purchased by large pharmaceutical companies, which in turn have marketing and regulatory expertise lacked by startups. *Id.* at 791-93, 802, 804-05, 818. Richman et al. opine that the source of innovation has shifted to startups in part because of the increasing importance of biologics and concomitantly the new and complex scientific specialization necessary for biologic development, a specialization lacked by long-established pharmaceutical companies. *Id.* at 793, 800-02, 818-19. According to Richman et al., M&A's real threat to innovation arises from the concentration of marketing and regulatory expertise in the hands of a small number of large companies. *Id.* at 789-90, 818.

[124] *See id.* at 809, 811.

[125] *See supra* text accompanying and following notes 20-21; *infra* text following and accompanying notes 161-65.

[126] Richman et al., *supra* note 2, at 791-92, 802, 804-05, 818.

[127] *Id.* at 791-92, 802, 804-05, 818.

[128] *Id.* at 791-92, 802, 804-05, 818.

conclusion complements Chopra's conclusion that, in crafting divestiture orders, the FTC does not consider whether the buyer of the divested pipeline product has the necessary capital commitment and regulatory expertise to bring the product to market.[129]

Some acquisitions do provide large, consolidated pharmaceutical companies with drug pipelines, enabling the development and marketing of new products,[130] but most acquisitions by design terminate the acquired company's pipeline drug. The purpose of the termination is to prevent the acquirer from owning multiple versions—pipeline and on-market—of the comparable drugs. Otherwise, there is a risk that the acquirer obtains a pipeline product "solely to discontinue the target's innovation projects and preempt future competition."[131] Cunningham et al. describe these "killer acquisitions" in detail, finding that when a company acquires a pipeline drug that overlaps with its own drug, the company is significantly less likely to develop the acquired drug.[132] Additionally, they find that killer acquisitions "disproportionately occur just below thresholds for antitrust scrutiny,"[133] conservatively estimating that 5.3% to 7.4% of acquisitions in their sample are killer acquisitions and concluding that "killer acquisitions likely cause as much anticompetitive harm as pay-for-delay settlements."[134]

Regulators have noted that pipeline divestitures are relatively likely to fail, especially when one takes into consideration the pipeline drug's effect (or lack thereof) on competition.[135] Supposing company A acquires company B to kill B's pipeline drug, an FTC order requiring company B to divest B's pipeline drug may still end up dooming that pipeline drug. B's divested drug may not make it through to FDA approval, and even if it does, it may not gain a significant market share. In this sense, the FTC's current pipeline divestiture protocol creates a win-win for company A: If the FTC does not order divestiture, company A can kill company B's pipeline drug directly after the merger; if the FTC orders divestiture, B's

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[129] CHOPRA DISSENT, *supra* note 68, at 2-6, 13-14. Of course, whether non-divestiture of pipeline products then gives the merged company a competitive advantage, contrary to the usual goal of divestiture orders, is a separate issue, which is beyond the scope of this article. To put the issue starkly: Is it better for society if the FTC, when attempting to reduce the merged company's market dominance, requires divestiture of a pipeline drug, even if post-divestiture the pipeline drug is likely to fail and thus society is deprived of the pipeline drug? Or is it better for society if the pipeline drug remains with the merged company, with the result that society is likely to obtain the pipeline drug, though the merged company thereby obtains greater market dominance?

[130] *See* Richman et al., *supra* note 2, at 791–93, 802, 804-05, 818.

[131] Colleen Cunningham et al., *Killer Acquisitions*, 129 J. POL. ECON. 649, 649 (2021).

[132] *See id.*

[133] *Id.*

[134] *Id.* at 694; *see also id.* at 682 (finding "that (1) a project is less likely to be developed after being acquired by a firm with an overlapping existing drug . . . and that (2) these results are concentrated in markets with low levels of competition . . . and (3) when relevant acquirer patents are far from expiration . . . ."); *id.* at 694 (finding that killer acquisitions, while benefiting the acquirer and the target, hurt consumers "because there are fewer drugs and because the drugs that are developed and brought to market are sold at higher prices").

[135] *See* CAL. LTR., *supra* note 68, at 3 n.5 (citing Hoffman 2018, *supra* note 75, at 6-7).

pipeline drug is likely to die anyway, especially in view of Chopra's observation that merging entities are incentivized to propose weak buyers for the divested product.[136] Perhaps pipeline products are too dependent on the capital resources and regulatory expertise of large pharmaceutical companies to be able to survive the majority of divestiture orders.

The cost-cutting zeal that follows a merger is another reason why mergers end up dooming pipeline products. William S. Comanor and F.M. Scherer explain why mergers make pipeline products less likely to succeed, both when a post-merger entity and when a startup develops the divested pipeline product.[137] When a post-merger entity develops the pipeline product, it is most likely to innovate successfully when it uses parallel research teams, an approach called the "parallel paths" strategy.[138] But Comanor and Scherer found that post-merger entities tend to cut supposedly duplicative R&D teams and thus end up foreclosing the parallel paths strategy.[139] Meanwhile, when a startup develops the pipeline product, it often looks to a large, traditional pharmaceutical company to provide the capital and regulatory expertise needed for clinical testing and FDA approval. Mergers reduce the number of companies from which the startups can obtain this support.[140] Additionally, Comanor and Scherer rely on new drug approvals as a reliable determinant of whether innovative efforts are successful.[141]

John L. LaMattina offers an analysis similar to Comanor and Scherer's.[142] LaMattina first notes that post-merger entities review all company departments for integration purposes and that they typically review R&D departments last. Predictably, this delay in integrating R&D ends up slowing the product pipeline, halting new project starts, and freezing new hiring.[143] Like Comanor and Scherer, LaMattina concludes that post-merger entities often eliminate multiple research sites in an effort to cut costs and boost stock price, and that those cuts end up constricting the ability to innovate.[144] His analysis further emphasizes important results and heuristics used in other studies, namely, that innovation has a positive correlation with the number of companies in the market[145] and that FDA approval is the main indicium of successful innovation.[146]

Innovation—indisputably necessary for the success of pipeline products—is

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[136] CHOPRA DISSENT, *supra* note 68, at 5, 7, 14, 15.

[137] William S. Comanor and F.M. Scherer, *Mergers and innovation in the pharmaceutical industry*, 32 J. HEALTH ECON. 106 (2012).

[138] *Id.* at 106-07, 110-11, 113.

[139] *Id.*

[140] *Id.* at 111, 113.

[141] *See id.* at 110.

[142] John L. LaMattina, *The impact of mergers on pharmaceutical R&D*, 10 NATURE REVIEWS/DRUG DISCOVERY 559 (2011).

[143] *Id.* at 560.

[144] *Id.* at 559-60.

[145] *Id.* at 559.

[146] *Id.*

harmed by mergers in a double sense. Adding a novel perspective, Justus Haucap and Joel Stiebale find that "mergers are, on average, associated with a large decline in innovative activity of the merged entity *and among non-merging competitors*."[147] They note:

> R&D and patenting within the merged entity decline substantially after a merger, compared to the same activity in both companies beforehand. . . . On average, patenting and R&D expenditures of non-merging competitors also fell—by more than 20%—within four years after a merger. . . . What's the reason for this? At least for the mergers we looked at, acquirers often target firms that have a relatively similar patent portfolio. That means there's less competition for discovering and developing new therapies. If a non-merging rival is also researching similar therapies, that outside firm also now had one less competitor. It experiences a similar reduction in competition as the acquiring firm.[148]

Finally, Ilene Knable Gotts and Richard T. Rapp note that whether "future goods"—meaning pipeline products—will actually enter the market is highly unpredictable.[149] Orders divesting a merged entity of a "future good" therefore often fail to result in two on-market products (one sold by the merged entity and one sold by the divestiture buyer).[150] They argue that divestiture orders that have "one-product outcomes" cannot be considered successful.[151] The merged entity, with all of its resources, may have a better chance than the divestiture buyer of getting a pipeline product onto the market, but the act of divesting terminates that chance.[152]

III. THE EFFICACY OF THE FTC'S PIPELINE DIVESTITURE ORDERS

Although Part II discusses critiques of the 2017 Study as well as academic analysis of risks affecting pipeline divestitures, it was the inadequacy of the 2017 Study's definition of success that prompted the present study. This Part discusses the background, data sources, methodology, findings, and limitations of our study.

A. Background

This study evaluates the efficacy of pipeline divestiture as a remedy for

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[147] Justus Haucap & Joel Stiebale, *How Mergers Affect Innovation: Theory and Evidence from the Pharmaceutical Industry* 3 (Dusseldorf Institute for Competition Economics, Discussion Paper No. 218, 2016) (emphasis added).

[148] Haucap & Stiebale, *supra* note 9.

[149] Ilene Knable Gotts & Richard T. Rapp, *Antitrust Treatment of Mergers Involving Future Goods*, 19 ANTITRUST 100, 100-02 (2004); *see id.* at 101 (referring to "drugs in the development pipeline").

[150] *Id.* at 100-02.

[151] *Id.*

[152] *Id.* at 102.

anticompetitive mergers[153] between pharmaceutical companies. We have identified 26 pharmaceutical mergers between 2006 and 2018 where the FTC required at least one of the merging entities to divest a pipeline product.[154] In total, the FTC ordered divestiture of 75 pipeline drugs[155] in advance of the 26 proposed mergers. This study analyzes the life cycle and market performance of those divested pipeline drugs to determine if the divestiture remedy achieved the FTC's stated goal of "maintain[ing] or restor[ing] competition in the relevant market."[156]

As noted earlier,[157] the FTC's 2017 Study analyzed all 89 of the FTC's merger remedy orders issued between 2006 and 2012. Out of those 89 orders, 24 concerned the pharmaceutical industry and required divestiture of 60 on-market products[158] and 32 pipeline products. The FTC study found that *all* 32 pipeline-product divestitures were successful, making divestiture the most successful remedy for anticompetitive mergers. But here's the catch: The FTC considered a pipeline-product divestiture successful if the assets related to that pipeline product were transferred to the approved buyer.[159] Irrelevant to the FTC's study was whether the pipeline product survived in the market and restored competition subsequent to the divestiture.

Our study seeks to improve the FTC's 2017 Study in several ways. First, our study period was 2006-2018, which includes six more years of data than the FTC's study period of 2006-2012.[160] Since 2012, there have been several large-scale pharmaceutical mergers with divestiture orders; the largest involved the divestiture of 79 pharmaceutical products, including 19 pipeline products.[161] By including more recent mergers, our analysis provides an updated and expanded view of divestiture orders and their efficacy in protecting and restoring competition.

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[153] *See supra* Part II.A.2 for an overview of the Hart-Scott Rodino Act and the FTC's range of tools to remedy such mergers.

[154] For a definition of pipeline product, see *infra* text accompanying and following notes 166-68.

[155] This study defined a drug as any pharmaceutical product with a unique FDA application number (NDA, ANDA, or BLA number, *see infra* note 173 & Part III.D.3). In cases where a divestiture order included the name of the API(s) but not the application number, this study treated the unique API as a drug.

[156] 2017 STUDY, *supra* note 17, at 15.

[157] *See supra* Part II.B.

[158] 2017 STUDY, *supra* note 17, at 30 ("Of the total products divested in the 24 orders, 60 were on-market products, *sold* by both parties to the merger at the time of the merger.") (emphasis added).

[159] *Id.* at 2, 30.

[160] Although the FTC's 2017 Study analyzes mergers in a broad range of industries, this study concerns only mergers in the pharmaceutical industry.

[161] FED. TRADE COMM'N, STATEMENT OF THE FEDERAL TRADE COMMISSION IN THE MATTER OF TEVA PHARMACEUTICALS INDUSTRIES LTD. AND ALLERGAN PLC (July 27, 2016), https://www.ftc.gov/system/files/documents/public_statements/973673/160727tevaallergan-statement.pdf [https://perma.cc/V6SN-ZAAE]; FED. TRADE COMM'N, TEVA/ALLERGAN DIVESTITURE PRODUCTS TABLE (July 27, 2016), https://www.ftc.gov/system/files/documents/cases/160915teva-allergan-table.pdf [https://perma.cc/6EL5-72EJ] (providing a list of the divested products that include 19 pipeline drugs, 56 on-market drugs, and 4 drugs that had both on-market and in-development dosage strengths).

Additionally, our study provides a more nuanced analysis of pharmaceutical divestitures, focusing exclusively on pipeline products. We believe that failed divestitures require more granular analysis than past studies have provided, as divested pipeline products create a pronounced risk of the loss of competition.

Second, while transfer of the assets related to the pipeline product is indeed a necessary condition for a successful divestiture, we disagree with the FTC that such transfer alone is sufficient to maintain or restore competition. If the buyer of the divested product stops developing the drug, never receives FDA approval, or makes no significant sales after approval and marketing, then competition still suffers.[162]

The present study uses a more nuanced definition of success. If divestitures are intended to preserve competition,[163] then any evaluation of the divestiture remedy must determine whether the divested products have achieved significant sales post-divestiture. Specifically, we consider a pipeline-product divestiture successful only if the divested drug accounted for more than 1% of total sales in the relevant market[164] in 2023.[165]

Finally, the FTC study defines pipeline products as "products in development," and it defines on-market products as "products marketed by both parties to the merger at the time of the divestiture."[166] These definitions are slightly unclear. Consider, for example, the case where, at the time of divestiture, the divested product was fully approved by the FDA but was not yet marketed by its owner.[167] The FTC definitions do not specify whether that product would be considered a pipeline product or an on-market product. The present study eliminates that

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[162] *See supra* Part II.C. (describing various criticisms of the FTC's 2017 Study).

[163] The principal motivation for the FTC's divestiture orders is the concern that, absent any remedy, the proposed merger would reduce the number of current or potential participants in the relevant market. *See, e.g.*, Watson Pharms., Inc., Actavis Inc.; Actavis Pharm. Holding 4 ehf., and Actavis S.a.r.l., 77 Fed. Reg. 64515 (Oct. 22, 2012).

[164] Here we define the relevant market as the market for the API(s) of the divested drug product. Relevant markets can be defined in several ways. A narrowly defined market may consist of only those drugs containing the same API(s) that are also available in the same dosage form, strength, and route of administration. Indeed, the oral version of a drug may not be a substitute for the intravenous version of the same drug. A broadly defined market, on the other hand, may consist of an entire therapeutic class—drugs that have a similar mechanism of action or treat similar types of conditions. This study takes the middle road by defining the relevant market by API(s).

[165] A limitation of our study is that it looked only at sales data from 2023. A divested drug could, in theory, have no or very low sales in the year 2023 despite having significant sales in years before or after 2023. In that case, our study would still find that divestiture unsuccessful notwithstanding significant sales in proximate years. For further discussion regarding the limitations of our study, *see infra* Part III.E.

[166] 2017 STUDY, *supra* note 17, at 30.

[167] A few months of delay often intervene between a drug's receipt of FDA approval and the drug's marketing. *See, e.g.*, ANDA 76740 ("Nimodipine"); ANDA 202955 ("Brompheniramine maleate, Pseudoephedrine hydrochloride, Dextromethorphan hydrobromide"); NDA 206500 ("Rolapitant hydrochloride"). In some cases, an approved drug is never marketed. *See, e.g.*, ANDA 203407 ("Methotrexate sodium preservative free"); ANDA 77843 ("Cabergoline"). This study used the Orange Book for information related to a drug's FDA approval and the NDC Directory for a drug's earliest marketing date (if any). *See infra* notes 177-81 and accompanying and following text.

confusion by deeming a drug to be a pipeline product if it was not yet marketed at the time of divestiture, regardless of its approval status. In our study, we deemed a drug to be marketed as of the earliest "start marketing date" in the National Drug Code ("NDC")[168] associated with that drug.

B. Compiling the Datasets

We began by compiling a list of pharmaceutical divestment orders that were issued by the FTC between 2006 and 2018. To do so, we accessed the FTC's publicly available legal library of cases and proceedings[169] and filtered for administrative actions related to the pharmaceutical industry that occurred during our desired time range.[170] Selecting all divestiture orders[171] and analyzing the corresponding Federal Register notices,[172] we compiled a list of divested drug products that were not already on-market at the time of divestiture. For each of the drugs on our list, we also collected data regarding the date of divestiture, the name of the merger case, the names of the buyer and seller, the unique FDA application

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[168] The NDC is a unique, three-segment number that acts as a universal product identifier for any human drug marketed in the United States. The FDA identifies and tracks drug products through the NDC codes. *See National Drug Code Database Background Information*, U.S. FOOD & DRUG ADMIN. (Mar. 20, 2017), https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information [https://perma.cc/CD28-QF8J].

One drug may have multiple NDC codes. 21 C.F.R. § 207.35. The "start marketing date" of an NDC code is the date when the drug product associated with the NDC code enters commercial distribution. This study collected all the NDC codes associated with a divested pipeline drug product and deemed the drug to have been marketed on the earliest "start marketing date" of those NDCs. *See id.*

[169] *See Legal Library: Cases and Proceedings*, FED. TRADE COMM'N, https://www.ftc.gov/legal-library/browse/cases-proceedings [https://perma.cc/H3VB-N4UL] (last visited Sept. 28, 2025).

[170] We filtered the list of cases and proceedings using the following parameters: "Industry" → "Prescription Drugs"; "Type of Action" → "Administrative"; "Start Date" → "01/01/06"; "End Date" → "12/31/18."

[171] This document is usually titled "Decision and Order." *See, e.g.*, *In re Teva and Allergan,,* FTC File No. 151 0196, C-4589 (Sep. 15, 2016), https://www.ftc.gov/legal-library/browse/cases-proceedings/151-0196-teva-allergan-matter [https://perma.cc/3WU6-JQ2Y]; *In re Akorn, Inc.,* FTC File No. 141 0162, C-4479 (Sep. 19, 2014), https://www.ftc.gov/legal-library/browse/cases-proceedings/141-0162-akorn-inc-matter [https://perma.cc/SK6E-N43C]; *In re Actavis PLC and Forest Lab'ys*, FTC File No. 141 0098, C-4474 (Sep. 5, 2014), https://www.ftc.gov/legal-library/browse/cases-proceedings/141-0098-actavis-plc-forest-laboratories-matter [https://perma.cc/PSY4-6N88]; *In Re Valeant Pharms. Int'l and Precision Dermatology*, FTC File No. 141 0101, C-4477 (Aug. 21, 2014), https://www.ftc.gov/legal-library/browse/cases-proceedings/141-0101-valeant-pharmaceuticals-international-precision-dermatology-matter. [https://perma.cc/89S5-RUZ5].

[172] *See, e.g.*, *Teva Pharm. Indus. Ltd. and Allergan plc*, 81 Fed. Reg. 51893 (Aug. 5, 2016); *Mylan* N.V., 81 Fed. Reg. 51899 (Aug. 5, 2016); *Lupin Ltd., Gavis Pharms. LLC, and Novel Lab'ys*, *Inc.*, 81 Fed. Reg. 9467 (Feb. 25, 2016).

numbers (if available),[173] the name of the API(s),[174] and the dosage form and strength.

For each of the drugs on our list, we used the FDA's Orange[175] and Purple[176] Books to collect data regarding FDA approval status, date of approval (if any), and marketing status.[177] For this study, we used the July 2024 supplement of the Orange Book[178] and the August 2024 version of the Purple Book.[179] We then used the NDC

[173] The unique FDA application number can be an NDA, ANDA, or BLA number. *See Types of Application,* U.S. FOOD & DRUG ADMIN. (Oct. 23, 2014), https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications [https://web.archive.org/web/20250918122115/https://www.fda.gov/drugs/how-drugs-are-developed-and-approved/types-applications]. Note that not all the divested pipeline products mentioned in the FTC's "Decision and Order" documents include an FDA application number. *See, e.g.*, Decision and Order, *In re Teva and Allergan*, FTC File No. 151 0196, C-4589 (Sep. 15, 2016), https://www.ftc.gov/legal-library/browse/cases-proceedings/151-0196-teva-allergan-matter [https://perma.cc/3WU6-JQ2Y]; Decision and Order, *In re Hikma Pharms. PLC,* FTC File No. 151 0198, C-4568 (May 5, 2016), https://www.ftc.gov/system/files/documents/cases/160505roxanehikmado.pdf [https://perma.cc/S4AF-C6CV] (noting no application number for Flecainide). Note also that a drug can have an FDA application number without receiving FDA approval. *See Requesting a Pre-Assigned Application number*, U.S. FOOD & DRUG ADMIN. (Apr. 26, 2023), https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/requesting-pre-assigned-application-number [https://web.archive.org/web/20250809052049/https://www.fda.gov/drugs/electronic-regulatory-submission-and-review/requesting-pre-assigned-application-number] (documenting the method for obtaining pre-assigned application numbers).

[174] For the definition of API(s), *see supra* note 21.

[175] The Orange Book, formally known as "Approved Drug Products with Therapeutic Equivalence Evaluations," is a database published and maintained by the FDA that lists all FDA-approved small molecule drugs along with any associated patent and exclusivity information. *Orange Book Preface*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface [https://web.archive.org/web/20251004150334/https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface] (last visited Oct. 28, 2025).

[176] The Purple Book, also known as "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations," is a database published and maintained by the FDA that lists all FDA-approved large molecule biologic and biosimilar drugs along with certain associated patent and exclusivity information. *See Purple Book: Database of Licensed Biological Products*, U.S. FOOD & DRUG ADMIN., https://purplebooksearch.fda.gov [https://perma.cc/HA59-BKLB] (last visited Oct. 28, 2025); Kurt R. Karst, *The "Purple Book" Makes Its Debut!,* FDA L. BLOG (Sept. 9, 2014), https://www.thefdalawblog.com/2014/09/the-purple-book-makes-its-debut/ [https://perma.cc/9A5K-MJEN].

[177] The Orange Book lists four possible options for the marketing status of a drug: Prescription (RX), Over the counter (OTC), Discontinued not for safety and efficacy, and Discontinued for safety and efficacy. *Orange Book Cumulative Supplement 7*, U.S. FOOD & DRUG ADMIN. (July 2024), https://web.archive.org/web/20240816062854/https://www.fda.gov/media/72973/download?attachment [https://perma.cc/E6A6-7GPG].

[178] *Id.*

[179] *Download Purple Book Data*, U.S. FOOD & DRUG ADMIN., https://purplebooksearch.fda.gov/downloads/ [https://perma.cc/TVX5-3GC7] (last visited Nov 7, 2025).

Directory to collect all of the NDC codes[180] associated with each drug on our list.[181] We also collected data regarding the "start marketing date" of each of those NDC codes. Finally, we filtered our list of divested products to exclude any drug that had a "start marketing date" earlier than the date of divestiture.[182] At this stage, our dataset included only information related to divested pipeline products.

In addition, we collected market share data related to the drugs in our dataset. For each drug, we defined the relevant market as the market for all products with the same API(s) as the divested drug.[183] From IQVIA's National Sales Perspective (NSP) dataset,[184] we obtained data showing the sales in dollar amounts and units sold for all drug products whose API(s) appeared on our list. The IQVIA dataset was sorted by NDC codes, and covered August 2018 to April 2024. We compiled all the above-mentioned data into a final dataset ("Dataset").

C. Methodology

For the granular level of our analysis, we used unique FDA application numbers and API(s).[185] Using our Dataset, we calculated the total sales of the divested drug and the total sales for all drugs with the same API(s). Additionally, we compared those two sales figures to calculate the market share of our divested drug. If the drug had a market share higher than 1% in 2023, we deemed that drug to have created significant competition in the relevant market, and we therefore considered the divestiture of that drug a success. As noted, we chose a low figure of 1% for our market-share threshold in case our methodology understated the divested pipeline product's market share. In all other cases, we considered the divestiture a failure.

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[180] The FDA tracks all human drugs commercially available in the U.S. using a unique universal product identifier called the NDC. *National Drug Code Database Background Information*, U.S. FOOD & DRUG ADMIN. (Mar. 20, 2017), https://www.fda.gov/drugs/development-approval-process-drugs/national-drug-code-database-background-information [https://perma.cc/V7LK-JKMC]. The NDC Directory is a database published and maintained by the FDA that tracks the earliest marketing date associated with each NDC. *National Drug Code Directory*, U.S. FOOD & DRUG ADMIN. (Nov. 11, 2024), https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory [https://perma.cc/YX44-2LTV].

[181] For this purpose, we downloaded two datasets from the NDC database titled "NDC database file – Excel version (zip format)," and "NDC database excluded drugs database file (zip format)." Both files were downloaded in September 2024. *National Drug Code Directory*, *supra* note 180.

[182] Our study defined the date of divestiture as the date when the merger parties and the approved buyer(s) signed an asset purchase agreement covering the assets related to the divested pipeline drug.

[183] See *supra* note 164 for a discussion of the various ways to define the relevant market.

[184] *National Sales Insight*s, IQVIA (July 2021), https://www.iqvia.com/-/media/iqvia/pdfs/us/fact-sheet/iqvia-nsp-data-fact-sheet-2021.pdf [https://perma.cc/4B24-3ZTX] (last visited Nov. 7, 2025).

[185] Some of the drugs in our dataset did not have FDA application numbers. If two drugs had the same API(s) but no FDA application numbers, we considered them to be the same drug. This approach, in turn, could have made the market share of a divested drug appear larger than it really is.

D. Results

In total, we collected data on 26 merger remedy orders where the FTC required divestiture of 75 pipeline drugs—that is, drugs that were not marketed at the time of the divestiture. Out of those 75 divestitures, only 14 created significant competition in the relevant markets, while 61 failed to do so. In other words, between 2006 and 2018, pipeline-product divestiture as a remedy for anticompetitive mergers had a success rate of only 19%.

Furthermore, only 8 out of the 26 mergers analyzed in this study (30.8%) included at least one pipeline drug that created significant competition in the relevant market after divestiture. In the other 18 mergers, not a single divested pipeline drug managed to create significant competition in the relevant markets.

1. Successful Pipeline Divestitures

Only 14 of the divested pipeline products had a market share higher than 1% in their relevant markets in 2023. The median market share among those drugs was 20%, with 9 having a market share less than 35%. Only 5 drugs had a market share higher than 50% with 3 drugs having complete control over their relevant markets. The lowest market share for a successfully divested drug, on the other hand, was 2%.

The graph below shows the distribution of market shares for successfully divested pipeline drugs:

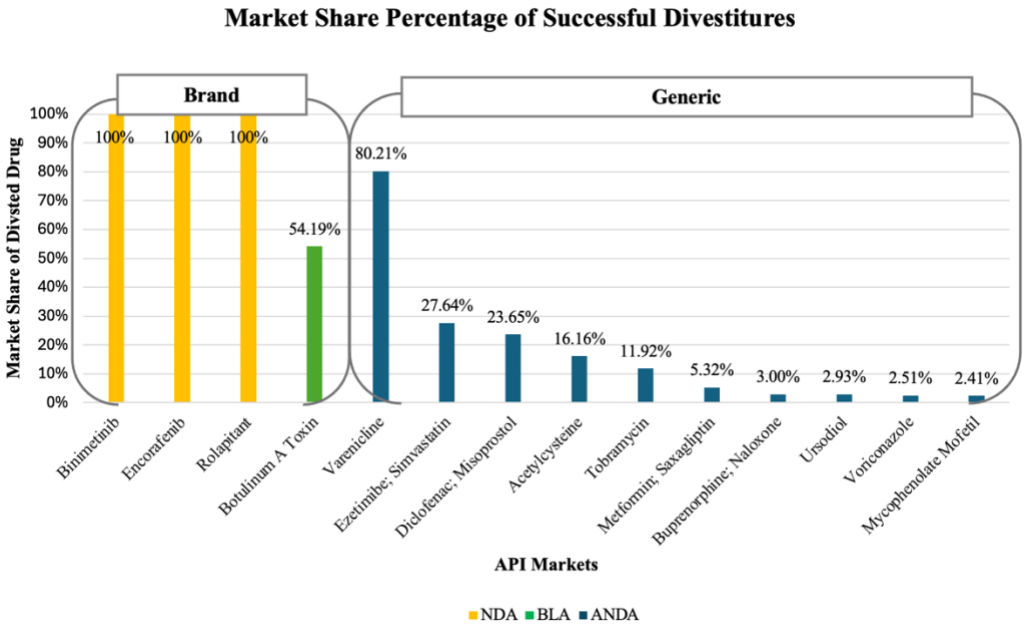

Figure 1: Market Share of Successfully Divested Drugs

Three of the divested pipeline products included in this study had complete

control over their relevant markets. All three of them are NDAs[186]—i.e., brand-name innovator products—and were the only approved and actively-marketed application for their corresponding APIs in 2023.[187] As such, there were no other drugs in those markets to take up market share. Additionally, one divested generic drug (ANDA 201785—Varenicline) controlled more than 80% of the relevant market. This is likely because ANDA 201785 was one of the only two approved and actively marketed applications for its API at the beginning of 2023.[188]

2. Failed Pipeline Divestitures

61 divested pipeline drugs did not meet our criteria for a successful divestiture. Almost half of those pipeline drugs (29 out of 61) never made it out of the developmental pipeline, having never received FDA approval as of 2024. The lack of FDA approval for those 29 drugs can hardly be attributed to a lack of time for regulatory processes: The average time between the divestiture of those drugs and the end of 2023 was 10.8 years, with a range of 7 to 17.8 years.[189]

18 other divested pipeline drugs were approved by the FDA but were discontinued by their manufacturers for reasons other than safety and efficacy before 2023. The remaining 14 drugs have valid FDA approvals and have not yet been discontinued, but none of them attained a significant market share by 2023. Their shares in the relevant markets range from 0% to 0.4%.

Pipeline Divestiture Status	Count	Percentage
Not FDA Approved Yet	29	39
Discontinued *Not* for Safety or Efficacy[190]	18	24

[186] These NDAs are NDA 206500 (Rolapitant), NDA 210496 (Encorafenib), NDA 210498 (Binimetinib).

[187] *Orange Book Cumulative Supplement, supra* note 177. There were two approved applications for Rolapitant (NDA 206500, and NDA 208399). However, NDA 208399 was discontinued prior to 2023. *Orange Book Data Files*, U.S. FOOD & DRUG ADMIN. (Dec. 2022), https://web.archive.org/web/20230126055817/https://www.fda.gov/media/76860/download [https://perma.cc/G7DF-DF4K].

[188] *Orange Book Data Files, supra* note 187. At the beginning of 2023, there were three approved applications for Varenicline: NDA 213978, NDA 21928, and ANDA 201785. Of those three, NDA 21928 was discontinued and no longer marketed.

[189] As a comparator, the FDA aims to evaluate 90% of standard NDAs and ANDAs within 10 months after the specified starting date (which varies somewhat depending on the FDA program). U.S. FOOD & DRUG ADMIN., PDUFA [PRESCRIPTION DRUG USER FEE AMENDMENTS] REAUTHORIZATION PERFORMANCE GOALS AND PROCEDURES FISCAL YEARS 2023 THROUGH 2027 4, 9, https://www.fda.gov/media/151712/download [https://perma.cc/689H-XWAH]; U.S. FOOD & DRUG ADMIN., PERFORMANCE REPORT TO CONGRESS, GENERIC DRUG USER FEE AMENDMENTS FY 2024, at 8 (2024), https://www.fda.gov/media/187051/download?attachment [https://perma.cc/T6UB-E7LX]. But the comparator is imperfect because an application to the FDA for drug marketing approval may not have been filed at the time of the pipeline drug divestiture.

[190] 21 C.F.R. § 314.161. There are many reasons for the withdrawal of a drug from sale, including lack of demand, undesirable price levels, production issues, or supply chain breakdowns. See *supra* note 22 for a more detailed discussion of drug discontinuation.

Negligible Market Share Drugs	14	19
Successfully Divested Drugs	14	19
Total	75	101*

Drugs with less than 1% of market share are considered Negligible Market Share Drugs. Drugs that received FDA approval and had higher than 1% market share in their relevant markets are considered Successfully Divested Drugs.

**Total percentage exceeds 100% because of rounding.*

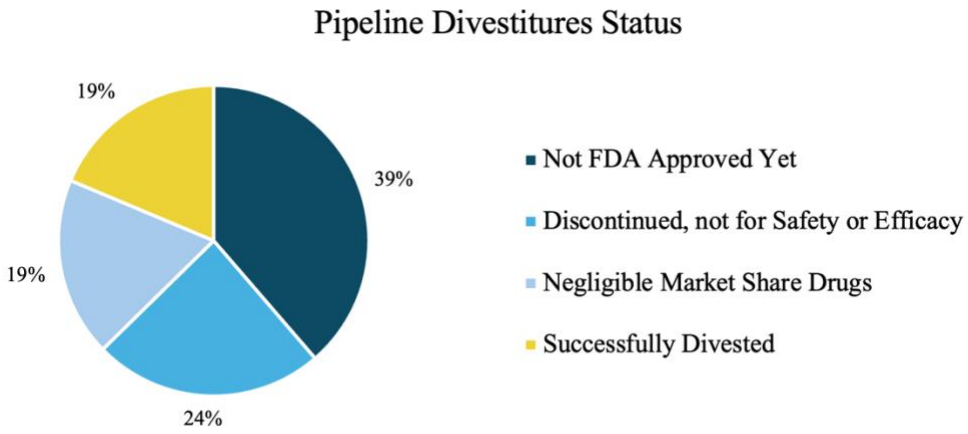

Figure 2: Status of the divested pipeline drugs analyzed in this study

3. Divestiture by Application Type

Of the 75 divested pipeline drugs on our list, only 4 had a New Drug Application ("NDA") submitted to the FDA, meaning that they were brand, rather than generic, drugs. Those 4 divestitures had a success rate of 75%, with 3 of the 4 attaining 100% of the relevant markets and 1 of the 4 failing to reach the market. Our Dataset also included one brand biologic that had a Biologics License Application ("BLA") submitted to the FDA.[191] This biologic, Dysport (Botulinum A Toxin),[192] created significant competition, as it attained more than half of its API

[191] All biological (i.e., large-molecule) products marketed in the United States—brand biologics, biosimilars, and interchangeables—must have an FDA-approved BLA. Brand biologics are approved through the FDA's 351(a) pathway while biosimilars (including interchangeables) are approved through the separate 351(k) pathway. The only biological product on our list, Dysport (Botulinum A Toxin), was approved through the 351(a) pathway and thus was considered a brand biologic. *See Biosimilars Info Sheet*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/media/154914/download [https://perma.cc/EVP4-T557] (last visited Nov 7, 2025).

[192] *Purple Book: Product Details for: Dysport*, U.S. FOOD & DRUG ADMIN., https://purplebooksearch.fda.gov/productdetails?query=125274 [https://perma.cc/MFH5-Q5A6] (last visited Nov. 7, 2025).

market in 2023.

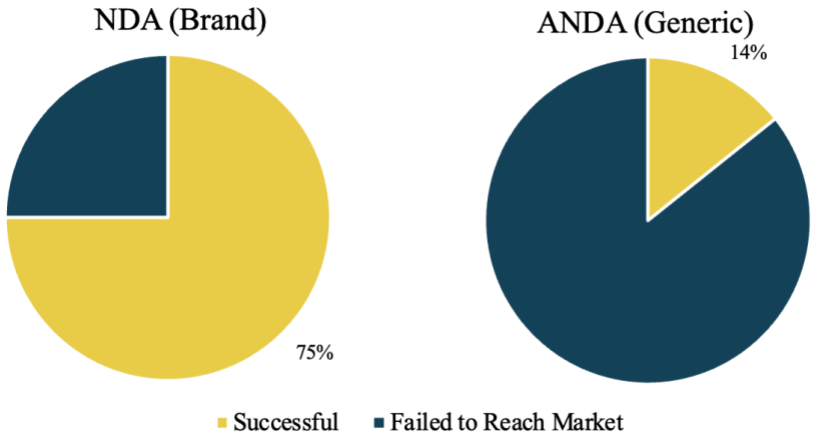

Figure 3: Divestiture Outcome by Application Type

Surprisingly, the success rate of the 70 divested pipeline drugs that had an Abbreviated New Drug Application ("ANDA") submitted to the FDA (meaning that they were generic, rather than brand, drugs) was only 14%.

Given that ANDA applicants have significantly lower requirements for receiving FDA approval,[193] one might expect that the divestiture of pipeline drugs with ANDAs would have a higher rate of success. A potential explanation for this unexpectedly low rate of success could be that most drugs with approved NDAs are brand-name drugs that enjoy lengthy patent protection and regulatory exclusivities, often yielding lucrative monopoly profits. Most drugs with approved ANDAs, on the other hand, are generic drugs without patent protection or lengthy exclusivities, and the prices for generic drugs fall substantially with every new market participant.[194] These lower returns may have reduced the chance that generics succeed post-divestiture.[195]

4. Divestiture by Market Size

The figure below shows divestiture outcome based on the market size of the divested API(s):

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[193] Unlike NDA applicants, ANDA applicants do not have to conduct their own preclinical and clinical trials to prove the safety and efficacy of their drugs. *See* 21 U.S.C. § 355; *Abbreviated New Drug Application (ANDA)*, U.S. FOOD & DRUG ADMIN., https://www.fda.gov/drugs/types-applications/abbreviated-new-drug-application-anda [https://perma.cc/7VHQ-C8VU] (last visited Nov. 14, 2025).

[194] CONRAD & LUTTER, *supra* note 10.

[195] Our study found that the median market size for drugs that were successfully divested was almost twice the median market size for drugs that were *not* divested successfully. Since lower unit prices essentially translate into smaller market sizes, the lower prices of the generic drugs might explain the high failure rate for divestitures of generic pipeline products. *See infra* Part III.D.4.

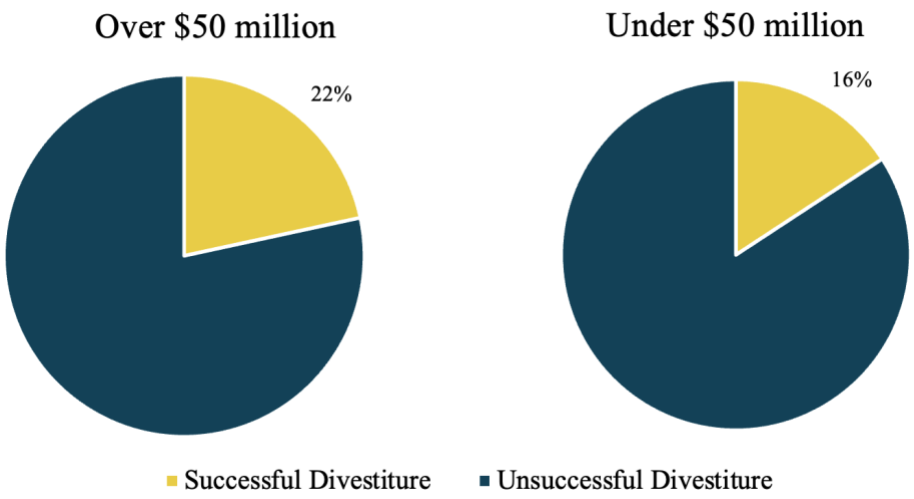

Figure 4: Divestiture Outcome by Market Size

Although some unsuccessful pipeline divestitures occurred in relatively large markets, our analysis found that, in general, pipeline divestitures in larger markets are more likely to be successful.

The median market size for all divested drugs included in this study was $50 million. Indeed, our analysis found that the success rate for divestiture of drugs with market size of over $50 million was 22% (8 out of 37) while the success rate for divestiture of drugs with market size under $50 million was only 16% (6 out of 38). Furthermore, the median market size for drugs that were successfully divested was approximately $79 million, while the median market size for drugs that were not successfully divested was roughly half that figure, at approximately $39 million. These findings indicate that, in general, divestitures of pipeline drugs with higher market sizes are more likely to succeed.

Although one cannot determine any degree of causation from this observational analysis, one explanation could be that a larger market may have made it more attractive for the company to continue pursuing the drug. After all, a larger pot of gold can create a stronger incentive to keep moving forward, which could result in more success at the end of the day. Regardless of whether the hypothesis has merit, we note that our data only indicate somewhat of a trend and that one cannot determine any degree of causation from this observational analysis.

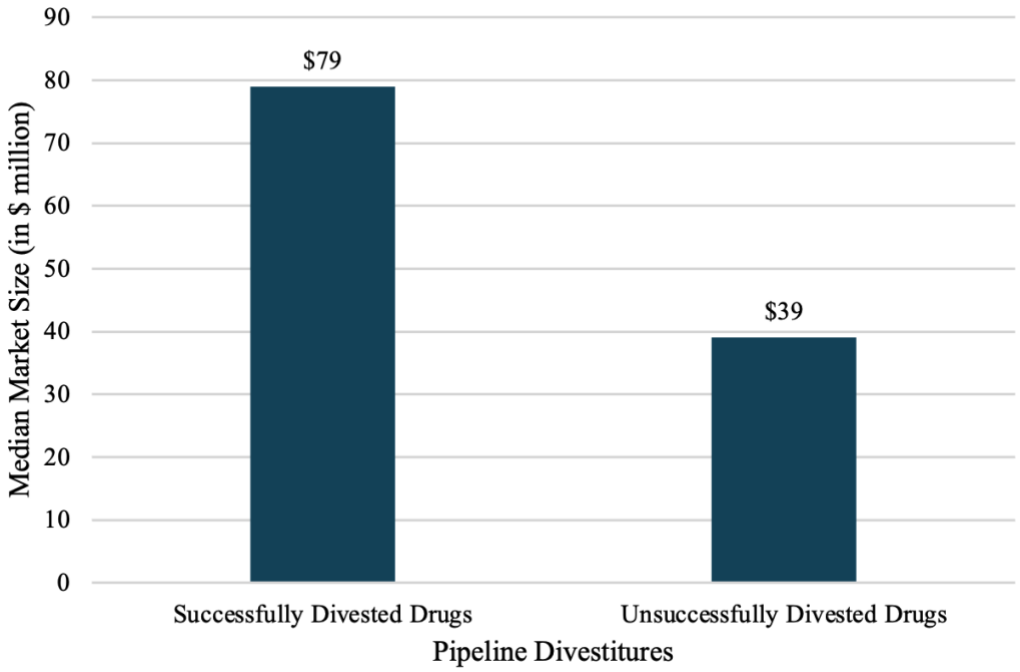

Figure 5: Median Market Size of Divested API(s)

5. Multiple APIs

Our study found that divestiture of pipeline drugs with multiple APIs had a slightly lower chance of success compared to drugs with one API. Of the 75 divested pipeline drugs in our study, 49 had only one API and 20% of them (10 out of 49) created significant competition in their relevant markets. On the other hand, only 4 out of the 26 divestitures involving drugs with multiple API(s) created significant competition, with a success rate of 15%.

The higher success rate of drugs with a single API comes with a caveat. Drugs with multiple APIs often receive different application numbers for different dosage combinations, while drugs with a single API tend to have all of their dosage strengths approved under one application number. Given that our granular analysis was primarily based on application numbers,[196] it is possible that the divestiture of pipeline drugs with single and multiple API(s) have a similar chance of creating significant competition in the relevant markets after all.

We also note that the numbers are small. One more success in the multiple API space would have yielded similar success ratios for multiple-API drugs and single-API drugs. Thus, although it is possible, for example, that multiple API-drugs could face additional technical challenges in their development or simply more potential substitutes once they get to market, the number of multiple-API drugs in our sample

[196] *See supra* notes 155, 173, 185 and accompanying and following text.

size may be too small to create a reasonable indication of difference.

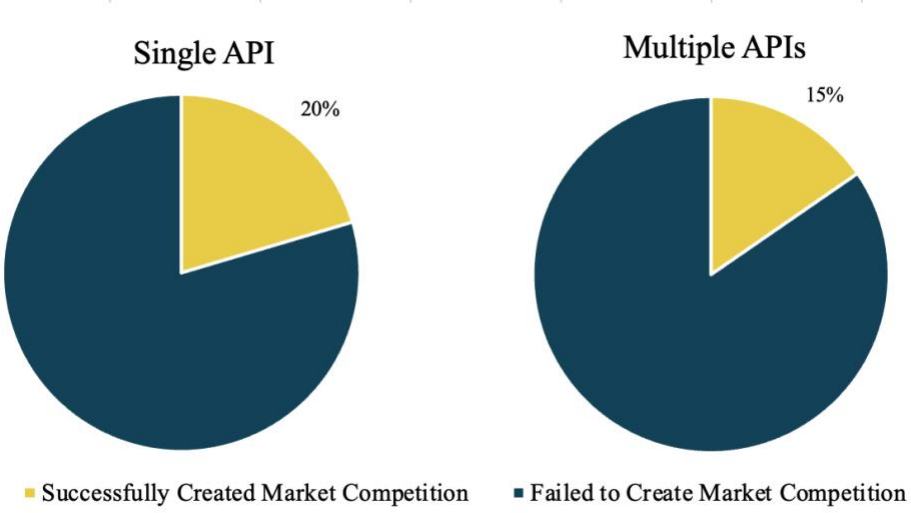

Figure 6: Divestiture Outcome by API(s) Type

6. Multiple Divestitures

Nine pipeline drugs were divested twice between 2006 and 2018. Not one of the doubly divested drugs created significant competition in the relevant markets. On the other hand, when a pipeline drug was divested only once during the timeframe of our study, the success rate was 21% (i.e., 14 out of 66 divestitures).

The complete failure when drugs are divested multiple times presents a striking contrast with drugs that are only divested once. Additional divestitures could suggest that the drug in the pipeline shows little promise of profitability in the market. Alternatively, additional divestitures could indicate that the initial divestiture was never intended to be successful; rather, the divesting company intended to simply slough off the product to a buyer that would have little interest in pursuing the drug. Regardless of the cause, regulators might wish to watch for additional divestitures as a sign that the original divestiture plan has gone awry.

E. Limitations

As with most data-driven studies, our analysis has limitations. First, our Dataset is small, with only 75 pipeline drugs, and thus conclusive correlations are hard to infer. Additionally, in determining the success of a divestiture, we looked at sales data only from 2023. It could well be that a divested drug was initially successful at creating competition, but it either was withdrawn from the market or lost its significant market share by 2023. Furthermore, a main assumption underlying our study was that, were the 26 mergers not to have occurred, the pipeline drugs would have come to market and attained a significant portion of sales. However, it is plausible that some of those drugs would have failed to gain traction in (or would have been withdrawn from) their relevant markets even if they had not been

divested.[197]

Another limitation of our study is that, in determining the relevant market for a divested pipeline drug, we relied only on API(s). We did not account for variations in dosage form and strength. This limitation leads to the possibility that we might have overestimated the size of the relevant market and consequently underestimated the market share of the divested pipeline product. We tried to mitigate this issue by choosing a low cutoff of 1% for our market-share criterion. Additionally, the divestiture orders for some of the divested pipeline drugs in our analysis did not include an application number. We assumed that the reason for this omission was that either an application was never filed, or, if an application was filed, it was never approved by the FDA. Although we diligently attempted to locate these datapoints, we may have missed some.

Finally, our data vendor, IQVIA, was unable to provide any sales data for the relevant markets of two divested pipeline products included in our study.[198]

IV. IMPACT ON PRICING/CONSUMER ACCESS

This Part discusses the consequences of failed divestures for patients and payors, from reduced drug access and affordability to the risk of decreased innovation.

Failed divestitures foreclose potential competition, and the consequent harm to drug access and affordability is hardly trivial. One study of pharmaceutical mergers involving brand-name drugs found that mergers between companies with overlapping products led to price increases of 12% per quarter.[199] Another group of researchers observed that large mergers involving companies with overlapping brand-name drugs saw the price of overlapping drugs increase by 13% per year, on average.[200] Analyzing mergers involving both brand-name and generic drugs, Bonaime et al. concluded that after a merger, the price of the overlapping drug

[197] The majority of drugs in our study were generics. Whether a generic drug would have come to market and attained significant sales depends on many factors, including the extent to which competitor generic drugs and non-generic substitute drugs are already on the market.

[198] Each of these two drugs is a generic that includes multiple APIs. One of the two (ANDA 202955) includes three APIs: Brompheniramine maleate, Dextromethorphan hydrobromide, and Pseudoephedrine hydrochloride. The other (ANDA 202999) includes two APIs: Dienogest and Estradiol valerate.

[199] Sarah Schutz, Mergers, Prices, and Innovation: Lessons from the Pharmaceutical Industry 31-33 (Nov. 8, 2023) (unpublished manuscript) (on file with SSRN) ("In the case when the target and acquiring firm have overlapping product portfolios, I observe a significant increase in drug prices by almost 12%.").

[200] Josh Feng, Thomas Hwang, Yunjan Liu & Luca Maini, Mergers that Matter: The Impact of M&A Activity in Prescription Drug Markets 20 (Oct. 3, 2025) (unpublished manuscript) (on file with SSRN) ("[D]eals above the HSR threshold experience on average a 13 percent increase in net price . . . .").

increases by 2.2% more than the price of drugs for which there is no such overlap.[201] This price increase takes place immediately after the merger and stays elevated for one year.[202] Another study found that drugs associated with mergers and acquisitions had a 24.3% higher chance of experiencing a shortage compared to similar drugs not involved in mergers and acquisitions.[203]

All but five pipeline products included in our study are generic drugs, and each failed pipeline-product divestiture reduces the number of competitors in the relevant market by at least one. It is well-documented that the price of generic drugs decreases substantially with each new entrant to the market.[204] When a pharmaceutical pipeline divestiture fails, patients and payors are deprived of savings that would have been available to them had the merger never occurred.

In support of mergers in general, pharmaceutical companies argue that pre-merger entities have crucial institutional knowledge and technological know-how and that, by sharing complementary knowledge and technology, the post-merger entity can attain a higher level of innovation and efficiency and thus lower prices.[205] Studies have indeed found an uptick in innovation after a merger. The increased innovation, however, was almost entirely related to secondary applications, such as adding a new indication to an already approved drug or changing a drug's labeling, dosage, or manufacturing process.[206] By definition, mergers reduce the number of players in the field of discovery, so there is naturally a risk that genuinely meaningful drug innovation will suffer.[207]

V. POTENTIAL SOLUTIONS

This Part urges adoption of two readily achievable solutions to the problem of

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[201] Alice Bonaime & Ye (Emma) Wang, *Mergers, Product Prices, and Innovation: Evidence from the Pharmaceutical Industry*, 79 J. FIN. 2195, 2197, 2214-16 (2024). *See also* Mosab Hammoudeh and Amrita Nain, *Seeking Efficiency or Price Gouging? Evidence from Pharmaceutical Mergers*, 87 J. CORP. FIN. (2024). Readers should note that Bonaime et al. used pre-rebate NADAC prices to calculate the changes in drug price. Feng et al. and Schutz, on the other hand, used commercially available post-rebate net price data in their calculation. Schutz, *supra* note 199, at 2; Feng et al., *supra* note 200, at 10; Bonaime & Wang, *supra*, at 2202-3.

[202] Bonaime & Wang., *supra* note 201, at 2197.

[203] U.S. DEPT. HEALTH AND HUMAN SERVICES, MERGERS AND ACQUISITIONS (M&AS) IN PHARMACEUTICAL MARKETS: ASSOCIATIONS WITH MARKET CONCENTRATION, PRICES, DRUG QUANTITY SOLD, AND SHORTAGES 32 (2025).

[204] CONRAD & LUTTER, *supra* note 10.

[205] Bonaime & Wang, *supra* note 201, at 2202, 2227. *See also* Jan Bena & Kai Li, *Corporate Innovations and Mergers and Acquisitions*, 69 J. FIN. 1923, 1955 (concluding that technological synergy between merging entities leads to stronger post-merger innovation outcomes).

[206] Bonaime & Wang, *supra* note 201, at 2207-8, 2230-4. *See* Schutz, *supra* note 199, at 24-25 (finding that although research expenditure increased by $380 million after a merger, it did not accelerate new drug development).

[207] This article uses the phrase "genuinely meaningful drug innovation" to refer to pharmaceutical innovations that provide patients with tangible clinical advantages. Such innovations include new molecules, significant improvements in safety or efficacy, and treatments of hitherto untreatable indications.

failed pipeline divestitures: "crown jewel divestiture" and "skin in the game divestiture."

As described above,[208] the current protocol for pipeline divestiture has not achieved the FTC's stated goal of "maintain[ing] or restor[ing] competition in the relevant market."[209] Failed divestitures limit competition, reducing the number of competitors that would have existed had the mergers never taken place. As competition wanes, so too does the potential for lower-cost medications, and both patients and taxpayers have to foot the bill.[210] Addressing this problem, however, need not involve a major overhaul but rather feasible tweaks to the current approach, along with increased use of tools that already exist in the FTC's toolkit.

In most divestitures, the FTC's remedial orders stipulate that if the parties fail to divest the assets to a pre-approved buyer within an agreed upon time, the FTC may appoint a trustee to instead divest an alternative package of assets called the "crown jewel."[211] However, the FTC rarely takes this approach. The agency has enforced the divestiture of the "crown jewel" asset package only once, namely, in the merger that created the pharmaceutical company Aventis.[212] One of the merging entities—the French company Rhône-Poulenc—was developing a direct thrombin inhibitor called Revasc, while the other merging entity—the German company Hoechst Marion Roussel—owned an on-market direct thrombin inhibitor called Refludan.[213] The FTC initially ordered Rhône-Poulenc to divest its pipeline product, but when Rhône-Poulenc failed to find a suitable buyer, the FTC appointed a trustee who eventually found a buyer for the on-market "crown jewel" Refludan and divested that drug instead.[214]

In this case, divesting the on-market drug was more effective than divesting the pipeline equivalent at achieving the FTC's stated goal of "maintain[ing] or restor[ing] competition in the relevant market."[215] The FTC's 1999 Study confirms this result more generally, finding that divestiture of an on-market product is more likely to create and maintain significant competition than divestiture of a pipeline product.[216] The 1999 Study found that divestiture of an on-going business is more likely to succeed than divestiture of "assets selected to facilitate entry."[217] The 1999

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[208] *See supra* Parts I & III.D.

[209] 2017 STUDY, *supra* note 17, at 15.

[210] *See supra* Part IV.

[211] *Negotiating Merger Remedies*, FED. TRADE COMM'N, https://www.ftc.gov/advice-guidance/competition-guidance/negotiating-merger-remedies [https://perma.cc/PKH4-VNGH] (last visited Sept. 28, 2025).

[212] Elai Katz & Lauren Perlgut, *Appraising Crown Jewel Provisions in the United States, Canada, and Europe*, 10 THRESHOLD 72, 76 (2009), https://www.cahill.com/publications/published-articles/000086/[https://perma.cc/27UN-9L7J].

[213] *Id.* at 76-77.

[214] *Id.*

[215] *Negotiating Merger Remedies, supra* note 211; 2017 STUDY, *supra* note 17, at 11.

[216] 1999 STUDY, *supra* note 16, at 10-11.

[217] *Id.* at 10.

Study defines an on-going business as a package of assets whose market share can be transferred immediately and potentially for the long term. In the context of the pharmaceutical industry, an on-going business clearly fits the definition of an on-market product. Similarly, the phrase "assets selected to facilitate entry" fits the description of an asset package related to a pipeline product.

Given these findings, we propose "crown jewel divestiture" as an alternative to the FTC's current pharmaceutical divestiture practices. For this approach, if the merging parties each own a drug in the same market and one of them is on-market at the time of merger, the FTC will require divestiture of the on-market product instead of the pipeline product. "Crown jewel divestiture" has the highest likelihood of maintaining or even increasing the level of competition that would have existed absent the merger. The benefit of this approach is that the buyer of the divested assets receives a product that is already developed, approved, perfected for mass marketing, and enjoying established sales and distribution networks. Such an asset will be far easier for the buyer to manage than one that lacks all these factors, requiring that the new company successfully move through these phases from an earlier starting point. When the new company can enter at a later stage of the race, competition with the merged entity will be much more likely. Meanwhile, the merged entity retains the pipeline product and enjoys the combined human capital and institutional knowledge of the pre-merger entities, each of which has prior experience developing that product. These are assets the new company would lack, and their presence provides greater likelihood that the merging company can successfully bring the product to market and obtain substantial market share.

"Crown jewel divestiture" could provide a powerful and effective tool for mitigating competition concerns. Nevertheless, competition authorities must balance effectiveness with political and practical realities. Presumably, the merger parties would prefer to retain the on-market product and divest the pipeline version. After all, continuing to market an on-market product takes significantly fewer resources than developing a pipeline product, pursuing the lengthy and arduous regulatory approval process, and marketing the drug. Thus, companies are likely to resist divesting the "crown jewel," expressing that resistance within the halls of the agency, by bringing their complaints to the courthouse, and by raising their voices to Congress and the administration. Moreover, a remedy that is stronger than necessary could improperly dampen market activity that might be beneficial.

Where the FTC decides to allow the merging entities to keep the on-market product, we propose an alternative solution, which we call "skin in the game divestiture." In such a divestiture, the merging entities will be allowed to keep their on-market product and divest its pipeline equivalent, but if the divested pipeline product fails to receive regulatory approval or fails to create significant competition within a predetermined time, a trustee will be authorized to divest the on-market product. If feasible, the trustee will also ensure that the previously divested asset package related to the pipeline product is returned to the merging entities.

A "skin in the game divestiture" has obvious upsides. The merging entities will have a strong incentive to ensure that all assets necessary for developing and

marketing the pipeline product are successfully handed over to the buyer: If the buyer fails in marketing the product within a predetermined time, the merging entities stand to lose a product that is actively generating revenue.[218]

If the FTC wishes to have both "crown jewel" and "skin in the game divestitures" as arrows in the quiver, the agency could choose to allow the lesser, "skin in the game" remedy when factors indicate that the solution will be successful. Such factors could include that the merging company will transfer other relevant assets such as the relevant scientific division with the drug, including the human capital and facilities. Human experience, sometimes called "know-how" and "show-how," can provide essential industrial information, and such transfers could maximize the potential for the new company to move smoothly into the market. A second factor that could push the needle towards the lesser "skin in the game" remedy could be the expertise of the buyer. If the merging party can demonstrate that the chosen buyer provides advantages such as relevant experience in the pharmaceutical industry—perhaps even experience within this sector of pharmaceuticals—along with the capacity to manage the new drug, the agency would have greater assurance that a reasonable competitor will emerge.

In short, a "skin in the game divestiture" allows the agency to continue the chosen remedy of divesting the pipeline product while adding a backup plan if the future does not unfold as the merging parties predict. In contrast, a "crown jewel divestiture" shifts the landscape entirely but requiring that the merging parties relinquish the valuable on-market drug. Together, these remedies offer a powerful replacement for the simple pipeline-divestiture approach, which, as our study demonstrates, fails to provide the anticipated competition.

VI. CONCLUSIONS

Americans are living through an age of increased consolidation, rising drug prices, and decreased innovation, in part due to the FTC's failure to successfully regulate pharmaceutical mergers. By using pipeline divestiture as a remedy for anticompetitive pharmaceutical mergers, the FTC has not achieved its stated goal of "maintain[ing] or restor[ing] competition in the relevant market."[219] Between 2006 and 2018, the FTC ordered the divestiture of 75 pharmaceutical pipeline products in order to allow 26 potentially anticompetitive mergers to proceed.[220] Unfortunately, 81% of those divested pipeline products failed to attain a 1% share of their relevant markets.[221] The consequent harm to competition, as well as the increased burden on taxpayers and consumers, warrants attention.[222] Revealing the

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[218] *See also id.* at 30–31; William Baer, *Reflections on 20 Years of Merger Enforcement under the Hart-Scott-Rodino Act*, FED. TRADE COMM'N (Oct. 31, 1996), https://www.ftc.gov/news-events/news/speeches/reflections-20-years-merger-enforcement-under-hart-scott-rodino-act [https://perma.cc/ZW7E-2ZND].

[219] 2017 STUDY, *supra* note 17, at 15.

[220] *See supra* Part III.A

[221] *See supra* Part III.D.

[222] *See supra* Part IV.

dysfunction of current pipeline divestiture methods is a crucial first step.[223]

But groundbreaking, novel mechanisms are not needed to rectify the problem. Instead, using adjusted remedies like "crown jewel divestiture" and "skin in the game divestiture" can help align the incentives among merging entities and buyers. That alignment, in turn, can help maintain or even raise the competition that existed prior to the merger. These actionable solutions can mitigate the loss of competition, cultivate a more diversified, innovative market, and even lead to a healthier population.

[223] One of the insightful contributions for researchers and policymakers that our study provides is our evidence that only 19% of the divested pipeline drugs succeed and that brand drugs have higher success rates. This evidence demonstrates how brand-drug companies' economic market power plays a critical role in protecting drug success post-divestiture. Notably, beyond our inference about the disappointing outcome of the FTC's divestiture remedy policy, there is a critical unintended consequence. Whereas the FTC's mission is to "work to protect consumers and promote competition," FED. TRADE COMM'N, MISSION, *supra* note 15, our evidence indicates that the FTC's pipeline drug divestiture policy effectively operates *against* promoting competition, as its policy results in strengthening relatively strong companies and weakening relatively weak or new ones. This occurs because of the resulting favorable effects of the FTC policy on brand-drug companies (which tend to have high market power) relative to non-brand-drug companies (which tend to have low market power). Indeed, prior theoretical and empirical research in economics shows that brand-drug companies tend to have higher market power in terms of market share, profits, and/or profit margins. *See, e.g.*, Stephen A. Rhoades, *Market Share as a Source of Market Power: Implications and Some Evidence*, 37 J. ECON. & BUS. 343 (1985); Gregory S. Crawford & Matthew Shum, *Uncertainty and Learning in Pharmaceutical Demand*, 73 ECONOMETRICA 1137 (2005); Glenn Ellison & Sara Fisher Ellison, *Strategic Entry Deterrence and the Behavior of Pharmaceutical Incumbents Prior to Patent Expiration*, 3 AM. ECON. J.: MICROECONOMICS 1 (2011).