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In Re: Niaspan Antitrust Litigation

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PRECEDENTIAL

UNITED STATES COURT OF APPEALS
FOR THE THIRD CIRCUIT

No. 21-2895

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 Appeal from the United States District Court
For the Eastern District of Pennsylvania
(D.C. No. 2-13-md-02460)
District Judge: Honorable Timothy J. Savage

Argued
September 6, 2022

Before: JORDAN, HARDIMAN and MATEY, *Circuit
Judges*

(Filed: April 24, 2023)

Justin N. Boley
Tyler J. Story
Kenneth A. Wexler
Wexler Boley & Elgersma
311 South Wacker Drive – Ste. 5450
Chicago, IL 60606

Richard M. Brunell
Steve D. Shadowen
Hilliard & Shadowen
1135 West 6th Street – Ste. 125
Austin, TX 78703

Michael M. Buchman
Motley Rice
777 Third Avenue – 27th Fl.
New York, NY 10017

Ruthanne M. Deutsch
Hyland Hunt [ARGUED]
Alexandra P. Mansbach
Deutsch Hunt
300 New Jersey Avenue, NW – Ste. 900
Washington, DC 20001

Marvin A. Miller
Miller Law
145 South Wells Street – 18th Fl.
Chicago, IL 60606

Jeffrey L. Kodroff
John A. Macoretta
Spector Roseman & Kodroff
2001 Market Street – Ste. 3420
Philadelphia, PA 19103

Sharon K. Robertson
Cohen Milstein
88 Pine Street – 14th Fl.
New York, NY 10005
Counsel for Appellant

Elaine J. Goldenberg [ARGUED]
Sarah Weiner
Munger Tolles & Olson
601 Massachusetts Avenue, NW – Ste. 500e
Washington, DC 20001

Paul H. Saint-Antoine
John S. Yi
Faegre Drinker Biddle & Reath
One Logan Square – Ste. 2000
Philadelphia, PA 19103

Stuart N. Senator
Jeffrey Y. Wu
Munger Tolles & Olson
350 S. Grand Avenue – 50th Fl.
Los Angeles, CA 90071
*Counsel for Appellees Abbott Laboratories,
Abbott Respiratory LLC and Abbvie Inc.*

Devora W. Allon
Kirkland & Ellis
601 Lexington Avenue
New York, NY 10022

Alexandra I. Russell
Kirkland & Ellis
1301 Pennsylvania Avenue, NW
Washington, DC 20004
*Counsel for Appellees Barr Pharmaceuticals LLC,
Duramed Pharmaceuticals Sales Corp., Teva
Pharmaceutical Industries Ltd. Teva
Pharmaceuticals USA Inc., Teva Women's Health
Inc. f/k/a Duramed Pharmaceuticals, Inc.*

Matthew J. Perez
DiCello Levitt
485 Lexington Avenue – 10th Fl.
New York, NY 10017

Gary I. Smith, Jr.
Hausfield
325 Chestnut Street – Ste. 900
Philadelphia, PA 19106
*Counsel for Amicus Committee to Support
the Antitrust Laws*

Cory L. Andrews
John M. Masslon, II
Washington Legal Foundation
2009 Massachusetts Avenue, NW
Washington, DC 20036
Counsel for Amicus Washington Legal Foundation

Randy Stutz
10418 Ewell Avenue
Kensington, MD 20895
Counsel for Amicus American Antitrust Institute

Adam G. Unikowsky
Jenner & Block
1099 New York Avenue, NS – Ste. 900
Washington DC 20001
*Counsel for Amicus Chamber of Commerce of
The United States of America*

OPINION OF THE COURT

JORDAN, *Circuit Judge*.

The Appellants, a group consisting primarily of union health and welfare insurance plans, claim that Abbvie, Inc., the manufacturer of the drug Niaspan, paid off a potential manufacturer of a generic version of the drug to delay the generic's launch. This putative class action was brought to recover damages based on the allegedly inflated prices charged by Abbvie in violation of state antitrust and consumer protection laws, and this appeal concerns the District Court's denial of the motion for class certification. For reasons more fully discussed herein, the District Court held that the class was not ascertainable. *In re Niaspan Antitrust Litig.*, 555 F. Supp. 3d 155, 169 (E.D.P.A. 2021) ("*Niaspan III*"). The Appellants now propose to shore up their methodology for demonstrating ascertainability, but because their new suggestion was not properly put before the District Court, the argument is forfeited, and we will not consider its merits. The Appellants additionally challenge the District Court's factual findings and the legal standard the Court applied. As we explain, however, neither were in error. In their final bid to preserve their case, the Appellants ask us to reconsider our ascertainability requirement in its entirety, claiming it is inconsistent with Federal Rule of Civil Procedure 23. We are not at liberty to do so and, instead, reiterate our precedent. Accordingly, we will affirm.

I. BACKGROUND

A. Factual Background

1. The Functioning of the Prescription Drug Market

When consumers with health insurance enter a pharmacy to pick up their prescription drugs, they typically pay only a fraction or none of the cost of their medication. Instead, their prescription drug plan pays most, or all, of the drugs' cost. The sponsors of these plans are often called "end-payors" or "indirect purchasers" of the drugs because they do not purchase the products directly, as consumers do, but nevertheless pay a portion or all of the drugs' price.

Not all end-payors are health plan sponsors, and not all health plan sponsors are end-payors. The identity of the end-payor is based on the structure of each particular prescription drug plan. The sponsor of such plans is usually an employer or union, and they may organize their health plans as being fully insured, self-insured, or a hybrid of the two. In a self-insured health plan, the plan pays for its beneficiaries' prescription drugs using funds provided by the sponsor and by its beneficiaries. Because a self-insured plan sponsor bears the financial risk for the health benefits of its participants, it is an end-payor of prescription drugs. Conversely, in a fully insured plan, the plan sponsor pays premiums to a health insurer, and that insurer bears the financial responsibility for the payments of prescription drugs, making it, rather than the plan sponsor, the end-payor.

Before a pharmacy fills a prescription for a patient with a prescription drug plan, it must determine who the end-payor is and how the payment obligation will be met (i.e., how much will be paid by the consumer and how much will be paid by the end-payor). This process, known as “claims adjudication,” allows consumers to pay only a comparatively small portion, or none, of a prescription drug’s cost, rather than paying the entire cost up front and then seeking reimbursement from an insurer. A small number of companies, called Pharmacy Benefit Managers (“PBM”), facilitate the claims adjudication process about fifteen million times a day. The PBM industry is highly concentrated, with the seven largest PBMs processing over 90 percent of the annual U.S. prescription drug volume from 2016 through 2018.

Claims adjudication is made possible through the real-time exchange of data identifying end-payors. The electronic system that facilitates this exchange of information was developed by the National Council for Prescription Drug Programs (the “NCPDP”). Since 2003, federal regulations have required the use of the NCPDP Telecommunications Standards for electronic submission and processing of drug prescriptions. *See* Health Insurance Reform: Standards for Electronic Transactions, 65 Fed. Reg. 50,312, 50,368 (Aug. 17, 2000) (to be codified at 45 C.F.R. pts. 160 and 162). Under those standards, various reference numbers like Bank Identification Numbers, Processor Control Numbers, Plan ID Numbers, and Group Identification Numbers are used to ensure that each claim is properly routed. The reference numbers tell the electronic routing system where to direct the claim so that it can be adjudicated and paid to the pharmacy, ultimately generating a fixed payment liability between the PBM and the

end-payor on whose behalf the funds are transferred to the pharmacy.

As a result of this virtually instantaneous process facilitated by PBMs, a pharmacy can immediately know what amount to charge a patient. In short, “PBMs serve as intermediaries between prescription-drug plans and the pharmacies that beneficiaries use.” *Rutledge v. Pharm. Care Mgmt. Ass’n*, 141 S. Ct. 474, 478 (2020). When a consumer, as a direct purchaser of a drug and the beneficiary of a prescription-drug plan, has a prescription filled, “the pharmacy checks with a PBM to determine that person’s coverage and copayment information. After the beneficiary leaves with his or her prescription, the PBM reimburses the pharmacy for the prescription, less the amount of the beneficiary’s copayment. The prescription-drug plan, in turn, reimburses the PBM.” *Id.*

The PBM data captures only the identity of the entity responsible for paying it. While health plan sponsors may contract directly with a PBM to administer their prescription drug benefits, there are plan sponsors that elect to contract with yet another intermediary, called a third-party administrator (“TPA”), to work on their behalf with PBMs. A TPA helps the sponsor manage their group plan benefits and assists with the claims adjudication and reimbursement process. A TPA may be an insurance company or a company dedicated to providing only TPA services. When an insurer provides TPA services to another entity but does not provide a fully insured health plan, it is said to be providing an administrative-services-only plan and is called an “ASO” in that relationship. A TPA is never an end-payor because, even though it initially pays for the plan beneficiaries’ prescriptions, it is later reimbursed. When a

sponsor elects to contract with a TPA, the PBM has no relationship with the end-payor.

2. Niaspan and the Proposed Class

Abbvie Inc. markets and sells Niaspan, a brand-name prescription drug used to treat lipid disorders, such as high cholesterol. The active ingredient in Niaspan is niacin, or vitamin B3, which has been sold as a dietary supplement in the United States since the early 20th century. *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 742 (E.D. Pa. 2014) (“*Niaspan P*”). Niacin, however, has several side effects, including potential liver toxicity when consumed at high levels. *Id.* In the early 1990s, Kos Pharmaceuticals (“Kos”), later acquired by Abbvie, developed and patented a therapeutically effective time-released version of niacin, which does not cause some of the side effects previously associated with the vitamin, and it marketed the drug using the trademark Niaspan. Niaspan has been sold by Abbvie – and its predecessors – since 1997.

In 2001, Barr Pharmaceuticals (“Barr”), later acquired by Teva Pharmaceutical Industries Ltd., filed an Abbreviated New Drug Application (“ANDA”) with the Food and Drug Administration (“FDA”), seeking authorization to manufacture and sell a generic equivalent of Niaspan. The ANDA process provides for streamlined FDA approval of generic drugs and, as part of that process, Barr filed certifications with the FDA stating that it did not infringe any of the patents on Niaspan or that those patents were invalid or unenforceable. Kos, before its acquisition by Abbvie, responded by filing a patent infringement lawsuit against Barr in 2002. Because Barr was the first ANDA filer, it would have had, if successful in

clearing certain legal and administrative hurdles, a 180-day period of “exclusive” marketing rights for a Niaspan-equivalent generic drug. *Id.* But that period would have been exclusive only with respect to other ANDA applicants; it would not have prevented Kos from marketing its own brand-generic version of that drug. *Id.* at 471. When a brand-name drug manufacturer takes such a step, it is said to sell an “authorized generic.” *Id.* “Launch of an [authorized generic] allows the brand-name drug manufacturer to recover some of the sales and profits it would otherwise lose when an ANDA applicant begins to market and sell a generic version of that manufacturer’s brand-name drug.” *Id.*

Kos began manufacturing an authorized generic so that it could compete with Barr in the event Barr succeeded in launching a generic version of Niaspan. *Id.* at 743. “By the end of the first quarter of 2005, Kos had accumulated more than \$1.3 million in inventory in anticipation of launching an [authorized generic].” *Id.* But the authorized generic was never sold, and the merits of the patent infringement lawsuit were never decided, because the parties entered into a settlement agreement in 2005. *Id.* That settlement led to this lawsuit.

Direct-purchaser plaintiffs and end-payor plaintiffs filed separate suits in 2013. Both suits alleged that the settlement agreement constituted an unlawful “reverse payment” settlement. A “reverse payment” settlement, also known as a “pay-for-delay” settlement, occurs when a brand-name drug manufacturer brings a patent infringement action against a generic drug manufacturer but then, in some fashion, compensates the generic drug manufacturer for agreeing to delay entering the market with a competing version of the

brand-name drug. Such agreements are called “reverse payment” settlements because “the patentee ... pay[s] the alleged infringer, rather than the other way around[.]” *FTC v. Actavis, Inc.*, 570 U.S. 136, 141 (2013).

According to the end-payor plaintiffs in the present suit – now the Appellants – the reverse-payment settlement between Kos and Barr violated state antitrust and consumer protection laws.¹ They claim that Kos paid Barr to delay the launch of its generic competitor to Niaspan until 2012, thereby forcing the Appellants to pay hundreds of millions of dollars in inflated prices due to Kos’s extended monopoly in the market for Niaspan. Specifically, they assert that Kos agreed to pay Barr a royalty on all sales of Niaspan along with a lump-sum payment to compensate Barr for its investment in developing its generic and for delaying its market entry. *Niaspan I*, 42 F. Supp. 3d at 744. In support of their allegations, the Appellants point to public filings Barr made in 2007 and 2008, in which it claimed to have received \$45 million in payments from Kos for the 2006 calendar year, \$37 million for the 2007 calendar year, and that it expected to receive a similar amount of revenue for the 2008 calendar year. *Id.* at 745.

The Appellants claim that, as a result of the alleged reverse-payment settlement, putative class members “were

¹ The Appellants evidently are relying on alleged violations of state laws rather than violations of the Sherman Antitrust Act because indirect purchasers, which the Appellants are, have no claim for damages under federal antitrust law. *Ill. Brick Co. v. Illinois.*, 431 U.S. 720, 729 (1977).

denied the opportunity to purchase generic Niaspan before [2013], and were further denied the benefit of the price competition that would have ensued in a competitive environment where Kos launched an authorized generic Niaspan to compete with Barr[.]” (J.A. at 5.) They claim that this anticompetitive settlement cost them more than \$320 million in overcharges, and they sought certification of a class of end-payors who either purchased, paid for, or provided reimbursements for the purchase price of Niaspan or its generic version in various states from 2007 to 2018.

The proposed class excluded six types of entities:

- (1) Defendants and their subsidiaries, or affiliates;
- (2) All federal or state government entities other than cities, towns or municipalities with self-funded prescription drug plans;
- (3) All entities that, after September 20, 2013, paid and/or provided reimbursement for branded Niaspan and did not pay and/or provide reimbursement for generic Niaspan;
- (4) All entities who [sic] purchased Niaspan for purposes of resale or directly from defendants or their affiliates;
- (5) Fully insured health plans (i.e., plans that purchased insurance from another third party payor covering 100% of the Plan’s reimbursement obligations to its members); and

(6) Pharmacy Benefit Managers.

(J.A. at 74.) (alteration in original). Only the fifth exclusion – for fully insured health plans – is relevant in this appeal.

3. The Battle of the Experts

In seeking class certification, the Appellants argued that they could successfully identify and exclude fully insured health plans (which, by definition, are not end-payors) from the putative class because they could determine whether a plan is fully insured or self-insured based upon the records of PBMs. But the PBM data captures only the identity of the entity directly paying the PBM. It does not identify whether that entity is participating in the process as a fully insured health plan sponsor, a self-funded health plan sponsor, an insurer, or a TPA. Over the course of this litigation, the Appellants adopted shifting methodologies for determining what role an entity had in the payment process as a means for excluding fully insured health plans from the class. Indeed, the Appellants' methodology changed each time Abbvie tested its reliability.²

² Abbvie is not the only Appellee. In full, that list includes Abbott Laboratories, Abbott Respiratory LLC, Barr Pharmaceuticals LLC, Duramed Pharmaceuticals Sales Corp., Teva Pharmaceutical Industries Ltd., Teva Pharmaceuticals USA Inc., and Teva Women's Health Inc. f/k/a Duramed Pharmaceuticals, Inc. For ease of reference, however, we refer to the Appellees collectively and in the singular as "Abbvie."

In support of their claim that fully insured health plans can be identified from the PBMs' records and so excluded from the class in an administratively feasible manner, the Appellants presented several declarations from Ms. Laura Craft, a data analytics expert and the president of OnPoint Analytics, Inc. In her first declaration, dated October 19, 2018, Ms. Craft stated that she could apply the fully insured health plan exclusion and compile a list of class members from PBM records. She said, "OnPoint would be able to merge the data from various sources, identify and eliminate data errors, transform the data to standardize fields, eliminate duplicates, and compile a list reflecting the identities of the class members contained in the data." (J.A. at 704.) She also asserted that this process is "manageable and can be carried out programmatically[,] " and that OnPoint has "extensive experience applying these types of exclusions to pharmaceutical data." (J.A. at 703-04.) She did not, however, divulge the specifics of how she would apply the exclusion.

When Abbvie deposed Ms. Craft and asked her how she would identify and exclude fully insured health plans, she stated that a Form 5500, "a form ... filed by the IRS and used by the Department of Labor to track and monitor on an annual basis which health plans are fully insured[,] " is "the standard tool for identifying fully insured health plans, and it is routinely used whenever that process is undertaken." (J.A. at 376.) Abbvie, however, identified inconsistencies on the Form 5500 of one of the named plaintiffs as an example of the difficulties in identifying and excluding fully insured health plans using Form 5500 filings. Given those inconsistencies, the District Court rejected that proposed ascertainability methodology.

Ms. Craft accordingly abandoned that approach. Instead, she claimed in her August 25, 2020, supplemental declaration that, because NCPDP standards require “complete electronic transaction routing information[,]” for the claims adjudication process, “fully-insured health plans do not have to be ‘identified’ and ‘removed’ from the data provided by PBMs – the PBM data will reflect the fact that the third-party insurance provider *is the payor*.” (J.A. at 263-64.) In other words, she claimed that the PBM data fields would directly identify class members because the routing information would “identify the entity that issued the coverage and will be paying for the prescription, rather than the employer or plan that sponsored it.” (J.A. at 264.)

In response, Abbvie submitted a supplemental report by its own expert, Mr. Donald Dietz, a licensed pharmacist in Pennsylvania and co-founder of Pharmacy Healthcare Solutions, LLC, a business consulting organization that advises retail pharmacies, managed care plans, PBMs, pharmaceutical manufacturers, and software engineers on strategic business and marketing issues. Mr. Dietz stated that “the NCPDP data fields [Ms. Craft] references do not contain the necessary information to identify the relevant proposed [end-payor] Class Member, and specifically, do not distinguish between different types of entities that may be involved in a given transaction.”³ (J.A. at 458.) He explained that, although the NCPDP data fields can be used to identify who the PBM billed, it would remain unclear whether the billed entity qualifies for inclusion

³ Some documents in the record refer to “end-payors” as “third-party payors” or “TPPs.” For simplicity, we only use the term “end-payors.”

in the class, due to the complex contractual relationships that can exist among the parties involved in each transaction.

For instance, Mr. Dietz explained, many health plan sponsors contract with an intermediary – a TPA – to help them process their group health plan benefits. Additionally, many insurers provide TPA services in an ASO capacity. According to Mr. Dietz, it is unclear from the face of the PBM data whether an entity is a member of the proposed class because, as both self-insured and fully insured health plans may use an intermediary, “it may be difficult to recognize what role the intermediary is playing for a given transaction from PBM data alone.” (J.A. at 459.) For example, a self-insured health plan sponsor may contract with an insurer operating in an ASO capacity, who in turn subcontracts with a PBM. In that situation, “[i]t is necessary to determine the role the insurance company is playing, [that is, whether it is] acting as the insurer, and thus is a potential [end-payor] Class Member, versus simply acting as an ASO, in which case it is not a Class Member.” (J.A. at 460.) But Mr. Dietz stated that this determination “cannot be done with the available data.” (J.A. at 460.)

Ms. Craft later admitted in a deposition that PBM data “is not designed to identify the ASO or TPA relationships.” (J.A. at 859.) In that same deposition, she also asserted, for the first time, that the fully insured health plan exclusion can be applied based on “the nature of the plan.” (J.A. at 857.) On that point, she stated that, “if it’s an HMO,” a Health Maintenance Organization, “we know categorically that we must be looking at a fully insured plan[.]” (J.A. at 857.) Abbie countered that “Ms. Craft is wrong: in reality an HMO plan can be either self-funded or fully insured.” (J.A. at 85.)

Ms. Craft then submitted a deposition errata, eliminating the word “categorically” and changing her testimony to: “if it’s an HMO, it’s a fully funded plan, except in those cases typically involving a very large employer that is ‘renting’ the HMO network[.]” (J.A. at 970.)

Ms. Craft also responded to Mr. Dietz’s supplemental expert report in a reply report. She listed instances in which she purported to identify plans as fully insured based on data in the “Account” and “Carrier” fields of the PBM data. Abbie, however, presented public documents showing that for two of the four examples examined by the Court,⁴ Mitre Corporation and Target, Ms. Craft was incorrect because those two plans were self-insured. (See J.A. at 1038) (“Plan benefits are self-insured by The MITRE Corporation, which is responsible for their payment.”); (see also J.A. at 1051) (“[Target] retain[s] a substantial portion of the risk related to

⁴ Ms. Craft included a total of twenty-two examples in her reply report, but the District Court only credited four of the examples because:

Ms. Craft [did] not provide a systematic method for identifying mere intermediaries, which are not class members, in any of her examples. Instead, for each example in which she purported to identify a mere intermediary in the PBM data ... Ms. Craft relied on what she “would normally expect to see” in a particular situation The Court concludes that such an *ad hoc* approach for identifying and excluding non-class members falls far short of a reliable and administratively feasible mechanism.

Niaspan III, 555 F. Supp. 3d at 167 n.8.

... medical and dental claims.”). In those two examples, Kaiser Colorado and Kaiser California North were listed in the “Carrier” field and Mitre Corporation and Target in the “Account” field, respectively. Abbie stated that, based on the public documents it presented, Kaiser was acting as an ASO in both instances and not as an end-payor despite what Ms. Craft had said.

The Appellants argued in response that the identified errors were “legally irrelevant” because, at the class certification stage, they needed only to show that potential class members can be identified, not the actual identity of all class members. (J.A. at 1074.) They claimed to have met their burden because “the only two potential class members for these particular transactions are reflected in the data[.]” (J.A. at 1075-76.) From this, the Appellants asserted that the specific class member “can be verified” from the two potential class members “through affidavits[.]” but the Appellants did not explain what the affidavits would ask or how they would be corroborated. (J.A. at 1076.)

B. Procedural Background

Stepping back to the beginning of this litigation, the first of seventeen putative class-action lawsuits against Abbie was filed in April 2013 in the United States District Court for the Eastern District of Pennsylvania.⁵ *Niaspan I*, 42 F. Supp. 3d

⁵ Sixteen of those lawsuits were filed in the United States District Court for the Eastern District of Pennsylvania and one was filed in the United States District Court for the District of Rhode Island. *Niaspan I*, 42 F. Supp. 3d at 745, n.5.

at 745. The Judicial Panel on Multidistrict Litigation transferred eight of the cases to a judge of that Court, who issued an order: “(1) direct[ing] ... the eight transferred actions be coordinated for pretrial purposes with nine tag-along actions ...; and (2) consolidat[ing] all pending End-Payor Actions for pretrial purposes and all pending Direct-Purchaser Actions for pretrial purposes.” *Id.* The three direct-purchaser plaintiff actions and fourteen end-payor plaintiff actions were consolidated into two separate class actions, respectively, and both sets of plaintiffs filed consolidated amended class action complaints in January 2014.⁶ *Id.*; see also Practice and Procedure Order Upon Transfer Pursuant to 28 U.S.C. § 1407(a), *In re Niaspan Antitrust Litig.*, No. 13-MD-2460 (E.D. Pa. Dec. 23, 2013), D.I. 37.

After several years of discovery, the end-payor plaintiffs – again, the current Appellants – filed a motion for class certification under Rule 23(b)(3). They proposed a broad class, including both consumers and end-payors, with ten exclusions, one of which was the fully insured health plan exclusion discussed above, and they alleged violations of fifty-three state laws across twenty-six jurisdictions. The District Court denied class certification on several grounds, including the Appellants’ failure to establish ascertainability. *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 725 (E.D. Pa. 2020) (“*Niaspan II*”). The denial was without prejudice to the Appellants giving their motion another try on modified

⁶ The direct-purchaser plaintiffs allege that the reverse payment settlement violates the Sherman Antitrust Act. *In re Niaspan Antitrust Litig.*, 397 F. Supp. 3d 668, 674 (E.D. Pa. 2019). That class action was certified in 2019. *Id.* at 691.

grounds. *Id.* With respect to ascertainability, the District Court determined that “[the end-payor plaintiffs] have failed to carry their burden of showing a reliable and administratively feasible mechanism for identifying class members by a preponderance of the evidence.” *Id.* at 701.

In response, those plaintiffs filed a renewed motion for class certification with a significantly narrowed class definition. *Niaspan III*, 555 F. Supp. 3d at 159. They removed consumers from the class definition, reduced the number of exclusions from ten to six, and invoked twenty-three, as opposed to fifty-three, state laws. *Id.* at 160.

The District Court again denied class certification. It concluded that the plaintiffs “ha[d] not presented an administratively feasible mechanism to distinguish between class members and mere intermediaries such as fully insured plans.” *Id.* at 169. At the outset, the Court noted that the issue Mr. Dietz raised in his November 6, 2020, supplemental report – “that [end-payor plaintiffs] failed to present an administratively feasible methodology ‘for determining whom the ultimate payor was’ in transactions involving fully insured plans, or other intermediaries, such as TPAs or ASOs” – is not *de minimis*.⁷ *Id.* at 165. Relying on survey results from the

⁷ The Appellants have argued that the District Court was somehow suggesting that an administratively feasible method must be one in which fact-finding to discover class members is so data-driven that individualized inquiry approaches what could be called a “de minimis” level. (*See* Opening Br. at 40.) That is not a fair interpretation of the Court’s words. Read in context, it is apparent that the District Court was, with understatement, pointing out that the plaintiffs’ proposed

PBM Institute, a membership organization that helps healthcare purchasers maximize the value of their drug benefit plans, the District Court concluded, based on expert testimony from both sides, that “between 38 and 55 percent of employers’ contractual relationships with their PBM was through a TPA” and that “approximately 88% of all employment-based prescription drug plans are fully insured.” *Id.* (internal quotation marks omitted). It also gave little credence to Ms. Craft’s declarations because she “adopt[ed] a methodology that change[d] as [the] defendants test[ed] its reliability and, in the end, fail[ed] to accomplish what [wa]s required.” *Id.* at 169. Specifically, the Court noted “that fully insured plans [we]re included in Ms. Craft’s examples, and they cannot be class members.” *Id.* at 167. The Court held that, “[g]iven that fully insured plans are extremely common” and that the PBM data may include “‘approximately 20 million class transactions,’ it is insufficient for the [End-Payor Plaintiffs] to narrow the identification of ‘potential class members’ to one of two entities as in the examples selected by Ms. Craft.” *Id.* at 168.

In sum, the end-payor plaintiffs failed to persuade the District Court that they could “identify, without individualized inquiry, the ... class members in Ms. Craft’s examples, let alone [in] the millions of transactions at issue in this case.” *Id.* As the use of affidavits was not put squarely before the Court, it was not obligated to consider whether they constituted an administratively feasible mechanism to distinguish between class members and intermediaries.

methodology would leave an enormous amount of individualized fact-finding to be done.

The end-payor plaintiffs became the Appellants when, pursuant to Federal Rule of Civil Procedure 23(f), they were granted leave to appeal the denial of class certification.

II. DISCUSSION⁸

The Appellants argue that their proposed methodology for ascertaining class membership satisfies our criteria for administrative feasibility. They claim that the District Court’s factual findings on the prevalence of intermediaries, the Court’s understanding of their methodology, and the Court’s failure to consider the potential use of affidavits in identifying class members are all clearly erroneous. The Appellants also argue that the District Court applied the wrong ascertainability standard. Alternatively, they argue that, “[i]f ascertainability means that a class cannot be certified here, then [we] should reconsider whether [our] ‘implicit’ ascertainability requirement is consistent with Rule 23.” (Opening Br. at 55.) We address each of those arguments, though not in that order.

⁸ The District Court had jurisdiction pursuant to 28 U.S.C. § 1332(d). We exercise jurisdiction under 28 U.S.C. § 1292(e) and Federal Rule of Civil Procedure 23(f). “We review a class certification order for abuse of discretion, which occurs if the district court’s decision rests upon a clearly erroneous finding of fact, an errant conclusion of law or an improper application of law to fact.” *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 312 (3d Cir. 2008) (internal quotation marks omitted).

A. The Rule 23 Legal Framework

Our precedent requires that, in a class action under Rule 23(b)(3), “class [members] ... be ‘currently and readily ascertainable based on objective criteria.’” *Hargrove v. Sleepy’s LLC*, 974 F.3d 467, 477 (3d Cir. 2020). To satisfy that requirement, “[p]laintiffs must show that ‘(1) the class is defined with reference to objective criteria; and (2) there is a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.’” *Id.* at 469-70 (citation omitted). A plaintiff must propose a classification method with evidentiary support to meet the ascertainability requirement, and “trial courts ‘must engage in a rigorous analysis and find each of Rule 23[]’s requirements met by a preponderance of the evidence before granting certification. They must do so even if it involves judging credibility, weighing evidence, or deciding issues that overlap with the merits of a plaintiff’s claims.” *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 304 (3d Cir. 2016) (citation omitted) (alteration in original). If a district court harbors uncertainty about whether the plaintiff has satisfied the requirements of Rule 23, class certification should be denied. *Mielo v. Steak ‘n Shake Operations, Inc.*, 897 F.3d 467, 483 (3d Cir. 2018). But that “does not mean that a plaintiff must be able to identify all class members at class certification – instead, a plaintiff need only show that ‘class members can be identified.’” *Byrd v. Aaron’s Inc.*, 784 F.3d 154, 163 (3d Cir. 2015) (emphasis removed).

We have discussed the ascertainability requirement in several cases. We first addressed it in *Marcus v. BMW of North America, LLC*, where the plaintiffs proposed a class of New Jersey owners and lessees of BMW vehicles equipped with

“run-flat tires ... [that] ha[d] gone flat and been replaced[.]” 687 F.3d 583, 592 (3d Cir. 2012). “The proposed class raise[d] serious ascertainability issues” because the tires were manufactured in Germany by a different company, and BMW did not have records showing which vehicles were fitted with the “run-flat” tires. *Id.* at 593. Additionally, dealerships selling BMW vehicles regularly replaced the tires at customers’ requests. *Id.* at 593-94. Compounding those issues, the plaintiffs lacked a methodology for identifying, consistent with the class definition, the owners and lessees of BMW vehicles whose “run-flat tires” had gone flat and been replaced. *Id.* at 594. Because the answers to those questions were left to the “potential class members’ say so[,]” we remanded to the district court to “resolve the critical issue of whether the defendants’ records can ascertain class members and, if not, whether there is a reliable, administratively feasible alternative.” *Id.*

In *Hayes v. Wal-Mart Stores, Inc.*, a putative class of customers who purchased items with extended warranties attempted to certify a class that included customers who purchased a “Service Plan to cover as-is products.” 725 F.3d 349, 353 (3d Cir. 2013). The class excluded any customer whose “as-is product was covered by a full manufacturer’s warranty, was a last-one item [i.e., an item that is brand-new but the store wishes to clear out] ... who obtained service on their product, and ... who ha[d] been previously reimbursed for the cost of the Service Plan.” *Id.* That class definition required separate factual inquiries into: “(1) whether a [customer] purchased a Service Plan for an as-is item, (2) whether the as-is item was a ‘last one’ item or otherwise came with a full manufacturer’s warranty, and (3) whether the member nonetheless received service on the as-is item or a

refund of the cost of the Service Plan.” *Id.* at 356. On the then-existing record, the plaintiffs could not satisfy that burden. *Id.* We remanded so they could attempt to demonstrate a reliable and administratively feasible method for ascertaining the class. *Id.* We cautioned, however, that “class certification will founder if the only proof of class membership is the say-so of putative class members or if ascertaining the class requires extensive and individualized fact-finding.” *Id.*

In *Carrera v. Bayer Corp.*, the district court certified a “class of consumers who purchased Bayer’s One-A-Day WeightSmart diet supplement in Florida.” 727 F.3d 300, 303 (3d Cir. 2013). The defendants were the supplement manufacturers, and they did not have access to any retail records that could establish who purchased their products during the defined class period. *Id.* at 304. The plaintiffs’ proposed methodology involved using “retailer records of online sales and sales made with store loyalty or rewards cards,” along with affidavits attesting purchases of the diet supplements. *Id.* But the plaintiffs provided no evidence that any purchasers, let alone the entire class, could be identified using the proposed retail records. There was no evidence that retailers even had records during the relevant period, and there was no method to determine whether the affidavits would be reliable. *Id.* at 309-11. We rejected the plaintiffs’ proposal and remanded the case so that they could conduct further, limited discovery on whether there was a reliable and administratively feasible means of determining class membership. *Id.* at 312.

Next, in *Byrd v. Aaron’s Inc.*, the plaintiffs alleged that their leased computers contained spyware. 784 F.3d at 160. The proposed class included lessees and purchasers of the computers as well as members of their households who were

supposedly monitored through the spyware. *Id.* The defendants kept records that easily allowed identification of the lessees, but because there were no records of their household members, the district court denied certification for lack of ascertainability, finding that the class did not adequately define “household member.” *Id.* at 169. Although the plaintiffs asserted that they could identify household members with public records and affidavits, the district court rejected that method as insufficient to satisfy ascertainability. *Id.* at 160. We reversed, concluding that the term “household member” was not inherently vague, and that household members could be ascertained through affidavits indicating their household status. *Id.* at 171-72.

In *City Select Auto Sales Inc. v. BMW of North America*, the plaintiffs proposed a class of car dealers who were wronged by receiving unsolicited faxes from a credit agent. 867 F.3d 434, 437 (3d Cir. 2017). The district court ruled that the class was not ascertainable because a database of all the car dealers did not list who received the fax. *Id.* at 441. We remanded because an “[a]ffidavit[], in combination with records or other reliable and administratively feasible means, can meet the ascertainability standard,” and the “only factual inquiry required to determine class membership is whether a particular dealership in the database received the BMW fax[.]” *Id.* at 441-42.

Most recently, in *Hargrove v. Sleepy’s LLC*, a case under New Jersey labor laws, a mattress company required its drivers to sign a contract stipulating that they would not carry merchandise for other businesses while carrying Sleepy’s products. 974 F.3d at 471. Despite that contract, Sleepy’s characterized the drivers as independent contractors. *Id.* at

472. The plaintiffs brought an employee misclassification suit and sought class certification as a class of delivery drivers who performed deliveries for Sleepy's on a full-time basis and who drove at least one truck for Sleepy's. *Id.* at 474. In support of their motion for certification, they proposed using Sleepy's records to identify the members of the proposed class, but those records contained gaps. *Id.* at 472-73. The plaintiffs argued that they could nevertheless use testimony from drivers, in combination with Sleepy's records, to establish class membership. *Id.* at 473. The district court denied class certification, stating that, since Sleepy's records did not show which employees worked on a full-time basis, it was "unable to determine if Sleepy's was the only company [that] the drivers worked for." *Id.* at 475. Additionally, the district court said that the plaintiffs could not show "which potential class members were subject to improper deductions and which potential class members worked over forty hours a week without being paid over-time." *Id.* We reversed, holding that at the certification stage, the plaintiffs "do not have to prove ... that each proposed class member was indeed a full-time driver, but only that the members can be identified[.]" *id.* at 480, and that the district court was "too exacting and essentially demanded that [the] Appellants identify the class members at the certification stage." *Id.* at 470. We thus determined that the plaintiffs had identified records that, in combination with affidavits, established a reliable and administratively feasible method for determining class membership. *Id.* at 480.

B. Ascertainability is a Key Requirement for Class Actions

The Appellants ask us to reconsider our ascertainability requirement. They claim that "[t]he majority of other courts of

appeals to have considered the question have rejected the ascertainability requirement as an extratextual hurdle to class certification that is inconsistent with the text and purpose of Rule 23.” (Opening Br. at 55.) But even if we had authority to overrule our existing precedent, which we do not, *see In re Krebs*, 527 F.3d 82, 86 (3d Cir. 2008) (stating that a panel may not overrule precedent on the basis that our sister circuits have decided the issue contrary to that precedent or because we are no longer persuaded by its reasoning), we would decline to do so here.

“[T]he class-action device saves the resources of both the courts and the parties by permitting an issue potentially affecting every [class member] to be litigated in an economical fashion under Rule 23.” *Califano v. Yamasaki*, 442 U.S. 682, 701 (1979). Yet when members of a Rule 23(b)(3) class cannot be identified in an economical and administratively feasible manner, the very purpose of the rule is thwarted. Ascertainability serves several important objectives in preserving those efficiencies:

First, it eliminates “serious administrative burdens that are incongruous with the efficiencies expected in a class action” by insisting on the easy identification of class members. Second, it protects absent class members by facilitating the “best notice practicable” under Rule 23(c)(2) in a Rule 23(b)(3) action. Third, it protects defendants by ensuring that those persons who will be bound by the final judgment are clearly identifiable.

Marcus, 687 F.3d at 593 (internal citations omitted).

The ascertainability standard, including the administrative feasibility principle it contains, is true to the text, structure, and purpose of Rule 23. That is because, absent some mechanism to establish whether the standards of Rule 23 are met, courts could not meaningfully apply the Rule. Since “mere speculation is insufficient” to determine whether a plaintiff has established the prerequisites of Rule 23(a), *Hayes*, 725 F.3d at 357 (quoting *Marcus*, 687 F.3d at 596–97), a closer look at the alleged facts is necessary. What we call “ascertainability” and “administrative feasibility” is merely the way courts perform that role, a practice familiar under the civil rules. *Cf., e.g., Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 557 (2007) (“The need at the pleading stage for allegations plausibly suggesting (not merely consistent with) [conspiracy] reflects the threshold requirement of Rule 8(a)(2) that the ‘plain statement’ possess enough heft to ‘sho[w] that the pleader is entitled to relief.’”); *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (“As the Court held in *Twombly*, ... the pleading standard Rule 8 announces does not require ‘detailed factual allegations,’ but it demands more than an unadorned, the-defendant-unlawfully-harmed-me accusation.”) (citation omitted). So a court necessarily considers whether the proposed class is based on objective criteria, not speculation, by looking at administratively feasible methods of defining the class, consistent with the text of Rule 23.

We are not alone in holding that Rule 23(b)(3) has an implicit requirement that class members be ascertainable. Several of our sister circuits have followed our lead and apply our ascertainability standard, or a standard that is substantively

the same.⁹ And while it is true that our rule is not without critics,¹⁰ even in circuits that have rejected an ascertainability

⁹ See *In re Nexium Antitrust Litig.*, 777 F.3d 9, 19 (1st Cir. 2015) (“At the class certification stage, the court must be satisfied that, prior to judgment, it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members. The court may proceed with certification so long as this mechanism will be ‘administratively feasible,’ see *Carrera*, 727 F.3d at 307, and protective of defendants’ Seventh Amendment and due process rights[.]”); *In re Initial Pub. Offerings Sec. Litig.*, 471 F.3d 24, 44-45 (2d Cir. 2006) (denying certification of a class for failure to satisfy Rule 23’s predominance requirement because “ascertaining each purchaser’s intent would require an individualized determination”); *EQT Prod. Co. v. Adair*, 764 F.3d 347, 358 (4th Cir. 2014) (“We have repeatedly recognized that Rule 23 contains an implicit threshold requirement that the members of a proposed class be ‘readily identifiable.’ Our sister circuits have described this rule as an ‘ascertainability’ requirement.”) (internal citations omitted); *John v. Nat’l Sec. Fire and Cas. Co.*, 501 F.3d 443, 445 (5th Cir. 2007) (“The existence of an ascertainable class of persons to be represented by the proposed class representative is an implied prerequisite of Federal Rule of Civil Procedure 23.”).

¹⁰ See *Cherry v. Dometic Corp.*, 986 F.3d 1296, 1304 (11th Cir. 2021) (“We hold that administrative feasibility is not a requirement for certification under Rule 23. ... If a district court researches Rule 23(b), and the action involves a proposed Rule 23(b)(3) class, it may consider administrative feasibility as part of the manageability criterion of Rule 23(b)(3)(D).”); *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1124 n.4 (9th

requirement, some version of an administrative feasibility test is applied, albeit under a different name. For instance, in

Cir. 2017) (noting that the Ninth Circuit has not adopted a separate ascertainability requirement and “[i]nstead ... address[es] the types of alleged definitional deficiencies other courts have referred to as ‘ascertainability’ issues, through analysis of Rule 23’s enumerated requirements”) (internal citations omitted); *Sandusky Wellness Center, LLC v. Medtox Scientific, Inc.*, 821 F.3d 992, 996 (8th Cir. 2016) (declining to adopt ascertainability as a separate, preliminary requirement and instead “adher[ing] to a rigorous analysis of the Rule 23 requirements, which includes that a class ‘must be adequately defined and clearly ascertainable’”); *Mullins v. Direct Digital, LLC*, 795 F.3d 654, 663 (7th Cir. 2015) (rejecting the administrative feasibility requirement from *Carrera*, stating that the “concern about administrative inconvenience is better addressed by the explicit requirements of Rule 23(b)(3), which requires that the class device be ‘superior to other available methods for fairly and efficiently adjudicating the controversy.’ One relevant factor is ‘the likely difficulties in managing a class action’”); *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 525 (6th Cir. 2015) (declining to adopt *Carrera*). In *Rikos*, the Sixth Circuit expressly declined to follow our decision in *Carrera*, but that court has previously endorsed an administrative feasibility requirement. See *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 537-38 (6th Cir. 2012) (holding that “[b]efore a court may certify a class pursuant to Rule 23, ‘the class definition must be sufficiently definite so that it is administratively feasible for the court to determine whether a particular individual is a member of the proposed class’”).

Cherry v. Dometic Corp., the Eleventh Circuit stated that “administrative feasibility has relevance for Rule 23(b)(3) classes, in the light of the manageability criterion of Rule 23(b)(3)(D).”¹¹ 986 F.3d 1296, 1303 (11th Cir. 2021). The Ninth, Eighth, Seventh, and Sixth Circuits have all adopted a similar approach. Instead of having a separate administrative feasibility requirement, those courts often address administrative concerns through a rigorous analysis of Rule 23’s “superiority” requirement. *See supra* n.10. We thus do not agree that our ascertainability analysis is inconsistent with the text and purpose of Rule 23.

C. The District Court’s Factual Findings are not Clearly Erroneous

Turning back to this case, we next consider the Appellants’ argument that their protean methodology satisfies our criteria for administrative feasibility. They describe their methodology as an “overalls, belt, and suspenders approach[.]” that includes three layers of action to determine class membership: (1) PBMs identify class members when providing data (what the Appellants refer to as the “overalls”); (2) data is batch-filtered and name matched using Ms. Craft’s techniques to distinguish administrative intermediaries from class members (the “belt”); and (3) if the batch-filtering and name-matching results in two options, a single-question form

¹¹ “Rule 23(b)(3)(D) instructs district courts, in deciding whether ‘a class action [would be] superior to other available methods for fairly and efficiently adjudicating the controversy,’ to consider ‘the likely difficulties in managing a class action.’” *Cherry*, 986 F.3d at 1303.

affidavit is sent to the two identified potential class members to confirm which is the class member (the “suspenders”). The Appellants claim that the District Court’s factual findings were clearly erroneous because the Court misunderstood their proposed methodology, overstated the prevalence of intermediaries in the PBM data, and failed to consider the use of affidavits as a means of identifying class members.

1. Ascertainability Issues are Pervasive

As a threshold matter, we must first decide whether the prevalence of intermediaries in the PBM data poses an ascertainability issue. The Appellants assert that “[o]nly a small subset of the data could possibly present the potential intermediary-confusion issue” identified by Mr. Dietz. (Opening Br. at 17.) They argue that Mr. Dietz identified such confusion “only when a self-funded [health] plan uses an administrative intermediary[,]” but, they say, “fewer than 10% of employers are both self-funded and potentially use an ASO or [other] TPA[.]” (Opening Br. at 18.)

The Appellants arrive at that metric by first treating the District Court’s findings, taken from the PBM Institute’s survey data, as correct: that “between 38 and 55 percent of employers’ contractual relationships with their PBM was through a TPA” and that “approximately 88% of all employment-based prescription drug plans are fully insured[,]” leaving 12% as self-insured. *Niaspan III*, 555 F. Supp. 3d at 165. Then, assuming that the maximum 55% of the 12% of self-insured health plans use a TPA or ASO, they argue that, at most, only “6.6% of plans ... could potentially generate the confusion Dietz identified[.]” (Opening Br. at 18.) But the Appellants’ metric assumes precisely what they must prove –

that they can feasibly identify and filter out the fully insured health plans, the TPAs, and the ASOs from this data. The Appellants have made no showing that they can determine where any given transaction falls within the various categories of transactions. Abbvie aptly describes the problem with an analogy: “It is as if someone has given the Court one hundred \$20 bills and promised that only about 10% are counterfeit. It would be nice to spend \$1,800 in real money, but the Court must still determine whether each and every bill is genuine before spending it.” (Answering Br. at 36-37.)

The District Court found that the prevalence of intermediaries is a significant problem, especially since the same players in this industry may be end-payors, fully insured health plans, or merely administrators in any given transaction, and the PBM data does not indicate which role they are playing. That finding is not clearly erroneous.

2. The Appellants Forfeited their Affidavits Argument

The Appellants fault the District Court for failing to consider the use of affidavits to resolve ambiguities when two entities are identified as potential end-payors using Ms. Craft’s methodology. They claim that they raised this issue in their Renewed Motion for Class Certification, but that is plainly incorrect. No discussion about the use of affidavits appears until a footnote in their Reply Brief in Support of Class Certification, where they wrote “Plaintiffs also intend to use affidavits to ensure, at a minimum, that [end-payors] are in fact self-insured and not government-funded payors.” (J.A. at 997 n.9.) Even then, their passing remark was made in the context of a discussion of a different class-exclusion category, i.e., the

one for federal or state government entities, not the one for the fully insured health plans, which is the subject of this appeal.

The Appellants did mention the use of affidavits in regard to the fully insured health plan exclusion in a different filing in the District Court, their Reply to Defendant's Response to Plaintiff's Expert Reply Report. There, they asserted that, "to the extent necessary, affidavits, can identify class members at a later stage." (J.A. at 1074.) They claim that was enough to preserve their present argument for appeal because Abbvie could have responded to the use of affidavits in its "responsive briefing[.]" (Reply Br. at 22.) Leaving aside the fact that they made their argument in a reply brief, and no further "responsive briefing" was in order, the Appellants never explained how the use of affidavits would work, and their experts never discussed any specifics on how they would be used.

Arguments raised for the first time before a district court in a reply brief are deemed forfeited. *See Jaludi v. Citigroup*, 933 F.3d 246, 256 n.11 (3d Cir. 2019) ("Because Citigroup failed to invoke the provision until its reply brief in the District Court, we deem this argument [forfeited]."). The Appellants' tardy and fleeting references to the use of affidavits to resolve ambiguities were insufficient to preserve the matter for appeal. "To preserve a matter for appellate review, a party 'must unequivocally put its position before the trial court at a point and in a manner that permits the court to consider its merits.'" *Garza v. Citigroup Inc.*, 881 F.3d 277, 284 (3d Cir. 2018) (citation omitted). "It is well established that arguments not raised before the District Court are [forfeited] on appeal." *DirectTV, Inc. v. Seijas*, 508 F.3d 123, 125 n.1 (3d Cir. 2007). And that must be particularly so when the argument is not

about a purely legal question but about the sufficiency of evidence one has produced.

The Appellants cite *Hargrove* to argue that, because Abbvie had the opportunity to file additional briefing on the issue of affidavits, the argument should be deemed preserved.¹² But *Hargrove* involved a different issue on appeal. In that case, the appellants argued in their opening brief, albeit in a footnote, that the district court erred by applying the wrong standard of review to their renewed motion for class certification. *Hargrove*, 974 F.3d at 475 n.5. The district court there also expressly discussed and ruled on that issue. *Id.*; *cf. Lark v. Sec’y Pa. Dep’t of Corr.*, 645 F.3d 596, 607-08 (3d Cir. 2011) (noting that “the crucial question regarding [forfeiture]” is whether the proceeding “put the [d]istrict [c]ourt on notice of the legal argument”). Accordingly, we chose to address the issue. *Hargrove*, 974 F.3d at 476-77. Here, by contrast, the District Court did not address the hidden issue in its opinion on class certification. The Appellants nonetheless contend that the District Court was on notice of their argument because they mentioned the use of affidavits elsewhere, specifically in their Reply to Defendant’s Response to Plaintiff’s Expert Reply Report.

¹² The Appellants are confused about who had the burden here. It was not Abbvie’s obligation to seek permission to address the Appellants’ tardy argument. The Appellants could have raised their argument in a timely fashion but did not. Having failed to bring the issue up when they should have, they can hardly fault Abbvie for focusing its advocacy on arguments that were properly before the District Court.

Their argument is unpersuasive. That they said something about affidavits in another reply brief on a different motion is of no moment. Even if we thought that, in this heavily papered case, with many issues and stretching over many years, there was some excuse for not properly bringing the affidavits issue to the fore in the class certification briefing, the Appellants still brought it up only in a reply filing dealing with a different dispute. Again, arguments raised for the first time in a reply brief are forfeited, *Jaludi*, 933 F.3d at 256 n.11, because the district court must have a fair opportunity to consider the arguments before we do, *Garza*, 881 F.3d at 284. The Appellants did not adequately present their argument about the use of affidavits to the District Court, and we will not consider it now.

3. The District Court’s Factual Findings Concerning PBM Identification Are Not Clearly Erroneous

The Appellants argue that PBM data is readily accessible, that PBMs can identify end-payors for every Niaspan purchase, and that this data set meets the ascertainability standard that we set forth in *Byrd* and *Hargrove*. The District Court, however, rejected the notion that PBMs can identify end-payors, *Niaspan III*, 555 F. Supp. 3d at 166-67, and, again, that finding is not clearly erroneous.

As mentioned earlier, the Court found that PBMs cannot identify class members because their data does not show whether, in any given transaction, an entity is an end-payor, a fully insured health plan, or an administrative intermediary. *Id.* That conclusion has ample support in the record. Ms. Craft admitted that the PBM standardized data contains “code

numbers,” not “names or descriptions,” (J.A. at 1001), and that it “is not designed to identify the [administrative] relationships[,]” (J.A. at 859). Unfortunately, that candor was paired with some confusion about identifying fully insured plans based on the nature of the plan. *Id.* She asserted that “if it’s an HMO ... we know categorically ... it’s a fully funded plan[,]” (J.A. at 857), but she later had to correct that assertion with the caveat that it would be a “fully funded plan, except in those cases typically involving [a sponsor] that is ‘renting’ the HMO network[,]” (J.A. at 970).

The Appellants nevertheless assert that, “like the lessees in *Byrd* whose names were listed on the defendants’ rental records[,] ... the class members are identified by the PBM records.” (Opening Br. at 32 (citation omitted).) Not so. The defendants in *Byrd* kept detailed records that easily allowed identification of a lessee on the face of each record. *Byrd*, 784 F.3d at 169. Again, the PBM data contains code numbers, not names or descriptions of entities, and those numbers are not designed to indicate the relationships between parties. The Appellants provided no evidence on how those numbers could be used to accurately identify class members, and Ms. Craft acknowledged that we don’t “know categorically” if an HMO is a fully insured health plan because there is an exception when sponsors rent the HMO network, so it cannot be said that class members can be identified based on the nature of the plan. (J.A. at 857.) Given the remaining ambiguity in the data, it was not clearly erroneous for the District Court to conclude that PBMs cannot adequately identify the end-payors.

4. The District Court Properly Concluded That the Appellants' Data Matching Technique is Unreliable

The Appellants also claim that they can use automated data matching to identify class members by identifying administrator transactions and then identifying the administrator's end-payor client. The District Court found that, on the contrary, the Appellants "have not shown they can identify, without individualized inquiry, the [end-payor] class members in Ms. Craft's examples, let alone the millions of transactions at issue in this case." *Niaspan III*, 555 F. Supp. 3d at 168. Ms. Craft submitted twenty-two examples that the District Court considered and rejected as "*ad hoc*." *Id.* at 167 n.8. In those examples, Ms. Craft relied on "what she 'would normally expect to see'" and "what 'typically appears' in a particular situation," but she was only able to affirm that certain codes "indicate[] a self-funded plan[.]" *Id.* When Abbvie examined her methodology in four of the examples, it discovered that she was wrong in half of them; she had listed two entities as fully insured health plan sponsors, but public documents showed that they were in fact self-insured sponsors. *Id.* at 167. The District Court saw that error as "support[ing] the conclusion that identifying class members will require 'individualized fact-finding.'" *Id.* (citation omitted). And the error was especially damning for the Appellants' methodology because "fully insured plans are extremely common and [the Appellants] expect PBM data to include 'approximately 20 million class transactions,' [so] it is insufficient for [the Appellants] to narrow the identification of 'potential class members' to one of two entities[.]" *Id.* at 168 (citation omitted).

The Appellants argue that the District Court’s conclusion that those two examples rendered the entire method unreliable is clearly erroneous because Ms. Craft reviewed transactions from 2012 and the public documents from 2017 do not discuss the drug plan funding five or more years earlier when the transaction at issue took place. The District Court, however, noted that the 2017 documentation “is relevant to whether [the entity] was [an end-payor] during the class period,” because the class period didn’t end until 2018. *Id.* at 167 n.9. Certainly, whether that entity was a fully insured or self-insured health plan sponsor during the class period is relevant, and the Appellants did not provide any 2012 documentation to support their argument.

Yet they protest that, by requiring them “to disprove [Abbvie’s] hypothetical extrapolations *ex ante*[,]” the District Court essentially demanded that they identify class members at the certification stage. (Opening Br. at 43.) Once again, we disagree. Although they are correct that they “do not have to prove at [the certification] stage that each proposed class member was indeed a [class member],” *Hargrove*, 974 F.3d at 480, they still must prove that they can identify class members “without extensive and individualized fact-finding or ‘mini-trials,’” *Marcus*, 687 F.3d at 593. The District Court’s conclusion that they failed to do that is not, on this record, clearly erroneous.

The Court relied heavily on *Vista Healthplan, Inc. v. Cephalon, Inc.*, in deciding that extensive and individualized fact-finding or mini-trials would be necessary to identify class members. No. 06-1833, 2015 WL 3623005 (E.D. Pa. June 10, 2015); *see Niaspan III*, 555 F. Supp. 3d at 165-66. In that case, a group of end-payors alleged that the defendants engaged in

an anticompetitive reverse-payment settlement. *Vista Healthplan*, 2015 WL 3623005 at *2. The class contained eight categories of exclusions, including an exclusion for fully insured health plans. *Id.* at *4, 9. The only evidence presented to determine class membership was the consumer history records of one named plaintiff that listed the various prescriptions that the named plaintiff had filled and the out-of-pocket expenses and amount covered by the plaintiff's insurance plan, along with a chart that identified claims made and patients by number rather than name. *Id.* at *9. The plaintiffs, however, did not show that those numbers could identify class members, and they provided no evidence that consumer history records were kept for all patients. *Id.* at *9-10. The district court in *Vista* noted that, “[u]ntil proceeding through each transaction and resolving factual disputes about who ‘bears the burden’ of the price in that transaction, the [c]ourt cannot say who is a member of the class, that is, who has paid or reimbursed a portion of the purchase price.” *Id.* at *8 (citation omitted). The court held that the proposed class was not ascertainable because resolving those factual disputes would “require[] ‘consideration of the individual contractual relationships underlying each transaction.’” *Id.* at *12 (citation omitted).

The District Court here had the same concern – namely, that it would have to examine the underlying contractual relationships of each transaction to distinguish between class members and mere intermediaries. Even if the Appellants could narrow the inquiry down to two possible candidates for class membership, the proper class member could not be identified without analyzing the contractual relationships behind each transaction. Given the record before the Court, it was not an error, let alone a clear error, to conclude

that Ms. Craft's data matching technique could not adequately determine class membership.

The Appellants direct us to decisions from outside our Circuit in which district courts approved certification based on the same methodology involving PBM data provided by the same expert, Ms. Craft. They claim that, based on those cases, the District Court here clearly erred in denying certification. *See, e.g., In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527, 548-50 (S.D.N.Y. 2021) (finding that Ms. Craft's methodology along with PBM data "can be used to identify the ultimate payor of the claim"); *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294, 308 (D. Mass. 2021) (finding that Ms. Craft's methodology sufficiently explained how "multiple data fields ... can be used jointly to identify efficiently ... non-class members"); *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 399-401 (D.R.I. 2019) (noting that the "Court is confident" that Ms. Craft's methodology in combination with PBM data can show whether a group plan is fully insured or self-insured). But the District Court here considered those thoughtful opinions and still was not persuaded that PBM data alone can readily identify fully insured health plans, as "evidence presented in this case is to the contrary." *Niaspan III*, 555 F. Supp. 3d at 168. Declining to follow non-binding decisions from other district courts, especially when the record developed in those cases is unknown, does not constitute clear error.

Taking another tack, the Appellants say that the "[D]istrict [C]ourt's failure to hold the evidentiary hearing requested by End-Payor Plaintiffs ... contributed to the [C]ourt's cursory and erroneous conclusion at odds with every other district court to have considered the materially same

methodology and class definition.” (Opening Br. at 47.) They claim that the District Court’s “divergent result here followed a minimal process that contrasts with the extensive review conducted by other courts, including multiday evidentiary hearings that allowed them to fully understand the database techniques.” (Opening Br. at 47.)

District court judges are accorded “considerable discretion to limit both discovery and the extent of [a] hearing on Rule 23 requirements.” *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 324 (3d Cir. 2008) (citation omitted). When they were before the District Court in this case, the Appellants were given three days of argument on their first class-certification motion, and the District Court considered four declarations from three different experts, as well as voluminous briefing, before writing a 70-page opinion deciding the motion. The Court also considered additional briefing in the Appellant’s Renewed Motion for Certification, and it requested additional briefing from the Appellants after Abbie pointed out errors in Ms. Craft’s analysis. Given the extensive investment of time and effort by the Court in considering the Appellants’ multiple submissions and arguments, and further given the Appellants’ failure to identify what more they would have shown, we can hardly say that the District Court abused its “considerable discretion” in declining to hold another hearing.¹³ *Id.*

¹³ The Appellants raise two additional arguments, but both are without merit and warrant only brief discussion. First, they argue that the District Court “erred by adopting a bright line rule... that *any* potential individualized inquiry defeats class certification.” (Opening Br. at 26.) But that is a mischaracterization of the Court’s opinion, as it concluded that

the “[Appellants] have not persuaded the Court that distinguishing between class members and mere intermediaries, which are excluded from the class, will not ‘require[] consideration of the individual contractual relationships underlying each transaction.’” *Niaspan III*, 555 F. Supp. 3d at 166 (quoting *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *12 (E.D. Pa. June 10, 2015)). The District Court reasonably concluded that, given the “millions of transactions at issue in this case,” *id.* at 168, Appellants’ methodology could not “systematically” enforce the class exclusion for fully insured plans without requiring an administratively infeasible degree of individualized inquiry, *id.* at 169. See *City Select*, 867 F.3d at 442 (suggesting that “individualized fact-finding” is permissible only when administratively feasible).

Second, the Appellants argue that the District Court improperly “demanded a ‘de minimis’ or less level of over-inclusiveness.” (Opening Br. at 27.) As already noted, see *supra* n.7, that argument too mischaracterizes the Court’s opinion. The Court stated that “the issue of whether the [End-Payor Plaintiffs] have presented a sufficient methodology for distinguishing between class members and mere intermediaries, such as fully insured plans and TPAs, is not *de minimis*.” *Niaspan III*, 555 F. Supp. 3d at 165. That statement was not a legal conclusion. It was rather an understated way of noting how dramatically the Appellants had downplayed the problem being discussed.

III. Conclusion

For the foregoing reasons, we will affirm the District Court's order denying class certification.