Exhibit A

No. 22-728

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

FEDERAL TRADE COMMISSION, STATE OF NEW YORK, STATE OF CALIFORNIA, STATE OF OHIO, COMMONWEALTH OF PENNSYLVANIA, STATE OF ILLINOIS, STATE OF NORTH CAROLINA, COMMONWEALTH OF VIRGINIA,
Plaintiffs-Appellees,

v.

MARTIN SHKRELI, individually, as an owner and former director of Phoenixus AG and as a former executive of Vyera Pharmaceuticals, LLC, *Defendant-Appellant*,

VYERA PHARMACEUTICALS, LLC, PHOENIXUS AG, KEVIN MULLEADY, individually, as an owner and director of Phoenixus AG and as a former executive of Vyera Pharmaceuticals, LLC, *Defendants*.

On Appeal from the United States District Court for the Southern District of New York No. 20-cv-706 (Hon. Denise Cote)

[PROPOSED] *AMICUS CURIAE* BRIEF BY THE AMERICAN ANTITRUST INSTITUTE IN SUPPORT OF PLAINTIFFS- APPELLEES

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March 30, 2023

CORPORATE DISCLOSURE STATEMENT

Pursuant to Appellate Rule 26.1(a), the American Antitrust Institute states that it is a nonprofit, non-stock corporation. It has no parent corporation(s), and no publicly traded corporations have an ownership interest in it.

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INTEREST OF [Proposed] AMICUS CURIAE

AAI is an independent, nonprofit organization devoted to promoting competition that protects consumers, businesses, and society. It serves the public through research, education, and advocacy on the benefits of competition and the use of antitrust enforcement as a vital component of national and international competition policy. AAI enjoys the input of an Advisory Board that consists of over 130 prominent antitrust lawyers, law professors, economists, and business leaders. *See* http://www.antitrustinstitute.org.[1]

Amicus' interest in this matter is as a public interest advocate seeking to improve the administration of the antitrust laws and to ensure that antitrust enforcement best serves the interests of competition and consumers. The Court's decision here affects the Amicus because its goals cannot be achieved if the FTC's ability to seek and obtain effective injunctive relief is limited.

[1] No counsel for a party has authored this brief in whole or in part, and no party, party's counsel, or any other person—other than amicus or their counsel—has contributed money that was intended to fund preparing or submitting this brief. Individual views of members of AAI's Board of Directors or Advisory Board may differ from AAI's positions.

INTRODUCTION

Years of precedent endorse injunctive relief as a front-line enforcement tool for the antitrust agencies, beginning at least as early as 1940s with Supreme Court decisions like *International Salt* and continuing through today in cases like *AMG Capital Management*. These cases yield two key observations. First, the agencies' core mission of preserving competition depends on the injunctive relief that they can obtain. Second, an injunction cannot be effective unless it prevents future antitrust violations at the same time it redresses current harms. *See AMG Capital Mgmt. v. FTC*, 141 S.Ct. 1341, 1348 (2021) ("Taken as a whole, the [injunction] provision focuses upon relief that is prospective, not retrospective.").

Given this context, Martin Shkreli's request of this Court to narrow the district court's injunction is especially dangerous. It would widen the paths for a proven recidivist to cause further harm to vulnerable pharmaceutical patient populations. Beyond that, it would chip away at the FTC's ability to prevent anticompetitive harms in other cases. If Shkreli were to succeed in reducing the scope of the relief in this case, both established and potential antitrust violators would understand that enforcement has been constrained and be further emboldened to commit future antitrust offenses.

Over the years, courts, agency experience, and the work of antitrust experts have led to an understanding of what makes an antitrust remedy work.

Collectively, they identify a set of elements that are essential to effective injunctive relief. As described in more detail below, each of these elements weighs in favor of sustaining the injunction as entered by the district court in this case.

First, effective injunctive relief will anticipate future paths an offender might take to get to the same anticompetitive goal. As a result, an injunction will likely need to be broader than past conduct and may need to include legal conduct as well as illegal conduct.

Second, any remedy, especially injunctive relief, must be administrable to be effective. An injunctive order must describe violations that are relatively easy to detect and identify, and the terms of the injunction must be easy to enforce. The need for administrability favors a clean and simple remedy that is broader over a narrow and complex set of prohibitions.

Third, a remedy must address the offender's underlying incentives if it is to be effective in the long term. Otherwise, the profit-maximizing motives that first led the offender to engage in the anticompetitive conduct will remain unchanged. Ample experience has shown that if the incentives remain the same, the offender will continue to try to evade the injunction's restrictions regardless of how extensive its monitoring and compliance mechanisms are.

Finally, previous experience suggests key limiting principles for injunctive remedies. The injunction should remain connected to the behavior at issue and

flow from the findings of liability. The relief should also be proportional to the behavior that created the liability. A history of similar prior conduct, for example, calls for a different kind of relief than a first-time offense. Similarly, a case where harmful acts were knowingly committed requires a different response than one where exercising market power through ordinary business conduct had anticompetitive effects. Further, any injunctive relief should consider the potential for stifling procompetitive behavior. Therefore, an injunction that does not implicate procompetitive behavior will not demand the same precautions as one that does. Given the relevant factual context, the district court's injunction in this case is structured to address these concerns.

Considerations in crafting an effective remedy apply with special force in the pharmaceutical context, where the complexities of the science, the various regulatory overlays, and the impact of anticompetitive conduct on some of the most vulnerable Americans make getting the right remedy both more difficult and more essential. In the pharmaceutical space, the FTC is an expert antitrust enforcer with unparalleled experience in pursuing anticompetitive conduct. The complexities of pharmaceutical markets also make the agency the front-line and sometimes only enforcer available. As a result, limiting the injunctive relief available to the FTC by narrowing the scope of its enforceability has the potential

to harm a large number of American consumers that rely on already expensive pharmaceuticals for their well-being.

ARGUMENT

I. The FTC Must Have the Ability to Seek, and District Courts the Ability to Grant, Injunctions Broad Enough to Prevent a Recurrence of the Proven Harm

The Supreme Court has warned that close attention must be paid to remedies in antitrust cases. In *United States v. E.I. Du Pont de Nemours & Co.*, for example, it declared that "[t]he proper disposition of antitrust cases is obviously of great public importance, and their remedial phase, more often than not, is crucial. 366 U.S. 316, 323 (1961). For the suit has been a futile exercise if the Government proves a violation but fails to secure a remedy adequate to redress it." *Id.* at 323-24. In other words, antitrust enforcement depends as much on the ability to obtain effective relief as it does on the ability to prove liability.

A. It is Well Recognized that an Injunction May Need to be Broader than the Conduct at Issue to Effectively Prevent Antitrust Violations

In *Int'l Salt Co. v. U.S.*, the Supreme Court grappled with how broad an antitrust injunction must be to be effective. 332 U.S. 392 (1947). There, the defendant appealed to strike provisions of a district court decree that broadly prohibited leasing practices similar to the conduct found to violate Section 1 of the Sherman Act. *Id.* at 396-97. The Court rejected the company's petition to limit

the injunction to the specific leases that the district court found illegal. It explained that, because defendant was not "entitled to stand before the court in the same position as one who has never violated the law at all," the defendant was in no position to argue that "the injunction should go no farther than the violation or threat of violation." *Id.* at 400. The Court continued:

> "The District Court is not obliged to assume, contrary to common experience, that a violator of the antitrust laws will relinquish the fruits of his violation more completely than the court requires him to do. . . . When the purpose to restrain trade appears from a clear violation of law, it is not necessary that all of the untraveled roads to that end be left open, and that only the worn one be closed. The usual ways to the prohibited goal may be blocked against the proven transgressor, and the burden put upon him to bring any proper claims for relief to the court's attention." *Id.*

Numerous courts since have concluded that injunctions in antitrust cases need not be limited to the exact conduct that violated the antitrust laws, and that, on the contrary, such a narrow scope is often not enough. *See, e.g.*, *Int'l Salt Co.*, 332 US 392, 400; *United States v. United States Gypsum Co.*, 340 US 76, 89-93 (1950); *Int'l Boxing Club v. United States*, 358 US 242, 258-59, 262 (1959); *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 US 100, 132 (1969); *Nat'l Soc. of Prof'l Eng'rs v. United States*, 435 US 679, 697-99 (1978). Breadth is so crucial to a remedy's effectiveness that, in some antitrust cases, appellate courts considering a lower court's injunctive relief have felt compelled not just to affirm, but also proactively broaden, the scope of the remedy to better protect the public interest. *See, e.g.*, *United States Gypsum Co.*, 340 US 76, 89-93; *Int'l Boxing Club*, 358 US

at 258-59, 262; *E. I. Du Pont De Nemours*, 366 US 316, 323-34; *United States v. Loew's, Inc.*, 371 US 38, 52-56 (1962); *United States v. Glaxo Group, Ltd.*, 410 US 52, 60-64 (1973).

Antitrust experts agree that the scope of a remedy may well need to extend beyond the antitrust violation. In crafting the scope of the injunction, "[t]he agency must anticipate the [defendant's] likely response. The enforcement agency must assume that the defendant is adaptable and will try to sidestep the remedy. By blockading recourse to certain commercial tactics, a remedial decree will inspire the defendant to pursue other paths that circumvent the judicially imposed constraints." William Kovacic, *Designing Antitrust Remedies for Dominant Firm Misconduct*, 31 Ct. L. Rev 1285, 1311 (1999). Imposing a narrow remedy on a wily defendant, "even construe[d] in the most favorable light, […] would be like trying to stop traffic on a five-lane highway by closing one lane." Einer Elhauge, *Soft on Microsoft: The Potemkin Settlement*, Weekly Standard 17-18 (March 25, 2002).

The lesson these cases and experts provide on adequate injunctive breadth is salient here. Shkreli suggests that, among other modifications, the injunction on his participation in the pharmaceutical industry should extend only to conduct involving drugs whose patents have expired but have no current competition. But it is easy to imagine any number of ways to sidestep that narrow a remedy.

Exclusive contracts that restrict the supply of active pharmaceutical ingredients to competitors, for example, can be just as harmful in markets with current competition as in those without. As a result, such a remedy would be facially inadequate to protect the public interest. *See Zenith Radio Corp.*, 395 U.S. at 132 (1969) ("[A] federal court has broad power to restrain acts which are of the same type or class as unlawful acts which the court has found to have been committed or whose commission in the future unless enjoined, may fairly be anticipated from the defendant's conduct in the past."); *accord NLRB v. Express Publ'g Co.*, 312 U.S. 426, 435 (1941).

B. To Ensure an Effective Remedy, an Injunction May Need to Ban Otherwise Legal Conduct

Courts also recognize that to ensure an injunction's efficacy a remedy may need to prohibit otherwise legal conduct in addition to proven illegal acts. In *FTC v. Nat'l Lead Co.*, for example, the Supreme Court upheld an injunction limiting the use of zone-delivered pricing, which was not itself illegal, because the history of its unlawful use was pervasive in the industry. 352 U.S. 419, 430 (1957) ("Although the zone plan might be used for some lawful purposes, decrees often suppress a lawful device when it is used to carry out an unlawful purpose."). Similarly, the Court in *U.S. Gypsum* found a district court's injunction on pricing conduct inadequate because it extended only to the geographies and specific gypsum products where a violation had been found. The Court concluded an

injunction could only be effective if it encompassed all gypsum products and all geographies nationwide, including those where no antitrust violation had been alleged. 340 U.S. at 89-93.

Appropriate relief can include banning the wrongdoer from participating in an industry altogether. As the FTC brief notes, such bans are commonplace in cases brought under Section 13(b). FTC Br. at 26-28. Moreover, lifetime industry bans have been explicitly endorsed by the Supreme Court as a potential antitrust remedy. In *United States v. Grinnell,* the Court concluded that an injunction preventing an antitrust violator from further employment in the industry, although not warranted due to the circumstances of that case, would be appropriate where the offender's "predatory conduct was more conspicuous." 384 U.S. 563, 579 (1966). It is difficult to imagine as conspicuous a case of harmful conduct as the one currently before this Court.

II. Injunctive Antitrust Remedies Must be Administrable to be Effective

Antitrust experts, regardless of whether they advocate for greater enforcement of the antitrust laws or caution against government intervention in business, agree on at least one point: Antitrust remedies must be administrable to be effective. *See, e.g.*, Thomas Barnett, Assistant Attorney General, U.S. Dept. of Justice, *Section 2 Remedies: A Necessary Challenge*, Fordham Antitrust Inst. 34th Annual Conference on Int'l Antitrust L. & Pol'y (September 28, 2007)

("[R]emedies that require government entities to make business decisions or that require extensive monitoring or other government activity should be avoided whenever possible."); Philip Weiser, Colorado Attorney General, *Prepared Remarks: The Enduring Promise of Antitrust,* Loyola Antitrust Colloquium (April, 2020) (agreeing with Judge Posner's comments that remedies should be "sufficiently clear to be judicially administrable" and should not "impose an undue administrative burden on the district court, which would have to administer the decree."); Jonathan Kanter, Assistant Attorney General, U.S. Dep't of Justice, *Remarks at N.Y. State Bar Assoc.* (January 24, 2022) ("We should not spend great sums to obtain decrees which are economically unenforceable . . . and, when carried out in form, are often only lessons in futility.").

Administrability has two components: violations must be relatively easy to detect and relatively easy to rectify. *See* OECD, *Remedies and Commitments in Abuse Cases*, OECD Competition Pol'y Roundtable Background Note at 13 (2022) (identifying "practicality" as key to effective remedies, "i.e. if they can be effectively implemented, monitored and enforced"). In other words, policing the injunction cannot require monitoring costs that outstrip available resources. *Id.* at 25 ("Effective enforcement requires competition agencies to devise adequate monitoring mechanisms, have powers to act in case of non-compliance, and commit sufficient resources to monitoring . . . [and is] fundamental for ensuring

the effectiveness of the remedy."); *see also* John Kwoka & Diana Moss, *Behavioral Merger Remedies: Evaluation and Implications for Antitrust Enforcemen*t, at 6 (Am. Antitrust Inst Whitepaper) (noting direct costs of monitoring and costs of evasion as among the most significant factors in evaluating conduct remedies).

In general, broader remedies are simpler, cleaner, and easier to monitor than narrower, more complex ones. For this reason, agencies and experts have advocated in the merger context for structural remedies such as divestment instead of complex behavioral remedies. *See E.I. du Pont de Nemours,* 366 U.S. at 330-31 (describing the importance of divestiture as an antitrust remedy because "[i]t is simple, relatively easy to administer, and sure"); Letter from Lina Kahn, FTC Chair, to Senator Elizabeth Warren (Aug. 6, 2021) ("Indeed, both research and experience suggest that behavioral remedies pose significant administrability problems and have often failed to prevent the merged entity from engaging in anticompetitive tactics enabled by the transaction."); *see also* Thomas Greaney and Barak Richman, *Consolidation in Provider and Insurer Markets: Enforcement Issues and Priorities*, Am. Antitrust Inst.'s Series on Competition in the Delivery and Payment of Healthcare Services at 17-19 (2018) (casting doubt on the likelihood that courts can craft conduct decrees that are both effective and narrowly tailored). The DOJ has also previously documented the challenges

presented by complex behavioral remedies, which "typically [are] more difficult to craft, more cumbersome and costly to administer, and easier than a structural remedy to circumvent." Dept. of Justice, Antitrust Division Pol'y Guide to Merger Remedies at 8 (Oct. 2004).

Informational asymmetries between the offender and the government as an external observer can also make it difficult to know when a behavioral remedy has been violated. *See* Kwoka & Moss, *Behavioral Merger Remedies* at 23. In such cases, enforcement agencies must rely on aggrieved purchasers or competitors to report violations. However, fear of retaliation makes it unlikely that either group will speak up. *See also infra*, Section V(B) (describing why direct purchasers do not bring private suits against pharmaceutical antitrust violators). Enforcement agencies must then turn to potentially invasive monitoring to detect lapses. To avoid the expense and uncertainty of such monitoring, remedies that are as self-enforcing as possible are preferred, such as structural remedies in the merger context.

A comparison of the injunction sought by Shkreli and the one ordered by the district court demonstrates the administrability advantages of a broader, cleaner injunction. Shkreli's version would, for instance, distinguish between different types of drugs and between activity relating to research and development and activity relating to manufacturing. Enforcing such an injunction is facially

unadministrable. The status of all the drug products in any company Shkreli was involved with would need to be continuously monitored for patent status, product acquisitions below the HSR thresholds would need to be tracked, and Shkreli's day-to-day decision-making within a company would need to be continuously examined to determine whether his activity falls on one side of the line or the other. In contrast, an outright ban makes violations easily identifiable events.

III. Effective Antitrust Remedies Must Address the Anticompetitive Incentives that Led to the Violations

Given the challenges of ensuring compliance through external monitoring, antitrust enforcers and experts have recognized that antitrust remedies are more effective if they address the incentives of the offender to engage in similar anticompetitive conduct. *See* Einer Elhauge, *Disgorgement as an Antitrust Remedy,* 76(1) Antitrust L.J. 79, 88 (2009) (noting conduct remedies often "have difficulty really changing the operation of markets, create perverse incentives, and are difficult to administer"). As a result, enforcement agencies face a bind:

> "The problem is that those prohibited acts are in the interest of the firm, which therefore can be predicted to seek workarounds and other methods to avoid or evade the intent of the remedy. The agency in turn labors under an informational disadvantage with respect to the firm's decisions and the intent of any action. This results in the likelihood that the firm will identify ways of minimizing the effect of the remedy, despite an agency's efforts at monitoring and overseeing the constraints it has imposed on the firm's behavior." John Kwoka & Spencer Waller, *Fix It or Forget It: A "No-Remedies" Policy for Merger Enforcement*, Competition Pol'y Int'l Antitrust Chronicle at 4 (Aug. 2021).

The issue of administrability is starkly demonstrated by the failure of the complex injunctive remedies that DOJ accepted instead of blocking LiveNation-Ticketmaster's 2010 merger. That decree prohibited Ticketmaster from using the threat of denying venues popular shows if they did not use its ticketing services. However, a DOJ investigation in 2020 revealed that, despite the decree, Ticketmaster had repeatedly engaged in the prohibited conduct and other similar tactics, which had "permeated the industry." DOJ then amended the consent to "clarify" the terms and extend its prohibitions for another five years. *See* Motion to Modify Final Judgment and Enter Amended Final Judgment, *United States v. Ticketmaster Ent., Inc. & Live Nation Ent. Inc.*, Case No. 1:10-cv-00139-RMC (D.D.C. Jan. 8, 2020). Even today, though, a steady stream of complaints allege that despite DOJ's efforts to improve enforcement, Ticketmaster continues to engage in the prohibited conduct and other illegal tactics to protect its monopoly position. DOJ is reportedly once again investigating the company's tactics, and observers are calling for the break-up of the company as the only remedy that will remove the company's incentives to engage in the illegal conduct.

The evasion that has plagued DOJ's enforcement efforts in LiveNation-Ticketmaster is attributable to a fundamental problem with complex behavioral remedies. Because conduct remedies invoke rules and requirements designed to constrain particular types of action rather than changing the parties' incentives or

ability to exercise market power, they create a strong motivation for the subject of the injunction to find "workarounds." *See* Diana L. Moss, *Chapter 3: Realigning Merger Remedies with the Goals of Antitrust*, The Guide to Merger Remedies (Global Competition Review 2019).

The kind of injunction Shkreli seeks suffers from the same weakness. The narrow restraints he argues for do not address his proven willingness to profit from exploitive drug pricing, nor his incentives to continue to try to find ways to game the medical system. So long as he has influence on the supply or pricing of pharmaceuticals, Shkreli has proven himself motivated to try again, especially when he has, by his own accounts, no remorse for his conduct. *FTC v. Shkreli*, 581 F.Supp.3d 579, 639 (2022) ("[Shkreli] refused to change course and proclaimed that he should have raised Daraprim's price higher."). Only the clean ban imposed by the district court ensures that Shkreli will not again be in a position where he has the ability and incentive to profit from anticompetitive pricing practices.

IV. The District Court's Injunction is Consistent with Appropriate Limiting Principles

The experience of courts and agencies also outlines appropriate limiting principles against which an antitrust remedy should be assessed including: (1) whether the terms of the injunction flow from the harm, (2) whether the injunction is proportional to the illegal acts, and (3) whether the injunction threatens to stifle

procompetitive conduct. The district court's injunction is consistent with each of these considerations.

A. The Terms of District Court's Injunction Flow from the Proven Harm and Are Proportional to It

Caselaw and agency experience both confirm that the effectiveness of a remedy depends on maintaining a nexus with the proven violation. Designing an injunction that anticipates with any accuracy future forms of a recurring harm requires the enforcer to extrapolate from the known facts of the violation. Therefore, keeping a reasoned link between the remedy and the harm is a fundamental component of the U.S. antitrust agencies' policies. The Merger Remedies Guidelines from 2020, 2011, and 2004 all contain variants of the same principle: the remedy should have a "logical nexus" to the violation and should "flow from the theory or theories of competitive harm." *See* Dep't of Justice, Merger Guidelines Manual at 2 (Sept, 2020); Dep't of Justice, Antitrust Division Policy Guide to Merger Remedies at 4 (June 2011); Dep't of Justice, Antitrust Division Policy Guide to Merger Remedies at 3-4 (October 2004).

The principle of logical nexus is illustrated by the Supreme Court's decision on injunctive relief in *Grinnell*. There, the Supreme Court agreed that the forward-looking ban on the defendants acquiring interests in any firms in industry was "fully warranted" because "acquisition was one of the methods by which the defendants acquired their market power" and perpetuate their anticompetitive

scheme. 384 U.S. at 580. Here as well, the district court connected the prohibitions imposed on Shkreli to his proven illegal conduct. The injunction's ban on activity by Shkreli outside the U.S, for example, is appropriate because the scheme could not have succeeded "without a coordinated effort that reached into the global pharmaceutical market." *Id.* Similarly, the limitations on "indirectly" participating in the industry relate logically to Shkreli's demonstrated ability to further his anticompetitive schemes through others, as he did while incarcerated by directing others via a contraband phone. *See id.*

The concept of proportionality is built into the U.S. caselaw on antitrust remedies. *See* OECD, *Remedies and Commitments in Abuse Cases* at 14-15. The need to vary a remedy based on context is a fundamental precept of antitrust enforcement policy. *See U.S. Gypsum Co.*, 340 U.S. at 89 ("In resolving doubts as to the desirability of including provisions designed to restore future freedom of trade, courts should give weight to . . . the circumstances under which the illegal acts occur."). In general, "remedies should be proportional in the sense that they reflect the dangers of the conduct by which a firm has achieved or sustained a position of dominance." Kovacic, *Designing Antitrust Remedies* at 1312-13.

Proportionality has several implications here. First, it means that prior conduct matters to the scope of the injunction, especially if there is a history of recidivism. As one commentator put it, "past behavior is arguably the best

indicator of future conduct . . . the preferred remedy is partially influenced by the path the offender has taken to achieve his anticompetitive ends and partially influenced by the [offender's] track record of compliance." Thomas Sullivan, *Antitrust Remedies in the U.S. and EU: Advancing a Standard of Proportionality*, 48(2) Antitrust Bull. 377, 409 (2003). Therefore, proportionality demands that a history of non-compliance result in more stringent remedies. Second, the offender's awareness of the harm matters. As the Supreme Court wrote in *U.S. Gypsum Co.*, "acts in disregard of law call for repression by sterner measures than where the steps could reasonably have been thought permissible." 340 U.S. at 89-90.

Judge Cote applied both considerations in her decision on injunctive relief. She observed that Shkreli's conduct was shown to be "egregious, deliberate, repetitive, long-running and ultimately dangerous." *FTC v. Shkreli*, 581 F.Supp.3d at 639. Shkreli, she explained, "recklessly disregarded the health of a particularly vulnerable population, those with compromised immune systems." *Id.* Shkreli carried out his scheme with two different companies "so that he could profit […] on the backs of a dependent population of pharmaceutical distributors, healthcare providers, and the patients who needed the drugs." *Id*. Based on these facts, Judge Cote appropriately concluded that she could not narrow the injunction without jeopardizing the public interest.

B. The District Court's Injunction Has No Effect on Pro-Competitive Conduct

Experts and courts have cautioned that injunctive remedies must consider potential effects on pro-competitve conduct. *See, e,g*, Kwoka & Moss, *Behavioral Merger Remedies* at 6 (noting that "restraining competitive behavior" is a potential cost of conduct remedies). The concern is irrelevant, however, where there is simply no pro-competitive conduct to affect. As Professor Kovacic noted:

> "An enforcement agency can properly request, and a court can justifiably impose, more drastic remedial measures where the behavior at issue is wholly or largely lacking in redeeming procompetitive traits. Using powerful remedies in these circumstances provides greater protection against repetition of clearly damaging behavior, justifiably dismantles market positions achieved through efficiency-suppressing means, and deters efforts by other firms to employ similar tactics." *Designing Antitrust Remedies* at 1313.

So too here. Shkreli's forays into the pharmaceutical industry have been universally and unabashedly anticompetitive. Shkreli suggests that he should be considered a market "participant" who should be allowed to try again in the pharmaceutical space. *See* Pet. Br. 43. But there is no support for the notion that Shkreli has contributed or would ever contribute to pharmaceutical competition. Noah Philips, an FTC Commissioner at the time of the district court case, explained that he endorsed the ban against Vyera's Shkreli and Mulleady because his usual concerns regarding the competitive effects of permanent injunction were inapplicable. Statement of Commissioner Noah Philips, *Vyera Pharmaceuticals, LLC*, File No. 161-0001 (December 7, 2021). Complete industry bans, he noted,

"are appropriate where, as here, there is compelling evidence that the defendant oversaw and directly participated in a diabolical anticompetitive plan that hurt consumers and the ban poses virtually no risk to competition." *Id.*

V. Maintaining the Full Scope of the FTC's Injunctive Authority is Essential Because the FTC is the Primary and Often Only Enforcer in Pharmaceutical Conduct Antitrust Cases

For all the reasons discussed above, the district court's injunction in this case should be upheld as necessary and appropriate given the facts of the case. But to narrow the scope of the relief here does not just weaken enforcement in this case, it also threatens effective enforcement in a whole class of antitrust cases that are vital to the U.S. consumer. In the pharmaceutical context, the FTC is an expert agency with unique experience and ability to enforce the antitrust laws. As a result, its ability to seek effective relief here has an outsized impact on consumers, including potentially vulnerable patient populations.

A. Courts Should Evaluate the Scope of the Court's Injunction's in Light of the FTC's Pharmaceutical Antitrust Expertise

There is heightened importance to taking FTC's guidance on injunctive relief in the pharmaceutical context. The FTC has unrivaled expertise in detecting and addressing anticompetitive conduct in the industry. *See* Michael Carrier & Fernando Araya, *Pharmaceutical Antitrust Enforcement in the United States and Chile*, 8(1) J. L. & Biosci. 1, 2 (2021) (detailing FTC's "critical expertise and experience in the pharmaceutical industry"). The agency is the lead

pharmaceutical antitrust enforcer in both the merger and non-merger contexts. *See* Sonia Pfaffernroth, *Non-Merger Civil Enforcement: An Overview of Recent DOJ and FTC Federal Court Litigation Merger Review*, 32(1) Antitrust 21, 23-25 (Fall 2017) (describing FTC's leading role in pharmaceutical non-merger litigation from 2009-2017); Nathan Wilson, *Editor's Note: Some Clarity and More Questions in Health Care Antitrust*, 82(2) Antitrust L.J. Chicago Vol. 435, 440 (2019) (noting FTC is lead reviewer for pharmaceutical mergers). Its enforcement expertise is expanded by the in-depth studies it has conducted on the most troublesome competition issues in the industry, including anticompetitive delays to generic entry. *See* Fed. Trade Comm'n, *Generic Drug Entry Prior to Patent Expiration*: *An FTC Study* (July 2002); Fed. Trade Comm'n, *Authorized Generic Drugs: Short-Term Effects and Long-Term Impact: A Report of the Federal Trade Commission* (2011); Fed. Trade Comm'n, *FTC Launches Inquiry into Prescription Drug Middlemen Industry* (June 7, 2022). In short, the FTC is well-equipped in the pharmaceutical space to "'serve as an indispensable instrument of information and publicity, as a clearinghouse for the facts by which both the public mind and the managers of great business undertakings should be guided.'" Daniel A. Crane, *The Institutional Structure of Antitrust Enforcement* at 130 (Oxford Univ. Press 2011) (quoting FTC Act legislative history).

The FTC's experience is also highly germane to the issues in this case. The FTC leads antitrust enforcement against novel anticompetitive exercises of pharmaceutical market power, and its expertise has allowed the agency to keep pace with the industry's ever-evolving anticompetitive efforts to restrict generic entry. *See* Phillip Areeda & Herbert Hovenkamp, Antitrust ¶ 302c (5th ed. 2022) ("[T]he Commission has also undertaken litigation enterprises that are best characterized as 'law reform,' such as . . . its continuous opposition to "reverse payment" settlements in pharmaceutical infringement cases . . . The Commission may be well suited to such enterprises, for it can develop a more coherent vision and achieve a degree of uniformity that is not available from the lower courts."). The agency was the first to realize the need for this kind of antitrust enforcement, beginning over twenty years ago "when no one was focused on the issue." Carrier & Araya, 8(1) J. L. & Biosci. at 2; *see* Decision and Order, *Abbott Lab'ys*, Docket No. C-3945 (F.T.C. 2001). Since then, the FTC has been the most successful and prolific enforcer, public or private, in the pharmaceutical space. For instance, the FTC was the first to identify and develop legal theories around many of the tactics used to delay generic entry. *See FTC v. Actavis*, 133 S. Ct. 2223 (2013) (confirming that pay-for-delay agreements can be antitrust violations); *Impax Lab'ys, Inc. v FTC*, 994 F.3d 484 (5th Cir. 2021) (upholding broad injunction in pay-for-delay case); *FTC v. Cephalon, Inc.*, 551 F.Supp.2d 21 (D.D.C. 2008)

(same); *FTC v. Indivior, Inc.*, Case 1:20-cv-00036-JPJ-PMS, Doc. No 1 (W.D. Va. July 24, 2020) (developing product hopping theory, injunction granted); *Bristol-Myers Squibb Co.*, Docket No. C-469 (F.T.C. Jan 13, 2020) (finding defendant abused regulations intended to hasten generic entry to delay said entry).

For these reasons, the FTC's institutional expertise puts it in a uniquely strong position to gauge the effectiveness of injunctive relief in cases like this. *See* Crane, *The Institutional Structure of Antitrust Enforcement* at 130 (Oxford 2011) ("Congress expected that federal judges and other policymakers would defer to the Commission on competition matters because it would 'serve ... as a clearinghouse for the facts by which both the public mind and the managers of great business undertakings should be guided.'") (citing FTC Act legislative history). In fact, courts routinely follow the FTC's expert guidance. For example, in *Impax Laboratorys*, the FTC procured, and the 5th Circuit upheld against claims of overbreadth, an injunction that barred any agreement that may have an effect that "disincentivizes competition," prohibited any form of reverse payment, and ordering payment of royalties to another pharmaceutical company. 2019 WL 1552939, at *42 (F.T.C. 2019), *review denied sub. nom. Impax Lab'ys, Inc. v. FTC*, 994 F.3d 484 (5th Cir. 2021). To drastically narrow a remedy against the advice of the FTC would be risky in a complex industry like pharmaceuticals,

where effective relief complicated by the regulatory overlay and the need to balance innovation against competition concerns.

B. Limiting the Scope of Court Injunctions in Pharmaceutical Misconduct Cases Would Neuter the Nation's Frontline, and Often Only, Enforcer

Courts should also be reticent to limit the FTC's power because the FTC is uniquely positioned to enforce against anticompetitive conduct in the pharmaceutical arena. A court cannot expect, for example, that private enforcement will inevitably fill any gaps created in FTC's power to seek appropriate relief. In fact, given the size of the industry, there are relatively few successful private lawsuits challenging anticompetitive conduct in pharmaceuticals. *See* Stephen Calkins, *Civil Monetary Remedies Available to Federal Antitrust Enforcers*, 40 U.S.F. L. Rev. 567, 572 (2006). That is because the "most logical plaintiffs," the health insurance companies, "are loath to sue providers with whom they desire a long-term, mutually beneficial business relationship." *Id.* at 573. And, even for those willing to sue, there are numerous obstacles. *See* Joseph Bauer, *The Stealth Assault on Antitrust Enforcement: Raising the Barriers for Antitrust Injury and Standing*, 62 U. Pitt. L. Rev. 437, 444–46 (2001).

For example, class action certification issues, which have become increasingly difficult, often limit private enforcers in the antitrust space. *See*

Elhauge, 76(1) Antitrust L. J. at 83-84 ("Where once courts recognized that, because antitrust cases involve market-wide injuries, they are uniquely suitable for class action treatments, many courts now seem willing to accept arguments that in markets with product differentiation, buyer negotiation, or price discrimination, injuries are individuated in a way that undermines common proof of injury, even when the case involves horizontal price fixing."). The FTC is also able to avoid some of the thorniest issues facing private plaintiffs, including certain causation and standing issues that too often trip up private enforcement. *See* Joseph P. Bauer, 62 U. Pitt. L. Rev. at 444-46. Finally, government enforcement may be the only option in cases where arbitration clauses prevent class actions entirely. *See Am. Exp. Co. v. Italian Colors Rest.*, 570 U.S. 228, 236 (2013).

The pool of potential private plaintiffs is also reduced because only a direct purchaser of a product or service may sue an alleged antitrust violator under federal antitrust law. *Apple Inc. v. Pepper*, 139 S. Ct. 1514, 1519-20 (2019). But direct purchasers are often unwilling to sue their suppliers because they depend on them. And these direct purchasers can often pass on any overcharge to their customers. *See* Andrew Gavil, *Thinking Outside the Illinois Brick Box: A Proposal for Reform*, 76 Antitrust L.J. 167, 192 (2009).

This case demonstrates why private enforcement is not enough. The direct purchasers of Daraprim were Vyera's distributors. However, no direct purchaser

brought suit until March 2021, over a year after the FTC filed its suit and despite the fact that Shkreli's egregious price increases occurred in 2014. *See* Erik Larson, *Martin Shkreli Sued by Blue Cross over 2015 Drug Price Hike*, Bloomberg Business (Mar. 4, 2021). That's unsurprising: Vyera's distributors were compensated on the basis of the drug's exorbitant list price and thus benefit from Vyera's conduct. And so, despite Vyera's blatant misconduct, there's been little private enforcement of any kind in this case. *See also* Bauer, 62 U. Pitt. L. Rev. at 446 (describing inability of consumers to challenge Ticketmaster's after the Eighth Circuit held they were not direct purchasers); Am. Antitrust Inst., *Comments of American Antitrust Institute Working Group on Remedies to Antitrust Modernization Commission*, at 19 (June 17, 2005) (auto-manufacturers illegally prevented cheaper Canadian cars from entering American market, but direct purchasers, car dealers, didn't sue).

C. Antitrust Enforcement by the FTC is Particularly Necessary Given Pharmaceutical Industry's Complex Economics and Outsized Impact

Preserving the FTC's full enforcement power has particularly high stakes in the pharmaceutical context. Anticompetitive conduct that raises prices of necessary drugs directly harms individuals and their quality of life. *See* Marin Gemmill et al., *What Impact Do Prescription Drug Charges Have on Efficiency and Equity?*, 7(12) Int'l J. Equity Health 1, 16 (2001) (metastudy finding that "[increasing] user charges lowered adherence to treatment and reduced the use of

essential and non-essential drugs, strongly suggesting a negative impact on health"). Additionally, individuals affected by higher drug prices are among the most vulnerable in society. No matter how much patients may need life-saving drugs, they will not get them unless they can find a way to pay. *See id.* at 12 ("Poorer households were most affected financially by user charges."). Even for those who are covered by insurance, small increases in copays on drugs still impact the health of those who are financially vulnerable. *See id.* at 9. Ultimately, anticompetitive efforts to delay generic competition are one of the main contributors to "skyrocketing [drug] costs and are causing deaths and harming patients on a daily basis." *See* Andrew Foreman, Deputy Assistant Attorney General, U.S. Dep't of Justice, Keynote at ABA's Antitrust in Healthcare Conference (June 3, 2022) (describing need for "extremely high bar" for remedies in healthcare antitrust cases because of the "deeply personal harm in people's everyday lives and pocketbooks."); Michael Carrier et al., *Playing Both Sides? Branded Sales, Generic Drugs, and Antitrust Policy*, 71 Hastings L.J. 307, 312-314 (2020) (discussing market incentives and impact of generic entry on drug prices).

Surrounding the pharmaceutical industry's impact on real American lives is "an unusual intersection of regulation, patent and antitrust law" and "atypical economics" which makes it one of the most complex U.S. industries. Patricia Danzon, *Competition and Antitrust Issues in the Pharmaceutical Industry* at 3, 6-8

(Wharton School Final Report) (July 2014). As a result of the industry's complexity, as well as the scientific expertise required to evaluate much of the potential anticompetitive conduct in it, it is difficult to police for anticompetitive conduct. *Id.* at 19-23 (outlining the complexity of anticompetitive conduct in pharmaceuticals). However, the industry is also inherently prone to substantial potential market power due to patent protection, regulatory exclusivities, and insurance coverage. Due to a history of pharmaceutical mergers, the industry is highly consolidated, ridden with bottlenecks that increase prices. Diana L. Moss, *From Competition to Conspiracy* at 11-12 (American Antitrust Inst. Whitepaper) (Sept. 3, 2020). Additionally, regulation of the pharmaceutical industry is a quagmire of overlapping incentives, with much of the risk of pursing anticompetitive conduct to delay generic entry "transferred to consumers." *See* Areeda & Hovenkamp at ¶ 2046a. Finally, market definition questions in the pharmaceutical industry are "particularly troublesome" because of a high degree of product differentiation and considerable overlap in the treatment of certain indications. Areeda & Hovenkamp at ¶ 2046d5.

This case is a leading example of why the FTC's rigorous conduct enforcement in the pharmaceutical industry is necessary. Shkreli saw the complex economics and vulnerable individuals in the pharmaceutical industry and explicitly exploited them to maximize his profit. His acquisition of Daraprim took advantage

of the characteristics of the pharmaceutical industry which lend themselves to anticompetitive abuse. Shkreli's misconduct permeated multiple levels of pharmaceutical development, including blocking product samples generic companies needed to conduct bioequivalence testing, entering vertical exclusivity agreements with key suppliers, and cutting off generic companies from receiving key sales data it needed to assess the profitability of a competing drug. *See FTC v. Shkreli*, 581 F.Supp.3d 579, 602-610 (S.D.N.Y. 2022). Shkreli ignored pleas that Vyera's high prices were making it impossible for hospitals to obtain Daraprim. *See* Complaint, *FTC v. Vyera*, 2020 WL 12814032, ¶ 86 (S.D.N.Y. 2020) (writing that Daraprim's price increases were "unjustifiable for the medically vulnerable patient population in need of this medication and unsustainable for the health care system."). And, unlike the generic entry that pharmaceutical regulation was meant to encourage, here there are no redeeming procompetitive factors to offset Shkreli's actions. First, Shkreli's price spike unexplained by anything other than opportunistic behavior. *See FTC v. Shkreli*, 581 F. Supp. 3d at 621 (Shkreli founded Vyera "with the intention to use Vyera to acquire a pharmaceutical that was the sole source of treatment for a life-threatening ailment, raise the drug's price sky-high, and keep it sky-high for as long as possible."). Second, Daraprim was long off-patent, and there is no indication of any innovation resulting from any part of Shkreli's conduct. Finally, new entry did not occur, nor was there any

indication that Shkreli's conduct would make new entry likely within any reasonable time.

CONCLUSION

The injunction entered by the district court in this case is consistent with the law and with the principles of effective antitrust remedies. Any weakening of the injunction against Shkreli not only weakens that order's specific deterrence but would also make the FTC's essential enforcement actions more difficult across the pharmaceutical space. As the expert enforcer in the industry, the FTC must be able to pursue proscriptive, forward-looking action that will fully prevent such abuses, especially where, as here, there is a high risk of recidivism. For these reasons, we respectfully request that the district court's injunction be upheld in its entirety.

Respectfully submitted,

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Dated: March 30, 2023

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