No. 21-8042

IN THE UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

IN RE: NIASPAN ANTITRUST LITIGATION A.G.C. BUILDING TRADES WELFARE PLAN; CITY OF PROVIDENCE, RHODE ISLAND; ELECTRICAL WORKERS 242 AND 294 HEALTH & WELFARE FUND; INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 49 HEALTH AND WELFARE FUND; INTERNATIONAL UNION OF OPERATING ENGINEERS LOCAL 132 HEALTH AND WELFARE FUND; NEW ENGLAND ELECTRICAL WORKERS BENEFITS FUND; PAINTERS DISTRICT COUNCIL NO. 30 HEALTH & WELFARE FUND; UNITED FOOD & COMMERCIAL WORKERS LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE FUND; MILES WALLIS; CAROL PRASSE,

Appellants.

On Permission to Appeal from the United States District Court for the Eastern District of Pennsylvania (Dubois, D.J.; D. Ct. Case No. 13-md-2460)

BRIEF FOR THE AMERICAN ANTITRUST INSTITUTE AS *AMICUS CURIAE* IN SUPPORT OF APPELLANTS

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Local Appellate Rule 26.1.1, *amicus* states as follows:

The American Antitrust Institute is a nonprofit, non-stock corporation. It has no parent corporations, and no publicly traded corporations have an ownership interest in it.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES & REGULATIONS

OTHER AUTHORITIES

Terry Moon Cronk, *Defense Official Calls Artificial Intelligence the New Oil*, DOD News (Oct. 19, 2020), *available at* https://www.defense.gov/News/News-Stories/Article/Article/2386956/defense-official-calls-artificial-intelligence-the-new-oil/#:~:text=Artificial%20intelligence%20is%20the%20new,chief%20technology%20officer%20said%20Oct 18

Joshua P. Davis & Rose Kohles, 2020 Antitrust Annual Report: Class Action Filings in Federal Court 2 (Aug. 2021), *available at* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3898782 26

Joshua P. Davis & Robert H. Lande, *Defying Conventional Wisdom: The Case for Private Antitrust Enforcement*, 48 Ga. L. Rev. 1 (2013) 26

Express Scripts, *Research*, Express-Scripts.com, https://www.express-scripts.com/corporate/insights/research (last visited Jan. 14, 2022) 18

Executive Off. of the President, Exec. Order on Promoting Competition in the American Economy, No. 14036 § 5(h)(iii) 26

Adam J. Fein, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation*, Drug Channels Inst. (April 6, 2021), *available at* https://www.drugchannels.net/2021/04/the-top-pharmacy-benefit-managers-pbms.html 16

Robin Feldman, *Antitrust Law: Pharmaceutical "Pay for Delay" Reexamined*, *in* 5 The Judges' Book 2021: Scholarship for the Bench (2021), *available at* https://repository.uchastings.edu/judgesbook/vol5/iss1/4/ 25

Martin Ford, AI as the New Electricity, *in* Rule of the Robots: How Artificial Intelligence Will Transform Everything (2021) 18

FTC Mem., *Fed. Trade Comm'n v. Cephalon, Inc.*, No. 2:08-civ-2141, 2015 WL 5583757 (E.D. Pa. Feb. 17, 2015) 25

FTC Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010) 24, 25

INTEREST OF *AMICUS CURIAE*[1]

The American Antitrust Institute ("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.[2]

SUMMARY OF ARGUMENT

The administrative feasibility prong of this Court's ascertainability doctrine has become clear over the last decade. This Court's early opinions emphasized when plaintiffs had *not* provided an administratively feasible way to determine

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[1] All parties consent to the filing of this *amicus* brief. 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 curiae* or its counsel—has contributed money that was intended to fund preparing or submitting this brief. During the drafting of this brief, Prof. Joshua Davis left a full-time faculty position at the University of San Francisco Law School and became a Research Professor at U.C. Hastings College of the Law and a shareholder at Berger Montague PC, which represents a class of *direct* purchasers in litigation involving the same conduct at issue in this case. *See In re Niaspan Antitrust Litig.*, 397 F. Supp. 3d 668 (E.D. Pa. 2019) (class certification granted). The ascertainability issues addressed in this brief were not at issue in the direct purchaser action, *id*. at 691, and Prof. Davis has done no work in the direct or indirect purchaser actions.

[2] The views of individual members of AAI's Board of Directors or Advisory Board may differ from AAI's positions.

class membership. This Court's more recent opinions have emphasized when plaintiffs *have* established administrative feasibility. Taken together, the opinions provide a standard for administrative feasibility that is practical, serves the purposes of Rule 23, and should be readily satisfied in antitrust cases involving prescription drugs.

Third Circuit law imposes two ascertainability requirements under Rule 23(b)(3). The first is a class definition that uses objective criteria ("objectivity"). The second is that class membership can be determined in a reliable and administratively feasible way ("administrative feasibility").

The second requirement is at issue here. It is practical. This Court has focused the analysis on a limited number of tasks required by Rule 23(b)(3). One is to provide notice so that class members have a reasonable opportunity to (1) opt out of a certified class, (2) object to any class settlements, and (3) participate in any class recoveries. Another is to resolve any disputes about class membership in (1) allocating any class recoveries or (2) enforcing a final class judgment against class members who later file precluded claims.

In light of these practical concerns, this Court has adopted concrete rules for administrative feasibility:

(1) Affidavits from potential class members that are unreliable and lack any records to corroborate them are insufficient;

(2) Plaintiffs do not have to create a list of class members; and

(3) Data combined with affidavits that are generally capable of determining class membership suffice, even if the data come from multiple sources and are incomplete.

Hargrove v. Sleepy's LLC, 974 F.3d 467, 470, 480 (3d Cir. 2020); *City Select Auto Sales, Inc. v. BMW Bank of North America, Inc*., 867 F.3d 434, 439 (3d Cir. 2017); *Byrd v. Aaron's Inc*., 784 F.3d 154, 163, 170–71 (3d Cir. 2015).

No doubt these concrete rules will prove difficult to apply in some instances. But antirust claims involving prescription drugs should not number among them. Businesses maintain detailed records about purchases of prescription drugs because they are legally required to do so, because they need to do so for business reasons, and because the relevant data are extraordinarily valuable. As a result, antitrust cases involving prescription drugs, particularly when they are brought on behalf of third-party end payors, should generally meet the standard for administrative feasibility. Data combined with reliable affidavits can identify who payed for a prescription drug subject to allegedly supracompetitive prices.

The federal government and leading health policy experts have made antitrust enforcement a top priority in a longstanding campaign to improve access to generic drugs. Private antitrust class actions play a critical role in achieving that goal. This Court can promote free markets, protect the rule of law, and help control Americans' healthcare costs by maintaining its practical approach to ascertainability. Applying that approach, courts should find that end-payor plaintiff classes

generally are ascertainable under Rule 23(b)(3) when antitrust claims arise in the pharmaceutical industry.

ARGUMENT

I. THE ASCERTAINABILITY STANDARD IS PRACTICAL

This Court's approach to ascertainability has been practical. That makes sense. The term ascertainability appears nowhere in Rule 23. It is not a formal requirement that courts might apply rigidly based on authoritative language. Rather, this Court derived ascertainability from the tasks that Rule 23 imposes on courts and parties.

Those relevant tasks are few. Trial courts need to ensure class notice meets the requirements of Rule 23 and Due Process. Absent class members need to be able to opt out of any certified class, to object to any settlements, or to participate in any financial recoveries from settlement or trial. Plaintiffs' counsel need to be able to allocate funds from a settlement or trial. Defendants need to be able to enforce any final judgments, protecting themselves from precluded claims. This Court has reasoned that, if these tasks are not manageable, then individual issues may come to predominate over common issues, rendering class certification inappropriate.

The objectivity prong of the ascertainability requirement addresses that risk. A class definition that uses objective criteria allows notice to class members from

which they can determine membership. They do not have to guess whether they are in the class. That makes their rights to opt out, object, and recover funds meaningful. Similarly, plaintiffs' counsel do not have to exercise subjective judgment in allocating funds. Objective criteria also promote certainty and predictability if defendants are later sued by plaintiffs whose claims were extinguished by a class action.

The same points apply to the administrative feasibility prong of the ascertainability requirement. For class members to exercise their procedural rights, they need to be able to figure out whether they are members of the class in a feasible and reliable way. Parties, lawyers, and courts need to be able to do the same in resolving disputes about who gets to recover in a class action and who is bound by a final judgment.

None of those tasks requires a list of class members. When disputes arise about who falls within a class definition, the issue can be addressed by considering relevant records and affidavits, as long as there is reason to believe those sources will be reliable. Such disputes are rare and should not embroil parties or courts in unmanageable individualized litigation. Plaintiffs can protect against that risk by identifying a reliable and administratively feasible mechanism for determining class membership. The *potential* for disputes about class membership does *not*

justify requiring plaintiffs to create a list of class members at class certification or later in litigation.

Rule 23 and Due Process doctrine similarly reject a rigid approach to class notice. Rule 23 instructs a court to "direct to class members the best notice practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2)(B). Rule 23 does *not* require that all members of a class be identifiable through reasonable effort. It assumes that at times *they will not be*. And it requires individual notice only to those class members who can be reasonably identified. The same is true for Justice Jackson's opinion establishing the Due Process standard that applies to class actions and from which the drafters of Rule 23(c)(2)(B) borrowed. *Mullane v. Central Hanover Bank & Trust Co.*, 339 U.S. 306, 317–19 (1950) (requiring only "best notice practicable" and individual notice only to affected parties where providing it is practical).

Another point is important. *Amgen* held that for Rule 23(b)(3), common issues need to predominate in a case *as a whole*, not as to each element of plaintiffs' claims. *Amgen Inc. v. Conn. Retirement Plans and Trust Funds*, 568 U.S. 455, 459 (2013). It follows that the same is true for ascertainability. It should not entail a rigid test that applies regardless of the rest of the issues in litigation. Instead, a court should consider ascertainability in the context of an overall proposed class

action. A court should find predominance if, as a practical matter, common issues will predominate in a case as a whole, even if the litigation could give rise to some individual issues in determining class membership. *See id.*; *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2412 (2014); *Hargrove*, 974 F.3d at 480 (gaps in data permissible for administrative feasibility).

The above framework is consistent with this Court's early decisions on ascertainability. In them, plaintiffs had not identified reliable and administratively feasible ways to determine class membership, but rather tended to rely on class member affidavits that might not be reliable and for which there might not be any possible corroboration. *Carrera*, for example, involved proposed class claims against manufacturers of an over-the-counter dietary supplement over several years in Florida. *Carrera v. Bayer Corp*., 727 F.3d 300, 304 (3d Cir. 2013). Class members themselves easily could have been mistaken about which dietary supplements they purchased. Further, it was unclear whether the retail sellers of the supplement had any records of purchases and, if they did, whether those records would identify *any* buyers. *Id*. at 308–09. This Court remanded for discovery on whether there was a reliable and administratively feasible way to determine class membership. *Id*. at 312.[3] This Court's early cases thus made clear that potentially unreliable

[3] *See also Hayes v. Wal-Mart Stores, Inc*., 725 F.3d 349, 356 (3d Cir. 2013) (remanding for plaintiffs to propose reliable and administratively feasible way to assess whether purchasers (1) bought a service plan on an "as-is" item that (2)

class member affidavits were insufficient on their own for administrative feasibility.

Some district courts took this Court's early ascertainability cases as imposing a more stringent standard than they did. Perhaps for that reason, this Court's more recent cases have emphasized that administrative feasibility does *not* require a list of class members or prohibit some inquiry into individual circumstances. *Byrd*, for example, involved lessees of computers in which spyware was installed and activated without their consent. This Court held that records of the lessees sufficed for ascertainability of a class that comprised not only them, but also the other members of their households. That was so even though no evidence was put forward establishing how the non-lessee household members could be identified. 784 F.3d at 170–71. This Court characterized the facts before it as "a far cry from an unverifiable affidavit, or the absence of any methodology that can be used later to ascertain class members." *Id*. at 170 (citing *Carrera*, 727 F.3d at 310–11).

Similarly, *City Select* involved an automobile dealership that brought a proposed class action against a consumer financing division of a car manufacturer,

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came with a manufacturer's full warranty and (3) received service on the as-is item or a refund on the cost of the service plan); *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593–94 (3d Cir. 2012) (membership in a proposed class of New Jersey purchasers of BMW cars equipped with "run-flat tires" that had "gone flat and been replaced" depended on various factors which plaintiffs offered no reliable or administratively feasible way to assess, just "potential class members' say so").

BMW, and its contractor, Creditsmarts. The dealership alleged BMW and Creditsmarts violated the Telephone Consumer Protection Act by sending it junk faxes. The district court found a proposed class of car dealers was not ascertainable because a database did not indicate which dealers actually received unsolicited faxes. 867 F.3d at 441. This Court vacated and remanded, based in part on the possibility that affidavits from potential class members combined with data could satisfy the ascertainability standard. *Id*. at 440–41.

In so doing, this Court denied that plaintiffs have to come up with a list of class members at class certification. *Id*. at 439. It explained that "plaintiff need not 'be able to identify all class members at class certification—instead, a plaintiff need only show that "class members *can* be identified."'" *Id*. (quoting *Byrd*, 784 F.3d at 163 (quoting *Hayes*, 725 F.3d at 355)). It thus drew a crucial distinction. Administrative feasibility requires a method by which class members generally *can* be identified, that is, a method that *can* "establish[] class membership," *id*. at 441 (citing *Byrd*, 784 F.3d at 163), or that *can* "determine class membership." *Id*. at 442. It does *not* require a list of class members at class certification or at any later time.

City Select identified "three principal rationales" for its holding:

(1) to protect opt out rights, *id*. at 439 (citing *Carrera*, 727 F.3d at 306);

(2) to enforce a final judgment, *id*. (citing *Marcus*, 687 F.3d at 593); and

(3) to otherwise protect the "efficiencies of a class action," *id*. (quoting *Carrera*, 727 F.3d at 307), such as providing class notice and resolving any disputes about which entities may participate in any class recovery.

Hargrove confirmed *City Select*. There, the plaintiffs offered potential class members' affidavits and several distinct data sets as a reliable and workable means for determining whether drivers worked full time for the defendant, Sleepy's, as was required by the class definition. 974 F.3d at 479–80. This Court rejected as "too exacting" a trial court's demand that plaintiffs "identify the class members at the class certification stage." *Id*. at 470. The class was ascertainable even though there were "gaps in the records" of the defendant that would hamper plaintiffs in determining class membership. *Id*. As long as plaintiffs identify records, along with reliable affidavits, that could be pieced together to perform the tasks required by Rule 23, plaintiffs "establish a 'reliable and administratively feasible mechanism' for determining class membership." *Id*. at 480 (quoting *Byrd*, 784 F.3d at 163 (quoting *Carrera*, 727 F.3d at 306)).[4]

[4] *Hargrove* applies to antitrust cases notwithstanding that it involved wage-and-hour claims, in which courts refused to penalize employees based on an employer's failure to keep adequate records. *See Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036 (2016); *Anderson v. Mt. Clemens Pottery Co.*, 328 U.S. 680 (1946). This Court in *Hargrove* did not rely on *Tyson Foods* or *Mt. Clemens* in justifying its approach; it merely noted that its reasoning is particularly appropriate in the employment context. 974 F.3d at 477–81. Further, even had *Hargrove* adapted the acertainability standard to the wage-and-hour context, *Mt. Clemens* relied on antitrust precedents for the rule it articulated, so the adapted ascertainability standard would apply in antitrust cases. *Mt. Clemens*, 328 U.S. at 688 (citing *Bigelow v. RKO Radio Pictures*, 327 U.S. 251, 263–66 (1946) (antitrust); *Story Parchment*

In sum, this Court's early cases show that unverifiable and unreliable affidavits from potential class members do not suffice for administrative feasibility. Its subsequent cases establish that reliable affidavits in combination with data—even incomplete data—do suffice.

II. CLASS ANTITRUST CLAIMS IN THE PRESCRIPTION DRUG INDUSTRY GENERALLY SATISFY THE ASCERTAINABILITY STANDARD

Plaintiffs generally should be able to establish ascertainability in antitrust cases involving purchases of prescription drugs. The reason is that the pharmaceutical industry is rich with reliable data. That data can be used to determine whether an entity or person meets the class definition in an end-payor antitrust case like this one.

Reliable data are available because:

(1) the law requires comprehensive and accurate electronic records reporting individualized sales of prescription drugs in a specific, standardized form;

(2) market actors must maintain the electronic records of these transactions for practical business reasons; and

(3) the transactional data have extraordinary commercial value, providing financial incentive for its preservation.

Co. v. Paterson Parchment Co., 282 U.S. 555, 563 (1931) (antitrust); *Eastman Kodak Co. v. Southern Photo Materials Co*., 273 U.S. 359, 377–79 (1925) (antitrust)).

A. Legal Obligations

U.S. law requires sellers of prescription drugs to create and retain detailed transactional data. The Health Insurance Portability and Accountability Act ("HIPAA") tasked the Department of Health and Human Services ("HHS") with issuing regulations standardizing electronic healthcare transactions for (1) health plans, (2) healthcare clearinghouses, (3) healthcare providers (*e.g.*, pharmacies) in connection with retail pharmacy drug claims,[5] and (4) "Business Associates" who conduct transactions or are supplied with data on behalf of the entities in categories (1), (2), and (3) ("Covered Entities"), including Pharmacy Benefits Managers ("PBMs").[6] The National Council for Prescription Drug Programs ("NCPDP") was formed in 1977 to develop relevant standards[7] and in 2003 HHS made the resulting standards mandatory.[8]

Covered Entities and their Business Associates are required to exchange information consistent with NCPDP standards for each transaction. The exchange

[5] 42 U.S.C § 1320d(1)-(9) (2021).
[6] 45 C.F.R. §§ 162.923, 160.103 (2021).
[7] *See* Press Release, NCPDP, Surescripts Joins NCPDP's Elite Partner Program, Committing to the Highest Level of Sustained Support for NCPDP (Jan. 12, 2022). Web addresses for online sources cited in this brief are shown in the Table of Authorities.
[8] 45 C.F.R. § 162.1102. The applicable standards starting March 17, 2009, were set forth in the NCPDP Telecommunication Standard Implementation Guide, Version D, Release 0 (Version D.0) (Aug. 2010) (hereinafter "NCPDP Standard Guide"). *See* 45 C.F.R. § 162.1102(b)(2)(i).

addresses a patient's name and insurance identification, the health plan providing coverage, the prescriber's name and unique identifier, the pharmacy and its unique identifier, the date the prescription was filled, the specific drug product and quantity dispensed, and the amount paid, decomposing the price between consumer and insurer.[9]

In this system, and all others that track prescription drugs in the U.S. distribution chain, a unique ten- or eleven-digit number known as the National Drug Code ("NDC") identifies the precise product, manufacturer or "labeler," strength, and packaging, and it ties that product back to its FDA approval.[10] "Each person who engages in the manufacturing, repacking, relabeling, or private label distribution" of the product must obtain an NDC.[11]

Using the NDC, the NCPDP standard data exchange system creates a record of the sale of each drug and how much the end-payors paid for it, broken down between health plans and consumers. Numerous other laws require the retention of these records. *See, e.g.*, 42 C.F.R. § 423.505(d)(2)(xi) (2021) (requiring entities offering outpatient prescription drug coverage to Medicare Part C and Part D patients to maintain record of all prescription drug claims for 10 years); Drug Quality and Security Act of 2013, 21 U.S.C. § 360eee-1(b) (2021) (requiring manufacturers,

[9] NCPDP Standard Guide, *supra*, at 66–73, 89–92.
[10] 21 C.F.R. § 207.33(a), (b) (2021).
[11] 21 C.F.R. § 207.33(d)(1)(i).

wholesale distributors, and dispensers to record and maintain "transaction information"[12] for six years following the transfer of any prescription drug to ensure effective recall of unsafe drugs). As a result, participants in the pharmacuetical industry adhere to rigorous data retention policies.[13]

B. Business Needs

In addition, participants in the pharmaceutical industry have business reasons to identify end-payors. Any time an insured consumer seeks to fill a prescription, the claim must be "adjudicated" to determine whether it is covered, the agreed product price, and the division of payment required from health plan and consumer. The pharmacy initiates this process with an electronic message in NCPDP format sent to the PBM acting on behalf of the health plan using the approved nationwide switching infrastructure. The PBM responds, using that same system, with a message confirming the final purchase terms. All of this happens in real time using uniform NCPDP data templates.[14] The process accomplishes the following:

(1) confirms individual eligibility under any insurance coverage;

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[12] For this purpose, "transaction information" is defined to include the product's name, strength, dosage form, National Drug Code number, container size, number of containers, and lot number, as well as the transaction and shipment date, the business name and address of the recipient, and the business name and address of the subsequent transferees. 21 U.S.C. § 360eee(26) (2021).
[13] *See, e.g.*, Walgreens Health Initiatives, Inc., Pharmacy Manual 6 (Jan. 2011).
[14] *See* NCPDP Standard Guide, *supra*, at 34–37.

(2) determines whether and at what price the prescribed drug is covered and the amount to charge the consumer in light of any deductible, copay or coinsurance provisions; and

(3) creates a binding obligation for the health plan—or the PBM acting on its behalf—to pay the remainder.[15]

Through claims adjudication, PBMs and pharmacies are left with matching electronic records identifying each product, price, and payor.[16] Pharmacies assign each drug an "Rx number," and PBMs assign a unique claim number to each transaction, as part of the message exchange.[17] PBMs make this data available to their health plan payor clients, creating a third electronic record used to audit PBM performance and assure the health plan was charged only for proper claims and at correct prices.[18] If a purchase is supported by a coupon, a discount program, or manufacturer payment assistance, the administrator of that program has yet another copy of the record.[19]

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[15] *Id*. at 37, 41, 118, 332.
[16] *See id*. at 60–67.
[17] *Id*. at 66, 69 (requiring entry of a "Processor Control Number" and "Prescription/Service Reference Number").
[18] *See, e.g.*, Pharmacy Benefits Manager Services Contract between the State of Tennessee and OptumRx, Inc. § A.19, at 24 (Feb. 22, 2019) (requiring maintenance of records "necessary to demonstrate that covered services were provided in compliance with State and federal requirements").
[19] NCPDC Standard Guide, *supra*, at 78, 730 (Describing the necessary fields for billing coupon processors and noting "[p]rograms providing coupons want to 'track' their usage").

The PBMs performing this claim adjudication function—creating and preserving the records described above—are highly concentrated and few in number. In 2020, for example, the six largest PBMs processed—and retained electronic records of—over 95% of U.S. retail prescriptions filled.[20]

Insurers contract directly with PBMs to provide these claims adjudication services, and many insurers either own or are affiliated with large PBMs.[21] However, for a subset of employer or union sponsored health plans, the sponsor may choose to pay benefits directly, instead of purchasing insurance from a third party. In that case, the employer or union sponsor may retain a benefit administrator to handle the process on its behalf. If that intermediary is an insurer—which is typical—it provides what is referred to as an Administrative Services Only ("ASO") plan.[22] A non-insurer filling this role is called a Third Party Administrator

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[20] Adam J. Fein, *The Top Pharmacy Benefit Managers of 2020: Vertical Integration Drives Consolidation*, Drug Channels Inst. (April 6, 2021).

[21] For example, United Health owns PBM OptumRx, Blue Cross Blue Shield entities own PBM Prime Therapeutics, Cigna owns PBM Express Scripts, and Aetna merged with the pharmacy/PBM conglomerate CVS Caremark. *See* Prime Therapeutics, *Our History*, PrimeTherapeutics.com, (last visited Jan. 12, 2022); Angelica LaVito, *CVS creates new health-care giant as $69 billion merger with Aetna officially closes*, CNBC (Nov. 28, 2018, 12:19 PM); BusinessWire, *Cigna to Acquire Express Scripts for $67 Billion* (Mar. 8, 2018, 6:00 AM).

[22] *See, e.g.*, Anthem BlueCross, *Administrative Services (ASO Plans)*, Anthem.com (last visited Jan. 14, 2022) ("With an ASO plan, the employer funds the claim payments but pays Anthem Life to process the claims").

("TPA").[23] ASOs and TPAs rely on the same PBM claims data to carry out their responsibilities, including advancing funds to pharmacies to reimburse purchased drugs correctly and separately billing each plan sponsor for only the claims submitted by its members. As a result, the data the ASO or TPA receives from the PBM must link each claim to the correct self-funding client liable for payment, or else the ASO or TPA would not be able to conduct its business. For ASOs—which dominate this field—reporting that segregates insured policies from ASO business revenue is required by the National Association of Insurance Commissioners ("NAIC") [24] and also appears in insurer financial statements filed with the SEC.[25] These entities always know and can identify their self-funding clients who pay prescription drug claims.

In sum, the participants in prescription-drug markets must and do keep records identifying the end payors for each sale and indicating how much they paid for business reasons, not just for legal reasons.

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[23] Centers for Medicare & Medicaid Services, *Glossary*, CMS.gov (last visited Jan. 14, 2022) (A TPA is a "[b]usiness associate that performs claims administration and related business functions for a self-insured entity").

[24] *See* Nat'l Assoc. of Ins. Comms., U.S. Health Insurance Industry 2019 Annual Results Tbl. 1, at 1 (2020); Nat'l Assoc. of Ins. Comms., 2019 NAIC Health Risk-Based Capital Report 31–32, *in* Risk-Based Capital Forecasting and Instructions – Health, 2019 (Aug. 16, 2019); *see also* Nat'l Assoc. of Ins. Comms., *Risk-Based Capital*, NAIC.org (last updated Nov. 11, 2021); Nat'l Assoc. of Ins. Comms., Risk-Based Capital Forecasting and Instructions – Health, 2019, *supra*, at 14–18, 31–33.

[25] *See, e.g.*, Cigna Corp., 2016 Annual Report (Form 10-K) (Feb. 23, 2017).

C. Financial Incentives

Participants in the pharmaceutical industry also have financial incentives to retain sales information. Data, and AI for analyzing data, have been described as the new electricity and the new oil.[26] Sophisticated businesses keep it, exploit it, and sell it. That is particularly true in the prescription drug industry where billions of dollars are at stake.

Consider PBMs. They do more than just process claims. They employ the resulting data to advise their clients on drug utilization and cost, "maximizing generic switch opportunities and cost savings," and "optimization of generic dispensing opportunities."[27]

One of the country's largest PBMs, Express Scripts, declares, "Clients gain exclusive benefits from our original research and actionable analysis of their data, including learnings from our peer-reviewed publications that they won't get anywhere else."[28]

Another of the largest PBMs, OptumRx, offers the "Optum Research Database (ORD)" that "represents patients enrolled in one of the largest providers of

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[26] *See, e.g.*, Martin Ford, AI as the New Electricity, *in* Rule of the Robots: How Artificial Intelligence Will Transform Everything 11–30 (2021); Terry Moon Cronk, *Defense Official Calls Artificial Intelligence the New Oil*, DOD News (Oct. 19, 2020).

[27] Pharmacy Benefits Manager Services Contract between the State of Tennessee and OptumRx, Inc. § A.50.f.6., at 107 (Feb. 22, 2019).

[28] Express Scripts, *Research*, Express-Scripts.com (last visited Jan. 14, 2022).

commercial and Medicare Part D health plans. It comprises medical and pharmacy claims data from 1993 to current, covering 64.3 million lives."[29] An Optum white paper explains, "There is an overwhelming demand for high-quality, reliable, real-world information."[30] The white paper describes how individuals are assigned "unique identifiers that allow Optum to follow patients longitudinally as they enroll, disenroll and re-enroll in the health plan. In addition, the ORD contains actual patient copayments and deductible amounts, allowing for an accurate assessment of patient and payer burden."[31]

Nor are PBMs alone in exploiting claims data for financial gain. Commercial data publishers, such as IQVIA and Symphony Health, collect such data from pharmacies, health plans, and the shared switches that route transactions between pharmacies and PBMs. They aggregate the data—including categorizing it by plan and payor—and sell it to manufacturers, researchers and industry analysts.[32]

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[29] Optum, *Meeting real-world evidence challenges*, Optum.com (last visited Jan. 14, 2022).
[30] Optum, *Addressing the need for real-world observational research solutions* 1–2 (Optum white paper, 2018).
[31] *Id*. at 2.
[32] IQVIA, *Available IQVIA Data*, IQVIA.com (last visited Jan. 14, 2022); Symphony Health, *IDV Fact Sheet*, SymphonyHealth.com (last visited Jan. 14, 2022).

IQVIA—a company that specializes in "Human Data Science" [33]—has a market capitalization of over $50 billion[34] and annual revenues of over $10 billion.[35]

The prescription drug market is big business. So too is the market for the data it produces.

III. EXTENSIVE DATA ASSURES END-PAYOR CLASS CLAIMS IN PARTICULAR SATISFY THE ASCERTAINABILITY STANDARD

Extensive records of prescription-drug sales generally make end-payor classes readily ascertainable. That is particularly apt to be true for classes limited to third-party end-payor plaintiffs, such as insurance companies, large employers, and health and welfare plans, that keep robust records of their payments. For such classes, disputes over class membership should be rare and their resolution should be reliable and administratively feasible. No evidence suggests otherwise.

Providing notice to a class should not present a problem. As noted above, there is no requirement of individual notice. In any case, plaintiffs can obtain lists of likely class members from market actors or, at the least, lists of businesses that can pass along those notices to likely class members. Those potential class members should have no difficulty reviewing their data and contracts to determine whether they fall within an objective class definition.

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[33] *See* IQVIA, *Human Data Science*, IQVIA.com (last visited Jan. 14, 2022).
[34] Companies Market Cap, *IQVIA*, CompaniesMarketCap.com (last visited Jan. 14, 2022).
[35] *Id*.

Similar points apply to allocating any class recovery. In the rare case that a dispute arises about whether an entity is a class member, it should be able to supply data and contracts to substantiate its position.

Further, if more than one entity submits a claim for the same sale, the same data and contracts would make clear which entity should recover or the proper allocation if more than one entity should do so. Duplications can be detected through PBM transaction numbers or through pharmacy Rx numbers combined with date, pharmacy, member ID, or other reported variables. There should be no meaningful risk, and history provides no examples, of inappropriate multiple recoveries based on the same transaction.

Class action defendants also can contend with later litigation that they believe may be precluded by a class action judgment. Of course, small purchasers are very unlikely to bring individual claims as a practical matter. They are not economically viable (which is a reason antitrust cases of this kind are typically brought as class cases). In any case, data and records can establish whether a plaintiff was part of a certified class. If it was, and it is not listed as an opt out, its claims would have been extinguished by any class judgment. On the other hand, if it did not fall within the class definition, or it opted out, its claims would not be precluded. None of that should be difficult to determine.

As a result, to quote this Court's opinion in *Byrd*, the kinds of evidence available in end-payor pharmaceutical antitrust cases are "a far cry from an unverifiable affidavit, or the absence of any methodology that can be used later to ascertain class members." 784 F.3d at 170 (citing *Carrera*, 727 F.3d at 310–11).

Numerous antitrust cases in the pharmaceutical industry in this Circuit and others have been certified for class treatment. Some of them have been certified for litigation purposes[36] and others for settlement purposes.[37] Plaintiffs have won in some of them—or at least obtained settlements and distritbuted funds to class

[36] *See*, *e.g.*, *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 18-md-2836, 2021 WL 3704727 (E.D. Va. Aug. 20, 2021); *In re Opana ER Antitrust Litig.*, No. 14 C 10150, 2021 WL 3627733 (N.D. Ill. June 4, 2021); *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294 (D. Mass. 2021); *In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1 (E.D.N.Y. 2020); *In re EpiPen (Epinephrine Injection, USP) Marketing, Sales Practices and Antitrust Litig*., No. 17-md-2785-DDC-TJJ, 2020 WL 1180550 (D. Kan. Mar. 10, 2020); *In re Suboxone (Buprenorphine Hydrochloride and Nalaxone) Antitrust Litig.*, 421 F. Supp. 3d 12 (E.D. Pa. 2019).

[37] *See*, *e.g.*, *In re Thalomid & Revlimid Antitrust Litig.*, No. CV 14-6997, Order, ECF 325 (D.N.J. Oct. 2, 2020) (certifying class for purposes of settlement); *In re Aggrenox Antitrust Litigation*, No. 3:14-md-02516, Ruling and Order, ECF 766, at 5–6 (D. Conn. Mar. 6, 2018) (same).

members[38]—and lost in others.[39] Yet there is no pattern of individual issues predominating over common ones.

The claim in this litigation is not like one based on over-the-counter dietary supplements, where most consumers and retailers may lack any reliable records or recollections of who bought the product at issue. Courts and parties time and again have managed the tasks under Rule 23 in end-payor prescription drug antitrust class actions without any significant problems.

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[38] *See*, e.g., *In re Loestrin 24 FE Antitrust Litig.*, No. 1:13-md-2472, Order Approving End-Payor Plaintiffs' Distribution of the Settlement Funds, ECF 1470 (D. R.I. Aug. 18, 2021) (approving plan of allocating settlement funds to class members); *In re Aggrenox Antitrust Litig.*, No. 3:14-md-02516, Order Approving Distribution of Settlement Fund, Approving Payments of Claims Administrator, Approving Late-Filed Claims, and Award of Attorneys' Fees from Set Aside Fund, ECF 880 (D. Conn. Jan. 6, 2021) (same); *In re Thalomid & Revlimid Antitrust Litig.*, No. CV 14-6997, Order Granting Plaintiffs' Unopposed Motion to Distribute Notice to the Settlement Class, Appoint Notice and Claims Administrator, and for Approval of the Plan of Allocation, ECF 314 (D.N.J. May 20, 2020) (same); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 1:14-md-02503, Order Approving End-Payor Plaintiffs' Motion for Distribution of the Settlement Funds, ECF 1192 (D. Mass. Oct. 11, 2019) (same); *In re Lidoderm Antitrust Litig.*, No. 14-md-02521, End-Payor Plaintiffs' Second Post-Distribution Accounting, ECF 1087 (N.D. Cal. July 28, 2020) (providing statistics on TPP and consumer distributions).

[39] *In re Nexium (Esomeprazole) Antitrust Litig.*, No. 12-md-2409, Jury Verdict, ECF 1383 (D. Mass. Dec. 5, 2014); *id*., Rule 54(b) Entry of Judgment, ECF 1586 (D. Mass. Sept. 28, 2015) (entering judgment on jury verdict for defendants and against certified class without any individualized proceedings).

IV. POLICY SUPPORTS APPLYING THIS COURT'S PRECEDENTS TO PRIVATE ANTITRUST CLAIMS IN THE PHARMACEUTICAL INDUSTRY

In contrast to the lack of evidence of certified end-payor antitrust litigation getting mired in individual issues, there is an ample record of grave harm when private plaintiffs were not able to enforce the antitrust laws effectively. That includes harms from pay-for-delay agreements, like the one at issue in this case. In this regard, two points bear emphasis. First, antitrust law plays a crucial role in protecting consumers of prescription drugs. Second, private antitrust class actions are essential in enforcing antitrust law.

Congress passed the Hatch-Waxman Act to increase access to generic drugs and save money for American patients and taxpayers. *See In re Impax Labs.*, *Inc.*, FTC No. 9373, 2019 FTC Lexis 25, at *2 (Mar. 28, 2019) ("The Hatch-Waxman Act, together with other legislation at the federal and state levels, has facilitated a dramatic rise in sales of generic drugs, making them more widely available to Americans who would otherwise be forced to pay higher branded drug prices.") (internal quotation marks omitted).

Illegal pay-for-delay settlements subvert the Hatch-Waxman framework by delaying patient access to generic drugs, costing consumers $3.5 billion annually.[40]

[40] FTC Staff Study, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions* (Jan. 2010); *see also* Michael Kades, *Competitive Edge: Underestimating the Cost of Underenforcing U.S. Antitrust Laws*, Wash. Center for Equitable

Even a single illegal reverse-payment settlement on a blockbuster drug can cause devastating harm to patients.[41] In addition, such settlements can force patients to split pills in half or not to take needed medications at all.[42]

In 2013, the Supreme Court held that federal antitrust law prohibits pay-for-delay settlements. *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013). Nevertheless, the scourge persists. The FTC's most recent analysis suggests that pharmaceutical companies may be increasingly masking payments made to delay generic entry in complicated pretextual transactions.[43] It is thus unsurprising that Americans continue to pay the highest average prescription drug prices in the world—by a wide

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Growth (Dec. 13, 2019) (estimating past costs of reverse-payment settlements to be over $60 billion).

[41] *See, e.g.,* FTC Mem. 5, *Fed. Trade Comm'n v. Cephalon, Inc.*, No. 2:08-civ-2141, 2015 WL 5583757 (E.D. Pa. Feb. 17, 2015) (calculating ill-gotten gain on the drug Provigil to be between $3.5 and $5.6 billion).

[42] *See* Henry A. Waxman et al., Getting to Lower Prescription Drug Prices: The Key Drivers of Costs and What Policymakers Can Do to Address Them 6–7 (Oct. 2020) (discussing increased rates of hospitalization, sickness, and death associated with improper drug treatment caused by inflated costs).

[43] *See* FTC Staff Study, *supra* (noting that brand and generic firms may be structuring agreements to make compensation difficult for the government to detect); Robin Feldman, *Antitrust Law: Pharmaceutical "Pay for Delay" Reexamined*, *in* 5 The Judges' Book 2021: Scholarship for the Bench (2021) (discussing numerous indicators that "exotic variants" of reverse payments have "evolved to favor categories of value transfer less likely to attract antitrust scrutiny" and noting that FTC reporting shows agreements in "possible compensation" category rising over time).

margin[44]—and that a top priority of the federal government and leading health policy advocates is to use antitrust law to end pay-for-delay settlements.[45]

Private antitrust litigation, especially through class actions, plays a crucial role in compensating victims and deterring antitrust violations.[46] It may have a greater deterrent effect on antitrust violations than government criminal enforcement.[47] From 2009 through 2020, for example, federal antitrust class actions recovered over $27 billion for the victims of antitrust violations.[48]

That said, the combination of government and private enforcement is still inadequate, even for antitrust violations that give rise to criminal prosecution, such as horizontal price-fixing conspiracies. On average such conspirators pay damages amounting to less than half the harm they cause and virtually never fully compensate their victims.[49]

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[44] Peter Olson & Louise Sheiner, The Hutchins Center Explains: Prescription Drug Spending, Brookings.edu (Apr. 26, 2017).
[45] *See* Executive Off. of the President, Exec. Order on Promoting Competition in the American Economy, No. 14036 § 5(h)(iii); Waxman, *supra*, at 13; Feldman, *supra*, at 5.
[46] Joshua P. Davis & Robert H. Lande, *Defying Conventional Wisdom: The Case for Private Antitrust Enforcement*, 48 Ga. L. Rev. 1 (2013).
[47] Robert H. Lande & Joshua P. Davis, *Comparing Deterrence from Private Enforcement and Criminal Enforcement of the U.S. Antitrust Laws*, 2011 B.Y.U. L. Rev. 315 (2011).
[48] *See* Joshua P. Davis & Rose Kohles, 2020 Antitrust Annual Report: Class Action Filings in Federal Court 2 (Aug. 2021).
[49] John M. Connor & Robert H. Lande, *Not Treble Damages: Cartel Recoveries Are Mostly Less than Single Damages*, 100 Iowa L. Rev. 1997 (2015); John M. Connor & Robert H. Lande, *Cartels as Rational Business Strategy: Crime Pays*, 34

This Court would serve the "high purpose" of facilitating private enforcement of antitrust law by maintaining its practical approach to ascertainability. *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 130-131 (1969). Applying that approach, courts should find that end-payor plaintiff classes are generally ascertainable under Rule 23(b)(3) when antitrust claims arise in the pharmaceutical industry.

CONCLUSION

For the foregoing reasons, the decision below should be reversed.

Respectfully submitted,

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Cardozo L. Rev. 437 (2012); Robert H. Lande, *Are Antitrust 'Treble' Damages Really Single Damages?*, 54 Ohio St. L. J. 115 (1993).

CERTIFICATE OF COUNSEL

I, Randy M. Stutz, hereby certify that:

1. I am a member of the bar of this Court.

2. This brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,477 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(f).

3. This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5)(A) and the type styles requirements of Fed. R. App. P. 32(a)(6) because the brief has been prepared in a proportionally spaced typeface using Microsoft Word, in 14 point Times New Roman font.

4. Pursuant to Third Circuit Local Appellate Rule 31.1(c), the PDF file and the text of the paper version of the brief are identical. The electronic version of the brief has been scanned for viruses by OPSWAT MetaDefender Cloud (current version) and no viruses were found.

/s/ Randy M. Stutz

Dated: January 19, 2022

CERTIFICATE OF SERVICE

I hereby certify that on this 19th day of January, 2022, I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Third Circuit using the appellate CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the appellate CM/ECF system.

s/ Randy M. Stutz

Dated: January 19, 2022