

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

FEDERAL TRADE COMMISSION,
STATE OF CALIFORNIA,
STATE OF ILLINOIS,
STATE OF MINNESOTA,
STATE OF NEW YORK,
STATE OF WASHINGTON
and
STATE OF WISCONSIN,

Plaintiffs,

v.

AMGEN INC.
and
HORIZON THERAPEUTICS PLC,

Defendants.

Case No. 23-CV-3053

Judge John F. Kness

**MOTION OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF
AMERICA FOR LEAVE TO FILE *AMICUS CURIAE*
BRIEF SUPPORTING DEFENDANTS**

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) respectfully requests permission to file the attached *amicus curiae* brief supporting Defendants. Exhibit A. PhRMA consulted with Plaintiffs (both the FTC and the States), who declined to take a position on the motion without first having reviewed the brief.

MOVANT’S INTERESTS

PhRMA is a voluntary, nonprofit corporation representing the country’s leading research-based pharmaceutical and biotechnology companies. PhRMA’s member companies research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. Since 2000, PhRMA members have invested approximately \$1.1 trillion in the search for new treatments and cures, including an estimated \$102.3 billion in 2021 alone. PhRMA serves as the research-based pharmaceutical industry’s principal advocate, representing its members’ interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA’s mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an *amicus curiae*.

PhRMA has a strong interest in the issue before the Court. In recent years, much pharmaceutical innovation has been driven by startups and smaller companies. Though those small entities have been incubators for the discovery of innovative medicines, testing and development requires enormous financial resources that they may lack. The investment necessary to complete the development of those medicines and make them available to the patients who need them requires the involvement of established larger manufacturers. And without the prospect of acquisition to enable those larger manufacturers to complete the

development of such medicines—and to permit those who financed early-stage development to recoup their own investments—innovation would be curtailed. The Federal Trade Commission’s position appears to prohibit acquisitions involving any manufacturer that already has any unrelated product with an allegedly dominant position in the market because of speculation that such a transaction *might* lead to anticompetitive conduct in the future. But such hypothetical concerns are readily addressed through more tailored measures that would permit innovation to continue.

RELEVANCE OF MOVANT’S BRIEF

Given the novelty of the theory underlying the FTC’s lawsuit, PhRMA’s brief seeks to assist the Court in assessing the implications of that theory, both legally and practically. PhRMA has a unique perspective on this issue given its members’ involvement in the pharmaceutical industry and familiarity with the role mergers play in bringing new pharmaceutical products to market. PhRMA can comment on how mergers and acquisitions affect research and development and, ultimately, patients’ access to crucial medications. These issues are relevant because “liability in antitrust law turns on whether consumer welfare has been impaired,” and “[p]atients” are “the consumers of health care.” *Marion HealthCare, LLC v. S. Ill. Hosp. Servs.*, 41 F.4th 787, 790 (7th Cir. 2022) (citing *Reiter v. Sonotone Corp.*, 442 U.S. 330 (1979); *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1 (1979)).

As PhRMA would advise the Court, mergers play an essential role in the development of innovative medicines today. Small pharmaceutical companies develop an enormous number of promising new drugs, but they lack the financial resources, manufacturing facilities, and distribution networks necessary to complete their development and make them available to the patients who need them. Acquisitions are an important way for larger pharmaceutical

companies to further the development of such medicines. The prospect of these mergers gives small companies the incentive to develop such drugs and encourages others to provide the financing supporting early development. Thus, pharmaceutical mergers are associated with a demonstrated statistically significant increase in research and development.

The FTC's novel theory to block this merger has the potential to stifle innovation and harm patients. The lawsuit relies on pure speculation about how large pharmaceutical companies *might* behave after merging with small innovators and asks the Court to endorse a limitless principle that would theoretically prohibit any acquisition involving a pharmaceutical manufacturer that already has one or more successful products. If courts accept the FTC's new theory, it will send small innovators and their prospective investors an unmistakable message: the principal route for obtaining the enormous sums necessary to test and develop their innovative drugs for patient use is no longer available, so further research and development may never lead to a recoupment of costs or a marketable product. The inevitable consequence will be that innovation will be curtailed, and fewer patients will have access to innovative medicines.

CONCLUSION

For the reasons discussed, this Court should grant this Motion for leave and accept for filing the *amicus curiae* brief submitted with this Motion.

Dated August 25, 2023

Respectfully submitted,

/s/ Andre Geverola

Andre Geverola
Arnold & Porter Kaye Scholer LLP
70 West Madison Street, Suite 4200
Chicago, IL 60602-4231
(312) 583-2430
andre.geverola@arnoldporter.com

John P. Elwood
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave., NW Washington,
D.C., 20001
(202) 942-5000
John.elwood@arnoldporter.com

William T. Sharon
Arnold & Porter Kaye Scholer LLP
250 W. 55th St.
New York, NY, 10019
(212) 836-8000
William.sharon@arnoldporter.com

*Counsel for Amicus Curiae Pharmaceutical
Research and Manufacturers of America*

Exhibit A

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

FEDERAL TRADE COMMISSION,
STATE OF CALIFORNIA,
STATE OF ILLINOIS,
STATE OF MINNESOTA,
STATE OF NEW YORK,
STATE OF WASHINGTON
and
STATE OF WISCONSIN,

Plaintiffs,

v.

AMGEN INC.
and
HORIZON THERAPEUTICS PLC,

Defendants.

Case No. 23-CV-3053

Judge John F. Kness

**BRIEF OF *AMICUS CURIAE*, PHARMACEUTICAL RESEARCH AND
MANUFACTURERS OF AMERICA, SUPPORTING DEFENDANTS**

TABLE OF CONTENTS

	<u>Page</u>
INTERESTS OF <i>AMICUS CURIAE</i>	1
INTRODUCTION AND SUMMARY OF ARGUMENT	2
ARGUMENT	3
I. LEGAL BACKGROUND	3
II. PHARMACEUTICAL INDUSTRY MERGERS PROMOTE INNOVATION AND PATIENT CARE.....	4
III. THE FTC’S NOVEL THEORY TO BLOCK A MERGER THREATENS THE MODERN PHARMACEUTICAL ECONOMY	9
A. The FTC’s Novel Theory to Block This Acquisition Is Speculative.....	10
B. The FTC’s Expansive Theory Would Be Tantamount to a Prohibition on Beneficial Mergers.....	12
CONCLUSION.....	13

TABLE OF AUTHORITIES

	<u>Page(s)</u>
<u>Cases</u>	
<i>Broad. Music, Inc. v. Columbia Broad. Sys., Inc.</i> , 441 U.S. 1 (1979).....	3
<i>Brown Shoe Co. v. United States</i> , 370 U.S. 294 (1962).....	3, 11
<i>Cascade Heath Sols. v. PeaceHealth</i> , 515 F.3d 883 (9th Cir. 2008)	4, 10, 11
<i>Castro v. Sanofi Pasteur Inc.</i> , 2012 WL 12516572 (D.N.J. Aug. 6, 2012)	11
<i>Collins Inkjet Corp. v. Eastman Kodak Co.</i> , 781 F.3d 264 (6th Cir. 2015)	10, 11
<i>Ehredt Underground, Inc. v. Commonwealth Edison Co.</i> , 90 F.3d 238 (7th Cir. 1996)	3
<i>In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. and Antitrust Litig.</i> , 507 F. Supp. 3d 1289 (D. Kan. 2020).....	11
<i>F.T.C. v. Arch Coal, Inc.</i> , 329 F. Supp. 2d 109 (D.D.C. 2004).....	3, 4
<i>F.T.C. v. Church & Dwight Co.</i> , 665 F.3d 1312 (D.C. Cir. 2011).....	11
<i>F.T.C. v. Microsoft Corp.</i> , 2023 WL 4443412 (N.D. Cal. July 10, 2023).....	12
<i>Jefferson Par. Hosp. Dist. No. 2 v. Hyde</i> , 466 U.S. 2 (1984).....	4
<i>LePage’s Inc. v. 3M</i> , 324 F.3d 141 (3d Cir. 2003).....	10
<i>Marion HealthCare, LLC v. S. Ill. Hosp. Servs.</i> , 41 F.4th 787 (7th Cir. 2022)	3, 7
<i>Ortho Diagnostic Sys., Inc. v. Abbott Lab’ys, Inc.</i> , 920 F. Supp. 455 (S.D.N.Y. 1996)	11

Pfizer v. Johnson & Johnson,
333 F. Supp. 3d 494 (E.D. Pa. 2018) 11

Reiter v. Sonotone Corp.,
442 U.S. 330 (1979)..... 3

In re Remicade Antitrust Litig.,
345 F. Supp. 3d 566 (E.D. Pa. 2018) 11

Shire US, Inc. v. Allergan, Inc.,
375 F. Supp. 3d 538 (D.N.J. 2019) 11

United States v. AT&T, Inc.,
916 F.3d 1029 (D.C. Cir. 2019)..... 3

United States v. Marine Bancorporation, Inc.,
418 U.S. 602 (1974)..... 3

Virgin Atl. Airways Ltd. v. Brit. Airways PLC,
257 F.3d 256 (2d Cir. 2001)..... 4

Statutes

15 U.S.C. § 18..... 3

Other Authorities

Antitrust Modernization Comm’n, Report and Recommendations 94 (2007) 10

Barak Richman et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 Loy. U. Chi. L.J. 787 (2017)..... 6, 8

Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 4 (2021), <https://bit.ly/3spXIXl>..... 5, 6, 7

Fed. Trade Comm’n, Federal Trade Commission Report on Rebate Walls 3 (2021), <https://bit.ly/3YCxgjT> 4, 10

Geoffrey A. Manne et al., *Technology Mergers and the Market for Corporate Control*, 86 Mo. L. Rev. 1047 (2021)..... 7, 12, 13

Gordon M. Phillips & Alexei Zhdanov, *Venture Capital Investments and Merger and Acquisition Activity Around the World* 29 (Nat’l Bureau of Econ. Rsch., Working Paper No. 24082, Nov. 2017), <https://bit.ly/45kdegy>..... 8, 9

Henry Grabowski, *The Evolution of the Pharmaceutical Industry Over the Past 50 Years: A Personal Reflection*, 18 Int’l J. Econ. Bus. 161 (2011) 5

IQVIA, *Institute Report: Emerging Biopharma’s Contribution to Innovation*
(June 13, 2022), <https://bit.ly/3KR4CFP> 8

Joanna Shepherd, *Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*,
21 J. Health Care L. & Pol’y 1 (2018)..... 5, 6

Michael S. Ringel & Michael K. Choy, *Do Large Mergers Increase or Decrease the Productivity of Pharmaceutical R&D?*, 22 Drug Discovery Today 1749
(2017)..... 7

Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 749 (5th ed. 2023)..... 10

Richard T. Thakor & Andrew W. Lo, *Competition and R&D Financing: Evidence from the Biopharmaceutical Industry*, 57 J. Fin. & Quantitative Analysis 1885 (2022)..... 6

Ted W. Love, *New Attacks on the Drug Industry Would Have Made My Breakthrough Sickle Cell Treatment Impossible*, STAT (July 31, 2023),
<https://bit.ly/3KNs7jj> 4, 5, 8

INTERESTS OF *AMICUS CURIAE*

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a voluntary, nonprofit corporation representing the country’s leading research-based pharmaceutical and biotechnology companies. PhRMA’s member companies research, develop, and manufacture medicines that allow patients to live longer, healthier, and more productive lives. Since 2000, PhRMA members have invested approximately \$1.1 trillion in the search for new treatments and cures, including an estimated \$102.3 billion in 2021 alone. PhRMA serves as the research-based pharmaceutical industry’s principal advocate, representing its members’ interests in matters before Congress, the Executive Branch, state regulatory agencies and legislatures, and the courts. PhRMA’s mission is to advocate public policies that encourage the discovery of life-saving and life-enhancing medicines. PhRMA closely monitors legal issues that affect the pharmaceutical industry and frequently participates in such cases as an *amicus curiae*.

PhRMA has a strong interest in the issue before the Court. In recent years, much pharmaceutical innovation has been driven by startups and smaller companies. Though those small entities have been incubators for the discovery of innovative medicines, testing and development requires enormous financial resources that they may lack. The investment necessary to complete the development of those medicines and make them available to the patients who need them requires the involvement of established larger manufacturers. And without the prospect of acquisition to enable those larger manufacturers to complete the development of such medicines—and to permit those who financed early-stage development to recoup their own investments—innovation would be curtailed. The Federal Trade Commission’s position appears to prohibit acquisitions involving any manufacturer that already has any unrelated product with an allegedly dominant position in the market because of speculation that such a transaction *might* lead to anticompetitive conduct in the

future. But such hypothetical concerns are readily addressed through more tailored measures that would permit innovation to continue.

INTRODUCTION AND SUMMARY OF ARGUMENT

Mergers are critical to the pharmaceutical ecosystem and play an essential role in the development of innovative medicines today. Small pharmaceutical companies develop a significant number of promising new drugs, but they lack the financial resources, manufacturing facilities, distribution networks, and clinical expertise necessary to complete their development and make them available to the patients who need them. Acquisitions are an important way for larger pharmaceutical companies to further the development of such medicines. The prospect of these mergers gives small companies the incentive to develop such drugs and, even more importantly, encourages others to provide the critical financing to start these companies and fund early development. Thus, pharmaceutical mergers are associated with a demonstrated statistically significant increase in research and development.

The FTC's novel theory to block this merger has the significant potential to stifle innovation and harm patients. The lawsuit relies on pure speculation about how large pharmaceutical companies *might* behave after merging with small innovators and asks the Court to endorse a limitless principle that would theoretically prohibit any acquisition involving a pharmaceutical manufacturer that already has one or more successful products. If courts accept the FTC's new theory, it will send small innovators and their prospective investors an unmistakable message: the principal route for obtaining the enormous sums necessary to test and develop their innovative drugs for patient use is no longer available, so further research and development may never lead to a recoupment of costs or a marketable product. The inevitable consequence will be that innovation will be curtailed, and fewer patients will have access to innovative medicines.

ARGUMENT

I. Legal Background

“[A]ntitrust is designed to protect consumers from producers, not to protect producers from each other or to ensure that one firm gets more of the business.” *Ehredt Underground, Inc. v. Commonwealth Edison Co.*, 90 F.3d 238, 240 (7th Cir. 1996). “[L]iability in antitrust law turns,” therefore, “on whether consumer welfare has been impaired.” *Marion HealthCare, LLC v. S. Ill. Hosp. Servs.*, 41 F.4th 787, 790 (7th Cir. 2022) (citing *Reiter v. Sonotone Corp.*, 442 U.S. 330 (1979); *Broad. Music, Inc. v. Columbia Broad. Sys., Inc.*, 441 U.S. 1 (1979)). “Patients” are “the consumers of health care.” *Id.*

Section 7 of the Clayton Act prohibits mergers only where “the effect of such acquisition may be substantially to lessen competition.” 15 U.S.C. § 18. Although Section 7 “does not require proof of certain harm,” “the government must show that the proposed merger is likely to *substantially* lessen competition, which encompasses a concept of ‘reasonable probability.’” *United States v. AT&T, Inc.*, 916 F.3d 1029, 1032 (D.C. Cir. 2019) (citing *Brown Shoe Co. v. United States*, 370 U.S. 294, 323 n.39 (1962)). The “loss of competition” thus must be “sufficiently probable and imminent.” *United States v. Marine Bancorporation, Inc.*, 418 U.S. 602, 623 n.22 (1974). “[R]emote possibilities are not sufficient to satisfy the test set forth in [Section] 7.” *Id.* (citation omitted); *accord F.T.C. v. Arch Coal, Inc.*, 329 F. Supp. 2d 109, 115 (D.D.C. 2004) (“Section 7 deals in probabilities not ephemeral possibilities.”).

When the FTC sues to enjoin a “horizontal merger[.]” that would “produce [an] immediate change in the relevant market share,” it may “establish a presumption of anticompetitive effect through statistics about the change in market concentration.” *AT&T, Inc.*, 916 F.3d at 1032. But Amgen-Horizon is not a horizontal merger, so “the government cannot use [that] short cut” here. *Id.* Instead, the government must make a “fact-specific” showing that

the transaction is likely to be anticompetitive. *Id.* The government bears “the ultimate burden of persuasion” on “every element of [a] Section 7 challenge, and a failure of proof in any respect will mean the transaction should not be enjoined.” *Arch Coal*, 329 F. Supp. 2d at 116.

The FTC seeks to block Amgen’s acquisition of Horizon due to concerns that, in the future, Amgen *might* provide a “bundled” discount on the combined entity’s products. Even if Amgen were to do so despite its public commitment *not* to bundle Horizon’s products, that is not an appropriate basis for blocking the merger. The FTC has never before sought to prevent a merger on the basis that the combined entity would own products that do not otherwise compete or have the potential to compete but might theoretically be bundled together. Unlike “[a]n invalid tying arrangement,” which “conditions the purchase of one product to the purchase of a second product,” a “bundling arrangement offers discounted prices or rebates for the purchase of multiple products, although the buyer is under no obligation to purchase more than one item.” *Virgin Atl. Airways Ltd. v. Brit. Airways PLC*, 257 F.3d 256, 270 (2d Cir. 2001) (citing *Jefferson Par. Hosp. Dist. No. 2 v. Hyde*, 466 U.S. 2, 12 (1984)). “Bundled discounts generally benefit buyers because the discounts allow the buyer to get more for less.” *Cascade Heath Sols. v. PeaceHealth*, 515 F.3d 883, 895 (9th Cir. 2008).

Typically, antitrust challenges to bundling arise under Section 2 of the Sherman Act, which “cannot be satisfied by reference to bundled discounts unless the discounts result in prices that are below an appropriate measure of the defendant’s costs.” *Id.* at 903. Thus, “[a]pplication of [antitrust] theories [to bundling] is highly fact-specific.” Fed. Trade Comm’n, Federal Trade Commission Report on Rebate Walls 3 (2021), <https://bit.ly/3YCxgjT>.

II. Pharmaceutical Industry Mergers Promote Innovation and Patient Care

“Mergers like the Amgen-Horizon deal expand global access to medicines, plain and simple.” Ted W. Love, *New Attacks on the Drug Industry Would Have Made My Breakthrough*

Sickle Cell Treatment Impossible, STAT (July 31, 2023), <https://bit.ly/3KNs7jj>. The reason is straightforward: Small pharmaceutical and biotech companies play a significant role in researching and developing novel medications; but they often cannot afford or do not have the necessary expertise to take the additional steps necessary to run large late stage clinical trials and complete clinical development and win FDA approval, let alone make the medications available to patients, without investments underwritten by larger pharmaceutical companies. Acquisitions such as Amgen-Horizon thus are crucial to modern pharmaceutical medicine by promoting innovation and financing the delivery to patients of life-saving and life-enhancing medications.

“[A]bout two-thirds of New Molecular Entities . . . approved by the FDA originate in biotech and small pharmaceutical companies” Joanna Shepherd, *Consolidation and Innovation in the Pharmaceutical Industry: The Role of Mergers and Acquisitions in the Current Innovation Ecosystem*, 21 J. Health Care L. & Pol’y 1, 16 (2018); see also Cong. Budget Off., *Research and Development in the Pharmaceutical Industry* 4 (2021) (“CBO Report”), <https://bit.ly/3spXIXI> (small companies account for 70% of drugs in phase III trials). In the current environment, smaller companies are important to discovering new therapies. To begin with, their size often makes them nimble in pursuing new projects. See Shepherd, *Consolidation and Innovation*, *supra*, at 21. In addition, smaller companies frequently have close connections with personnel at research institutions and universities that help promote medical breakthroughs. See Henry Grabowski, *The Evolution of the Pharmaceutical Industry Over the Past 50 Years: A Personal Reflection*, 18 Int’l J. Econ. Bus. 161, 165 (2011). And such companies’ “culture of creativity and innovation, and greater risk tolerance attracts the

best scientists, many of whom leave traditional pharmaceutical companies for smaller biotech companies.” Shepherd, *Consolidation and Innovation*, *supra*, at 22.

But discovery and early development is where any strength small firms may have ends. Aspects of drug development—and particularly complex clinical trials—make it difficult if not impossible for small companies to proceed on their own. First, development is extraordinarily expensive: Companies developing brand-name drugs “spend an average of \$2.6 billion on R&D and the FDA approval process.” *Id.* at 6. Second, it is time-consuming: “The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug.” CBO Report at 2. Third, it is risky: “Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.” *Id.*

Small pharmaceutical innovators could not risk incurring those large costs without confidence in their ability to fund clinical trials, manufacture in bulk, and distribute their medications to patients. But “[s]mall firms developing drugs typically do not have the marketing capabilities required to bring those new drugs to global and segmented markets on their own.” Barak Richman et al., *Pharmaceutical M&A Activity: Effects on Prices, Innovation, and Competition*, 48 *Loy. U. Chi. L.J.* 787, 802 (2017). And “R&D investments require funding to produce innovation, funding that often must be externally financed, given the large scale of such investments.” Richard T. Thakor & Andrew W. Lo, *Competition and R&D Financing: Evidence from the Biopharmaceutical Industry*, 57 *J. Fin. & Quantitative Analysis* 1885, 1886 (2022).

This is where larger pharmaceutical companies such as Amgen come in. Larger companies are able to supply access to capital markets, broader expertise, manufacturing

capacity, and “established drug distribution networks.” CBO Report at 4. Thus, when a large company acquires a smaller innovator, the “large company might bring a drug to market more quickly than the small company could have or might distribute it more widely.” *Id.* This market access means many patients across the world get life-saving medicines they otherwise would not—or get them much sooner than they otherwise would.

Thus, “[a] large share of pharmaceutical projects result from long-term alliance agreements.” Geoffrey A. Manne et al., *Technology Mergers and the Market for Corporate Control*, 86 Mo. L. Rev. 1047, 1106 (2021). “It is not hard to point to pharmaceutical mergers (or long-term agreements) that have revolutionized patient outcomes.” *Id.* at 1171.

Mergers not only help smaller innovators get drugs to patients; the availability of mergers allows both small innovators and larger companies to do what they do best, and do it more efficiently. “The acquisition of a small company by a larger one can create efficiencies” by allowing companies “to specialize in activities in which they have a comparative advantage.” CBO Report at 4. Thus, “pharmaceutical mergers enable specialization within the pharmaceutical industry, with different types of players brin[g]ing their comparative advantages to bear on different parts of the pharma R&D cycle.” Manne et al., *Technology Mergers, supra*, at 1102 n.243. The increased efficiency that stems from mergers benefits “the consumers of health care”—that is, “[p]atients.” See *Marion HealthCare, LLC v. S. Ill. Hosp. Servs.*, 41 F.4th 787, 790 (7th Cir. 2022).

It is no surprise, therefore, that “recent large pharmaceutical mergers are associated with statistically significant increases in R&D productivity.” Michael S. Ringel & Michael K. Choy, *Do Large Mergers Increase or Decrease the Productivity of Pharmaceutical R&D?*, 22 Drug Discovery Today 1749, 1749 (2017). “[A]s merger activity in the United States increased over

the past ten years, there has been a steady upward trend of FDA approvals of new molecular entities . . . and new biological products . . .” Richman et al., *Pharmaceutical M&A Activity, supra*, at 799. “For launches over the five years from 2016–2020,” for example, “the most successful drugs were those originated by emerging biopharma companies and launched by larger companies.” IQVIA, *Institute Report: Emerging Biopharma’s Contribution to Innovation* (June 13, 2022), <https://bit.ly/3KR4CFP>.

Indeed, the prospect of such mergers helps small innovators to obtain the financial backing that allows them to develop novel medications. For example, in 2022, Pfizer acquired Global Blood Therapeutics, a company focused on treatments for sickle cell diseases. Global Blood Therapeutics had not turned a profit in the decade before the merger, but it had raised more than \$1.5 billion in funding. *See Love, New Attacks on the Drug Industry, supra*. As its President and CEO explained after the merger, the company would not have been able to secure that funding if not for the prospect of an eventual acquisition by a larger pharmaceutical company. *Id.*

Such mergers frequently preserve or even expand market participation. They “often result in the departures of important executives, and many of those executives then form new ventures that aid in turning discoveries . . . into commercialized products.” Richman et al., *Pharmaceutical M&A Activity, supra*, at 805. This “can result in more firm creation and hence VC funding as entrepreneurial employees leave to found new start-up companies.” Gordon M. Phillips & Alexei Zhdanov, *Venture Capital Investments and Merger and Acquisition Activity Around the World* 29 (Nat’l Bureau of Econ. Rsch., Working Paper No. 24082, Nov. 2017), <https://bit.ly/45kdegy>.

But just as the availability of mergers gives small pharmaceutical companies and investors the confidence to invest in research and development, “barriers to merger activity have been shown to significantly, and negatively, affect early company investment.” Manne et al., *Technology Mergers, supra*, at 1053. For example, state-level laws limiting mergers diminish capital investment in the states that have them because they “reduce M&A activity in th[ose] state[s].” See Phillips & Zhdanov, *Venture Capital Investments, supra*, at 29 (finding that “the enactment of a business combination antitakeover law in the US has a negative effect on subsequent VC investment”). Understandably, investment is less likely to be forthcoming if restrictions on mergers mean it will be more difficult to recoup that investment. And diminished investment means fewer life-saving or life-enhancing drugs will complete clinical trials and become available to patients.

III. The FTC’s Novel Theory to Block a Merger Threatens the Modern Pharmaceutical Economy

The FTC’s novel theory to block this merger threatens the modern pharmaceutical economy—and the patients who depend on cutting-edge medications. First, the FTC’s sweeping, speculative rationale undermines small innovators’ (and investors’) confidence that they can continue with the business combinations that are critically important to developing promising early-stage medicines. Second, by rejecting Amgen’s proposed court order that would place explicit limits on bundling—which would resolve the FTC’s purported concerns with the merger—the agency has signaled that there is nothing the pharmaceutical industry can do to win agency acceptance of mergers between small innovators and large pharmaceutical companies where one has an allegedly dominant product. The Court should not send this signal by blocking this merger on such a speculative showing of harm.

A. The FTC’s Novel Theory to Block This Acquisition Is Speculative

The FTC seeks to prevent Amgen’s acquisition of Horizon because Amgen *might* bundle its own products with those of Horizon—Tepezza and Krystexxa—and that this bundling *might* prove anticompetitive.

As the FTC recognizes (at 6), there is nothing unusual or inherently harmful about bundling. To the contrary, “[b]undled discounts are pervasive.” *Cascade Health Sols. v. PeaceHealth*, 515 F.3d 883, 894-95 (9th Cir. 2008); see Antitrust Modernization Comm’n, Report and Recommendations 94 (2007) (noting “the ubiquity of bundling”). That prevalence is unsurprising, since “[b]undled discounts generally benefit buyers because the discounts allow the buyer to get more for less.” *Cascade Health Sols.*, 515 F.3d at 895; see Antitrust Modernization Comm’n, Report and Recommendations 94 (2007) (“Because they involve lower prices, bundled discounts and bundled rebates typically benefit consumers.”). And because bundled discounts may induce customers to buy from one supplier over another, “the great majority of discounting practices are procompetitive.” Phillip E. Areeda & Herbert Hovenkamp, *Antitrust Law: An Analysis of Antitrust Principles and Their Application*, ¶ 749 (5th ed. 2023).

Thus, as the FTC itself has observed, “[a]pplication of [antitrust] theories [to bundling] is highly fact-specific.” Fed. Trade Comm’n, Federal Trade Commission Report on Rebate Walls 3 (2021), <https://bit.ly/3YCxgjT>. Courts have developed various antitrust-law tests to assess bundling cases, each applied on a case-by-case basis to concrete—not hypothetical—bundling practices. Compare, e.g., *Cascade Health Sols.*, 515 F.3d at 903, and *Collins Inkjet Corp. v. Eastman Kodak Co.*, 781 F.3d 264, 274 (6th Cir. 2015), with *LePage’s Inc. v. 3M*, 324 F.3d 141, 155–57 (3d Cir. 2003) (en banc). Most courts do not consider bundled discounts anticompetitive unless they “result in prices that are below an appropriate measure of the

defendant's costs." *Cascade Health Sols*, 515 F.3d at 903; see *Collins Inkjet*, 781 F.3d at 274; see also *F.T.C. v. Church & Dwight Co.*, 665 F.3d 1312, 1316 (D.C. Cir. 2011) (noting that the Third Circuit's bundling-skeptical test "has been roundly criticized"). This is why courts in antitrust cases involving pharmaceutical bundling assess the competitive effects of bundled discounts and rebates as they arise and do not presume that bundling will be anticompetitive. See, e.g., *In re EpiPen (Epinephrine Injection, USP) Mktg., Sales Pracs. and Antitrust Litig.*, 507 F. Supp. 3d 1289, 1356-57 (D. Kan. 2020); *Shire US, Inc. v. Allergan, Inc.*, 375 F. Supp. 3d 538, 547 (D.N.J. 2019); *Pfizer v. Johnson & Johnson*, 333 F. Supp. 3d 494, 501 (E.D. Pa. 2018); *In re Remicade Antitrust Litig.*, 345 F. Supp. 3d 566, 576-77 (E.D. Pa. 2018); *Ortho Diagnostic Sys., Inc. v. Abbott Lab'ys, Inc.*, 920 F. Supp. 455, 462 (S.D.N.Y. 1996); *Castro v. Sanofi Pasteur Inc.*, 2012 WL 12516572, at *5 (D.N.J. Aug. 6, 2012). And if a particular instance of bundling *turns out* to be anticompetitive, courts are perfectly capable of enjoining the practice at that point.

Until now, the FTC has recognized that the mere potential for bundling is an insufficient basis to enjoin a merger. This lawsuit is the first time the FTC has *ever* sought to enjoin a merger on such generalized anti-bundling grounds. In so doing, the FTC seeks to circumvent the legal standards typically applied to bundling cases under the Sherman Act, and instead asks the Court to apply the "less stringent" standards under the Clayton Act. *Brown Shoe Co. v. United States*, 370 U.S. 294, 329 (1962). But no court has ever endorsed such reasoning and enjoined a merger based on mere speculation about a company's potential to bundle. Under the FTC's novel theory, every merger involving two parties with unrelated but successful products would be suspect, and the pharmaceutical industry would need to find a

less efficient mechanism for funding the development of promising medicines and distributing them to patients around the country and the world.

B. The FTC’s Expansive Theory Would Be Tantamount to a Prohibition on Beneficial Mergers

Amgen has repeatedly told the Agency that it will agree to a “binding consent order” prohibiting it from “bundl[ing] its products with TEPEZZA[®] or KRYSTEXXA[®].” Ans. 2-3. “Amgen continues to stand ready to enter into such a binding commitment, which would fully resolve the FTC’s hypothesized concerns of Amgen bundling its products with TEPEZZA[®] or KRYSTEXXA[®]” *Id.* at 3. According to the FTC, Amgen’s *legally binding* commitment is insufficient because “behavioral remedies” are disfavored. But another court only recently rejected the FTC’s request to enjoin a merger between Microsoft and Activision, the maker of the videogame Call of Duty, because “Microsoft ha[d] committed in writing, in public, and in court to keep Call of Duty on PlayStation for 10 years on parity with Xbox.” *F.T.C. v. Microsoft Corp.*, 2023 WL 4443412, at *22 (N.D. Cal. July 10, 2023).

If accepted by this Court, the agency’s rejection (at 33-34) of Amgen’s offer of a binding commitment appears to eliminate any potential for a pharmaceutical company to address the FTC’s concerns. The entire rationale underlying the FTC’s novel theory in this lawsuit is that the *potential* for anticompetitive bundling is enough to prohibit pharmaceutical mergers outright. If pharmaceutical companies cannot merge with innovators because of the risk that the combined entity will engage in conduct that may prove anticompetitive, and cannot commit not to engage in the conduct that the FTC fears, then the FTC will have succeeded in simply outlawing all pharmaceutical mergers—and potentially all mergers—where either company has an allegedly dominant product. Such “barriers to merger activity have been shown to significantly, and negatively, affect early company investment.” Geoffrey A. Manne

et al., *Technology Mergers and the Market for Corporate Control*, 86 Mo. L. Rev. 1047, 1053 (2021). Such a step runs the risk of curtailing the development of life-saving and life-enhancing medicines.

CONCLUSION

For the reasons discussed, this Court should deny the FTC's motion for a preliminary injunction.

Dated August 25, 2023

Respectfully submitted,

/s/ Andre Geverola

Andre Geverola
Arnold & Porter Kaye Scholer LLP
70 West Madison Street, Suite 4200
Chicago, IL 60602-4231
(312) 583-2430
andre.geverola@arnoldporter.com

John P. Elwood
Arnold & Porter Kaye Scholer LLP
601 Massachusetts Ave., NW Washington,
D.C., 20001
(202) 942-5000
John.elwood@arnoldporter.com

William T. Sharon
Arnold & Porter Kaye Scholer LLP
250 W. 55th St.
New York, NY, 10019
(212) 836-8000
William.sharon@arnoldporter.com

*Counsel for Amicus Curiae Pharmaceutical
Research and Manufacturers of America*