United States Court of Appeals

for the

Third Circuit

Case 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 AN ORDER OF THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

BRIEF FOR APPELLANTS AND JOINT APPENDIX VOLUME 1 OF 4 (Pages A-1 to A-94)

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CORPORATE DISCLOSURE

Under Federal Rule of Appellate Procedure 26.1 and Third Circuit Local Appellate Rule 26.1, Appellants A.F. of L. – A.G.C. Building Trades Welfare Plan; The 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; and United Food & Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund make the following disclosure:

Appellants have no parent corporations, no publicly held companies hold ten percent or more of any appellant's stock, and no non-party publicly held corporation has a financial interest in the outcome of this proceeding.

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STATEMENT OF JURISDICTION

The district court had jurisdiction over the claims at issue here under 28 U.S.C. § 1332. The district court denied Appellants' renewed motion for class certification on August 17, 2021, and Appellants timely filed a petition for permission to appeal under Federal Rule of Civil Procedure 23(f) on August 31, 2021. This Court granted the petition on October 7, 2021, A92, and has jurisdiction under 28 U.S.C. § 1292(e).

ISSUE STATEMENT

Did the district court abuse its discretion by holding that any amount of "individualized inquiry," A89, precluded ascertainability of a class when comprehensive data identifies all class members and class membership can be confirmed by a proven methodology for analyzing that data, supplemented in a small subset of cases, if necessary, by single-question affidavits.[1]

STATEMENT OF RELATED CASES

This case has not previously been before this Court, and Appellants are not aware of any previous or pending appeal before this Court arising out of the same case or proceeding. This appeal involves the state law claims of a putative class of plaintiffs in multidistrict litigation arising out of reverse payment agreements made by Defendant drug manufacturers. A separate group of plaintiffs who are direct

[1] This issue was raised in Plaintiffs' Renewed Motion for Class Certification, Dkt No. 722-1, at pp. 7-15; Reply in Support of Class Certification, Dkt No. 751, at pp-1-17; and Reply to Defendants' Response to Plaintiffs' Expert Reply Report, Dkt No. 759-1, at pp. 1-3, and ruled on at A71-A90.

purchasers of Defendants' prescription drugs have brought federal antitrust claims arising out of the same agreements. Direct Purchaser Plaintiffs' claims are pending in the district court. Counsel is aware of no other case or proceeding that is in any way related, completed, pending or about to be presented before this Court or any other court or agency, state or federal.

STATEMENT OF THE CASE

Every day, consumers pick up prescriptions their doctors have just submitted, and drive off from the pharmacy minutes later with an expensive medicine for which they paid only a fraction of the price. That efficient transaction is made possible by the real-time exchange of data that permits identification of the entity responsible for paying the rest of the cost. A small number of companies, known as pharmacy benefit managers ("PBMs"), facilitate these transactions, about 15 million times a day. A255. Due to regulatory requirements and business necessity, PBMs maintain readily available, extensive electronic data for each prescription drug sale.

The question here is whether a class of health insurers and health plans that pay for prescription drugs is ascertainable, under this Circuit's standard, when this readily available PBM data includes all class members. More specifically, the question is whether it is possible to feasibly distinguish between end payors (health insurers and health plans) and intermediaries that sometimes help process claims on their behalf, using an expert methodology that has been accepted in courts across the

country.

The district court said no and denied Plaintiffs' renewed motion for class certification in this multidistrict case without a hearing, applying a too-exacting version of this Circuit's already-controversial ascertainability standard to a single exclusion of the class definition. The court did so even though Plaintiffs identified and produced examples of comprehensive purchase records that are used every day to identify the correct payors—data without which the prescription drug business could not function.

To the extent that data includes intermediaries in addition to payors, any over-inclusiveness is far below the "high degree" that raises ascertainability concerns. And Plaintiffs' proposed approach for identifying class members is, if anything, more feasible than methods this Court has already approved. If this comprehensive data and proven methodology are not enough to show that class members can be identified, then the door is effectively closed in this Circuit for the parties most affected by drug companies' anticompetitive behavior—the insurance companies and health plans that pay most of the cost—to seek redress for their damages. That is not, and cannot be, what the extra-textual ascertainability requirement demands.

A. Factual Background

This case involves a "pay-for-delay," or "reverse payment," settlement, where Plaintiffs allege "a brand-name drug manufacturer [brought] a patent-infringement

action against a generic drug manufacturer and then compensate[d] the generic drug manufacturer for its agreement to delay entering the market with a competing generic version of the brand-name drug." A3. The settlements are called "reverse payment" because "the patentee … pay[s] the alleged infringer, rather than the other way around." *FTC v. Actavis, Inc.*, 570 U.S. 136, 141 (2013). Such payments raise antitrust concerns given their "potential for genuine adverse effects on competition," that "at least sometimes prove unjustified," especially given research showing "the presence of higher-than-competitive profits—a strong indication of market power." *Id.* at 154-57.

The Federal Trade Commission estimates that pay-for-delay deals "cost consumers and taxpayers $3.5 billion in higher drug costs every year." FTC, *Pay-For-Delay: When Drug Companies Agree Not To Compete*, https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay. Class action lawsuits have proved critical in combatting such illegal activity. *See, e.g.*, *In re Aggrenox Antitrust Litig*., No. 3:14-MD-2516, 2018 U.S. Dist. LEXIS 138982 (D. Conn. July 19, 2018), *aff'd* 812 F. App'x 26 (2d Cir. 2020) (approving end-payor class settlement); *In re Loestrin 24 Fe Antitrust Litig*., No. 1:13-md-2472, 2020 U.S. Dist. LEXIS 158946 (D.R.I. Sept. 1, 2020).

The putative class action here involves Niaspan, a brand-name drug for treating lipid disorders developed by Kos Pharmaceuticals. A4. Defendant AbbVie

acquired Kos and now manufactures Niaspan. *Id.* In 2001, Defendant Barr, a generic drug manufacturer since acquired by Defendant Teva, sought FDA authorization to market a generic equivalent of Niaspan. *Id.* Kos sued Barr for patent infringement; they later reached several agreements terminating the patent litigation. A4-A5.

Direct-Purchaser and End-Payor Plaintiffs sued to recover for damages caused by those anticompetitive agreements. Direct purchasers are drug wholesalers, pharmacies, and others that purchased Niaspan directly from Defendants; they allege the agreements violate the Sherman Act. *See In re Niaspan Antitrust Litig.*, 397 F. Supp. 3d 668, 674-75 (E.D. Pa. 2019). End-Payor Plaintiffs include health insurers and health plans that were overcharged for their purchases of Niaspan and generic Niaspan. *See* A74. Only End-Payor Plaintiffs' claims are at issue here.

End-Payor Plaintiffs allege that Defendants' anticompetitive, "reverse payment" agreements extended the brand-name monopoly over the Niaspan market, unlawfully delayed the entry of the less expensive generic, and caused them to pay hundreds of millions of dollars in overcharges, violating certain state antitrust and consumer protection laws. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 745-46 (E.D. Pa. 2014). This appeal arises out of the district court's denial of class certification to the putative class of end payors.

B. Legal Framework

Federal Rule of Civil Procedure 23(a) has four requirements for class

certification: numerosity, commonality, typicality, and adequacy. A class must also meet one of three requirements in Rule 23(b). Here, End-Payor Plaintiffs seek certification under Rule 23(b)(3), requiring them to show predominance and superiority, *i.e.*, that "questions of law or fact common to class members predominate over" individual questions, and that a "class action is superior to other available methods" for resolving the controversy. Fed. R. Civ. P. 23(b).

Beyond these explicit requirements, this Circuit requires putative class plaintiffs to meet the "implicit" requirement that the class is "ascertainable," meaning "the class is defined with reference to objective criteria" and there is "a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition." *Byrd v. Aaron's, Inc.*, 784 F.3d 154, 161-63 (3d Cir. 2015).

Under Circuit precedent, plaintiffs need not be "able to identify all class members at class certification—instead, a plaintiff need only show that class members *can* be identified." *City Select Auto Sales, Inc. v. BMW Bank of N. Am., Inc*., 867 F.3d 434, 439 (3d Cir. 2017) (quotation marks omitted; emphasis in original); *see also Carrera v. Bayer Corp.*, 727 F.3d 300, 308 n.2 (3d Cir. 2013). A class is ascertainable even when "some level of inquiry [is] required to verify that a person is a member of a class." *Byrd*, 784 F.3d at 170. The class certification question thus boils down to whether end payors—*i.e*., the insurers and health plans

that paid for Niaspan on behalf of their beneficiaries—*can* be identified "without extensive and individualized fact-finding or 'mini-trials.'" *Carrera*, 727 F.3d at 307. The Court has never indicated that ascertainability requires plaintiffs to produce a conclusive list of class members at any point in the litigation.

C. Prescription Drug Plan Overview

1. To understand the contours of the putative class and the role of end payors, it helps to explain how different actors participate in facilitating payments for prescription drugs. Most consumers in the U.S. have some type of prescription drug coverage. *See* Kaiser Family Foundation, *Health Insurance Coverage of the Total Population 2019*, https://www.kff.org/other/state-indicator/total-population/ (listing number of Americans with health coverage from different sources). Typically, when a consumer with such coverage presents a prescription at a pharmacy, the consumer will pay a small share of the cost (called a co-pay or coinsurance, set by the terms of their health plan), and the remainder will be paid by an end payor, such as a health insurer or the consumer's health plan. *See* A248-A249 (Supplemental Expert Declaration of Plaintiffs' Expert Laura R. Craft ¶9, fig. 1 (Aug. 25, 2020), Dkt. No. 722-8 ("Craft Supplemental")) (describing how pharmacies determine how much is due from consumers and their health plan before filling a prescription).

2. Three kinds of insurance coverage matter here: (a) government programs like Medicare or Medicaid; (b) individual (or "non-group") coverage, for example a

policy that a consumer purchases directly from an insurer on one of the health insurance exchanges created by the Affordable Care Act; and (c) group coverage, which is typically sponsored by employers or affiliation groups. *See* Kaiser, *Health Insurance Coverage*, *supra*. Group health plans, in turn, can be categorized as fully-insured or self-funded.[2]

When an employer sponsors a fully-insured health plan, the employer pays premiums to an insurer like Aetna or Blue Cross, and the insurer bears all financial responsibility for payments for the plan beneficiaries' prescription drugs (minus beneficiary co-pays). A262 (Craft Supplemental ¶31); A327 (Dep't of Labor, Annual Report on Self-Insured Group Health Plans, at 4 (Mar. 2019), Dkt. No. 725-1 ("DOL Report")); SA459 (Supplemental Expert Report of Defendants' Expert Donald J. Dietz ¶29 (Nov. 6, 2020), Dkt. No. 726 ("Dietz Supplemental")). The insurer is thus the end payor for the drug costs incurred by plan beneficiaries, and therefore a class member; the fully-insured plan sponsor makes no payments for drugs, is not an end payor, and is not in the class.

[2] Like private-sector plans, government programs can also be fully-insured or self-funded. Tricare is the federal government's self-funded health coverage for members of the military; claims are paid from appropriated funds. A265 (Craft Supplemental n.76). Medicare's prescription drug benefit for seniors (often called "part D"), in contrast, is (with a narrow exception not relevant here) fully-insured because Medicare (along with seniors and sometimes their former employers) pays premiums to commercial insurers, and commercial insurers are financially responsible for paying for beneficiaries' prescriptions. *See* SA858, SA1010 (Deposition of Laura Craft 154:7-22 (Oct. 14, 2020), Dkt. No. 726 ("Craft Dep."); Craft Reply ¶13).

With a self-funded (or "self-insured") health plan, the employer itself pays for its beneficiaries' prescription drugs (again minus the co-pay). A327 (DOL Report at 4); SA459 (Dietz Supplemental ¶29). In that case, the health plan sponsor is the end payor. Health insurers and health plan end payors that make payments on behalf of consumers and make up the putative class are often collectively called "third-party payors."[3]

3. Third party payors like those in the class generally contract with PBMs to administer their drug benefits. PBMs "are a little-known but important part of the process by which many Americans get their prescription drugs." *Rutledge v. Pharm. Care Mgmt. Ass'n*, 141 S. Ct. 474, 478 (2020). When a consumer presents a prescription, "the pharmacy checks with a PBM to determine that person's coverage and copayment information." *Id.* If the prescription is covered, the PBM transfers the health insurer or health plan's share of the cost to the pharmacy. *See id*.

D. Initial Motion for Class Certification

In 2018, End-Payor Plaintiffs moved to certify a class that included not only health insurers and self-funded health plans, but also consumers, with four sub-classes and ten exclusions, including an exclusion for fully-insured plans (because

[3] Consumers can also be end payors if they are uninsured or their plans require them to pay the full price (up to their deductible) or a share of drug costs through co-pays and coinsurance. The proposed end-payor class here does not include consumers. *See* p. 11, *infra*.

they do not pay the prescription drug claims made by their beneficiaries). A5-A7.

For this initially proposed class, the district court found that while Rule 23(a) was satisfied, the End-Payor Plaintiffs had not established Rule 23(b) predominance, largely due to the presence of potentially uninjured consumers in the class. A61. The court also held that insufficient analysis of variation in applicable state laws raised predominance and superiority concerns. A66-A69.

As for ascertainability, the district court concluded that this initially-proposed class was defined by reference to objective criteria, A26, and that PBM data from which class members could be identified was obtainable, A31 ("[T]he necessary records of brand and generic Niaspan purchases can be obtained."). But the court expressed concerns about the proposed methodology for identifying class members and, in particular, the feasibility of applying three exclusions. A34. Specifically, government plans were not necessarily facially obvious, *id.*; it was unclear whether an IRS form (Form 5500) could be used to apply the exclusion for fully-insured health plans, A35-A36; and there was insufficient evidence that a certain exclusion specific to consumers could be applied, A36-A37. For these reasons, the district court denied class certification without prejudice to a renewed motion. A70.

E. Renewed Motion for Class Certification

1. Overview of End-Payor Plaintiffs' Narrowed Class

To address the issues identified in the initial class certification denial, End-

Payor Plaintiffs filed a renewed motion for class certification with a significantly narrowed class definition, including only third-party end payors, not consumers. A74. The narrowed class thus excluded the potentially uninjured consumers that the district court had earlier found presented a predominance problem. *See* A61. End-Payor Plaintiffs also withdrew more than half of the state law claims that had previously raised predominance and superiority concerns for the district court. A74-A75.

On ascertainability, End-Payor Plaintiffs' renewed motion simplified the class definition and expanded on the methodology for how class members could be identified. Under this simplified class definition, the number of exclusions was reduced from ten to six. A74. Defendants did not dispute that the class was defined by reference to objective criteria and challenged the administrative feasibility of only two exclusions: the exclusions for certain state and federal government entities and for fully-insured health plans. A78-A79.

End-Payor Plaintiffs' ascertainability evidence included declarations from PBMs regarding their records, A343-A361; a declaration about the cost of PBM data, A292-A298; claims data produced for the named Plaintiffs by their PBMs, *e.g.*, SA989-SA992; a sample of claims data produced by the PBM OptumRx, SA408-SA411, SA1079 (examples); and the expert opinions of Laura Craft, SA700-SA704 (Expert Declaration of Plaintiffs' Expert Laura R. Craft (Oct. 19, 2018), Dkt. No.

726 Ex. 5 ("Craft Declaration")), A241-A291 (Craft Supplemental), SA705-SA940 (Craft Dep.), and SA998-SA1025 (Expert Reply Report of Laura R. Craft (Jan. 6, 2021), Dkt. No. 751-2 ("Craft Reply")).[4]

Laura Craft is President of OnPoint Analytics, Inc., an economic and financial consulting firm specializing in data analytics for complex litigation. SA700 (Craft Declaration ¶2). OnPoint has extensive experience working with insurance and claims processing data for prescription drugs, including data from PBMs. SA700-SA702 (Craft Declaration ¶¶3, 5). Craft has provided expert testimony in multiple cases about how to identify class members in similar end-payor classes. A244 (Craft Supplemental ¶3).

Craft estimated that after PBM data was received, it would take OnPoint Analytics approximately two months and $250,000 to combine and analyze the data to produce a list of class members. A272 (Craft Supplemental ¶48). By comparison, the End-Payor Plaintiffs suffered between $320 million and more than $1 billion in overcharges. Expert Report of Meredith Rosenthal, Ex. 1 to Supplemental Declaration of Meredith Rosenthal, Att. C.10.d (p. 159), Att. C.11.d (p. 186), Att. C.12.d (May 31, 2018), Dkt. No. 722-7.

[4] PBMs charge nothing or only a minimal fee (for example, $1800) to produce their data, and doing so takes approximately three months. A293.

2. End-Payor Plaintiffs' Evidence Describing Prescription Drug Transaction Data

Craft described in depth the prescription drug transaction records that the district court had previously found obtainable, A31.

a. Each time a prescription is filled, data must be exchanged quickly between the pharmacy and the PBM in a claims adjudication process to determine plan coverage, how much the pharmacy should charge the consumer as a co-pay, and how much will be covered by the consumer's prescription benefit plan. A248 (Craft Supplemental ¶9). For that to happen in real-time, data for each transaction is exchanged in a standardized format developed by the National Council for Prescription Drug Programs (NCPDP) and mandated by federal law. A248-A250 (Craft Supplemental ¶¶9-12 & fig. 1). This standardized data exchange contains information specifying the patient, the prescription, the pharmacy, the price, and how it is split between the consumer and the consumer's plan. *Id.* It also allows the plan's share of the cost to be traced to the third-party end payor that is ultimately responsible for paying it, whether that is an insurer or a self-funded plan. *Id*.

The same NCPDP data fields that allow for routing a claim to the appropriate third-party end payor contain codes that are linked in PBM databases to names, descriptions, and further electronic information about the payor. A254-A255 (Craft Supplemental ¶¶17-19); SA1001-SA1003 (Craft Reply ¶¶3-5); A349, A351 (declarations from PBMs that they have "readily accessible records … by which

third-party payors … can be identified on every purchase of Niaspan and Generic Niaspan that [the PBM] adjudicates on behalf of its third-party payor clients."); SA979-SA980 (Deposition of Donald Dietz 101:9-20; 102:5-103:1 (Dec. 7, 2020), Dkt. No. 734-2 ("Dietz Dep.")). The claims data produced by PBMs for the named Plaintiffs included such additional payor-information fields. SA1001 (Craft Reply ¶4); *see, e.g.*, SA990 (listing "City of Providence" as "carrier"); SA992 (same for "Painters District Council Local 30").

b. PBMs typically process transactions on behalf of insurers and self-funded health plans that contract directly with them. But some end payors contract with intermediaries called third party administrators (TPAs) to administer their benefit programs, and then the TPA, not the end payor, may be the one to contract with the PBM. SA458-SA459 (Dietz Supplemental ¶28). When a division of a health insurance company provides such claims administration services, the claims-administering entities are called "administrative services only" entities (ASOs). *Id.*; SA1009-SA1010 (Craft Reply ¶13).

The parties agree that PBM data includes the end payors for each transaction; the dispute is whether the end payors can be distinguished from intermediaries by the PBM data alone. But there is no dispute that the PBM data allows the end payor to be identified from either the PBM data or the PBM data supplemented by information from intermediaries. For business necessity, PBMs maintain and organize their data

in a way that allows each transaction to be associated with the ultimate end-payor health insurer or self-funded plan responsible for paying for it. *See, e.g.*, A254-A255 (Craft Supplemental ¶17-19); SA977-SA978 (Dietz Dep. 93:23-94:12) ("Q. So the group number needs to be transmitted from a PBM to an ASO in order for the ASO to know who to bill for a given transaction, correct? … It can vary with client to client … but a group number would be an example of a data element that could be used …."). As Craft explained, the prescription drug business demands that each transaction be traceable to an end payor at the time the pharmacy permits someone to walk out the door having paid only a co-pay. A254 (Craft Supplemental ¶17). No PBM would transfer funds to the pharmacy if it did not know precisely who was responsible for paying for the prescription, and no TPA or ASO would permit a PBM to transfer funds on behalf of its client unless the claims data it received from the PBM made it possible automatically to bill and collect from the correct client, i.e., the end payor class member. *See id.*

c. Because the PBM industry is highly concentrated, this comprehensive prescription payment data is available from a small number of sources. Seven PBMs processed 89-96% of prescription transactions in 2015 through 2018, with the remainder being cash transactions involving uninsured consumers (who are not part of the putative class) or transactions processed by smaller PBMs. A251 (Craft Supplemental ¶13). PBMs maintain claims data for a long period of time, due to

contractual and regulatory data retention requirements, the commercial value of the data, and for other business reasons. A253 (Craft Supplemental ¶15); SA1005-SA1006 (Craft Reply ¶8).

3. End-Payor Plaintiffs' Evidence that Class Members Can Be Identified

Craft explained how class members (the end-payor insurers and self-funded health plans) could be reliably and feasibly distinguished from other entities that may appear in the data, but are not class members, such as fully-insured health plans (where health insurers are the end payors) and intermediaries like TPAs and ASOs.

a. It is undisputed that PBMs can identify the direct clients associated with a transaction, *i.e.*, the entity that they bill when they make a payment to a pharmacy. A343-A352 (PBM declarations); SA458 (Dietz Supplemental ¶27). PBMs' direct clients do *not* include plan sponsors that offer only fully-insured health plans, because fully-insured plan sponsors do not pay for covered prescription drugs (the insurer does). A262-A263 (Craft Supplemental ¶31-33). For fully-insured plans, the insurer is the PBM's client. *Id.*

b. Defendants' principal quarrel with use of the PBM data below was on the purported intermediary confusion issue; *i.e.*, how PBM data might fail to identify class members when the PBM's client is an intermediary TPA or ASO, and the insurer or self-funded class member is the TPA or ASO's client, but did not contract directly with the PBM. Defendants' expert Donald Dietz opined that the identity of

the class member "may not be determined" in the PBM data when plans "use an intermediary to help them process their prescription drug benefits." SA459-SA460 (Dietz Supplemental ¶30). Dietz posited that when the claims data refer to both an insurance company and a health plan, it might be unclear whether the insurance company is acting in an ASO role (in which case the plan is self-funded and is the class member) or as an insurer (in which case the plan is fully-insured and the insurer is the class member). *Id.* In other words, the claims data might be over-inclusive to the extent that it identifies two entities that could potentially be payors with respect to a transaction without facially making clear which one of them is the actual end payor and class member. Plaintiffs, however, introduced evidence that PBMs could identify the end payors for transactions involving intermediaries, and that even if not, it was a small and surmountable issue.

(1) Only a small subset of the data could possibly present the potential intermediary-confusion issue. First, Dietz raises the issue only for private sector group coverage, *i.e.*, coverage sponsored by an employer, union, or similar plan sponsor. *See* SA459-SA461 (Dietz Supplemental ¶¶30-32). For the fully-insured Medicare market—which based on the OptumRx data reflects more than half the transactions at issue—there is no evidence that TPAs or ASOs are involved; the insurer is the only payor reflected in the PBM data. SA1010 (Craft Reply ¶13). These plans and other non-group, fully-insured plan types where the insurer class member

is clearly identified as the payor can be easily filtered.[5]

That leaves fewer than half of the transactions in the data involving employer (or other plan sponsor) coverage. For those, Dietz identified potential confusion only when a self-funded plan uses an administrative intermediary. SA459-SA450 (Dietz Supplemental ¶30).[6] But fewer than 10% of employers are both self-funded and potentially use an ASO or TPA: The vast majority of employer prescription drug plans (88%) are fully insured. A262 (Craft Supplemental ¶31). Taking the remaining prescription drug plans (12%) as self-funded, Dietz opined that between 38% and 55% of employers engaged a TPA or ASO from 2013 to 2017. Multiplying the percentage of self-funded employers by the posited percentage that engages TPAs or ASOs works out to between 4.5% and 6.6% of plans that could potentially generate the confusion Dietz identified, as depicted in the following chart:[7]

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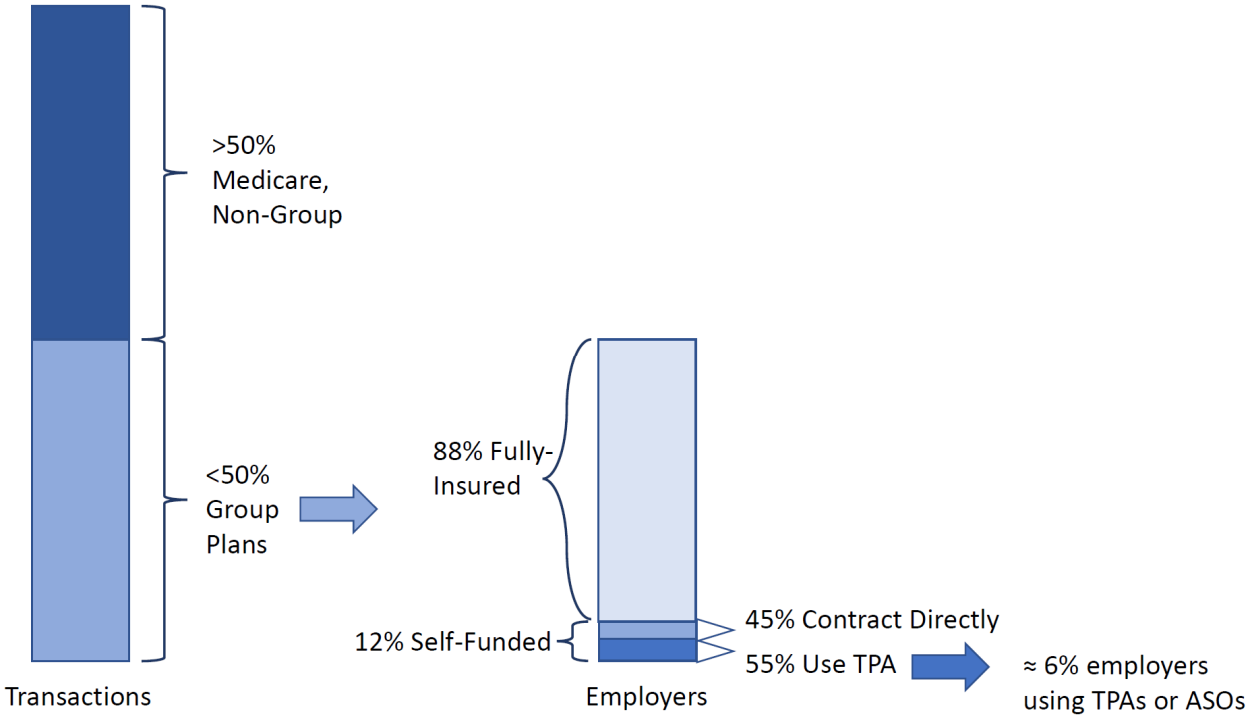
[5] Craft explained that PBM data includes a field that identifies, among other plan types, health marketplace exchange plans, fully-insured Medicare plans (Medicare Advantage and prescription drug plans), and fully-insured Medicaid managed care plans. A265-A266 (Craft Supplemental ¶37); SA749-SA750; SA858; SA870-SA872 (Craft Dep. 45:15-46:2; 154:7-22; 166:11-168:24); SA1016 (Craft Reply n.54).

[6] Dietz opined that both fully-insured and self-funded plans could choose to work with "an intermediary." Fully-insured plans' intermediaries are insurance companies, not TPAs or ASOs. *See* A262-A263 (Craft Supplemental ¶31). As Craft explained, Dietz erred when he concluded that TPAs operate as insurers or administer claims for fully-insured plans. SA1010 (Craft Reply ¶14). For fully-insured plan sponsors, TPAs offer insurance brokerage services, *i.e*., help employers choose which insurance product to buy. *See id.*

[7] Dietz opined that a second type of intermediary could make it difficult to identify class members: when a large PBM adjudicates claims on behalf of a smaller PBM.



(2) For the less than 10% of plans where the choice between two possible end payors could arise, Craft offered a multi-layered method to identify end payors.

First, PBMs can identify the ultimate payor. SA816 (Craft Dep. 112:8-18) ("Q. So you're saying that in collecting … the PBM data … from the PBMs, they would just be asked to identify in the claims payment data in each instance who is the third-party payor. A. Exactly. They could easily do that."). PBMs collect data on the ultimate payors when setting up client accounts, including asking whether their client is a TPA or ASO acting as an intermediary on behalf of another payor.

SA462 (Dietz Supplemental ¶33). These transactions are easy to identify given the limited number of PBMs. *See* SA487 (Dietz Supplemental ¶71). Craft examined OptumRx transactions involving a smaller PBM and found that the claims data also identified the class member payor. SA1006-SA1007 (Craft Reply ¶9 & tbl. 1).

SA1002-SA1003 (Craft Reply ¶*5*); SA810-SA811; SA825-SA829 (Craft Dep. 106:7-107:16; 121:12-122:1; 122:18-123:11; 124:7-125:2) ("[I]n those exceptions where you've got an ASO or TPA, the PBM knows which – which plans those are.").

Collecting such information is a business necessity; PBMs need to "be able to track their customers in this way and know . . . where their business is coming from and which entities it's coming from." SA818 (Craft Dep. 114:10-14); SA1002-SA1003 (Craft Reply ¶5). As Dietz explained:

> I would suspect—and this is just based upon my years of experience in the industry—that, you know, the PBM may ask and they may want to know to help from their financial security as to are they dealing directly with someone responsible, or is it the responsible party down the road? So it may help making business decisions, such as do you keep money on file or … that would be up to the PBM to decide.

SA982 (Dietz. Dep. 113:10-21). Dietz disputed that ASOs and TPAs were always willing to provide information about their clients to PBMs. SA982 (Dietz Dep. 110:19-111:11). But the record shows the information is available. For example, named Plaintiff (and self-funded plan) A.F. of L. – A.G.C. Building Trades Welfare Plan obtained records of its Niaspan transactions from PBM Prime, even though it uses an intermediary and does not contract with Prime directly. *See* SA989; SA1011-SA1012 (Craft Reply ¶15).

Second (and relatedly), PBMs know when their client is an ASO or TPA rather than an end payor. SA831-SA832 (Craft Dep. 127:13-128:9). Due to distinct regulatory requirements, health insurance companies must separately track fully-

insured accounts (for which they provide health insurance and therefore take the risk) and self-funded accounts (for which they are not providing insurance and receive fees for administration services only). SA1009-SA1010 (Craft Reply ¶13). PBM data is designed to facilitate that segregation. *Id*.

PBMs can thus produce a separate list of transactions *not* involving TPA/ASOs (for which the PBM client will be the class member, absent other exclusions not in dispute) and a list of the remaining transactions, involving TPA/ASOs. SA832-SA833 (Craft Dep. 128:1-129:17). PBMs also organize their data systematically in a "hierarchy." SA1001-SA1002 (Craft Reply ¶4); SA819-SA820 (Craft Dep. 115:12-116:16); SA979 (Dietz Dep. 98:2-99:16). Craft explains how that hierarchy can typically be used to identify the class member for each type of transaction (indicated by bold; hypothetical names in italics):

	"Carrier" or "Client" field	"Account" field	"Group" field
Intermediary contracts with PBM	TPA/ASO *Best Administrators*	**Self-funded plan** (account or group) *Widget Co.*	
	TPA/ASO *Best Administrators*	**Insurer** *Acme Health*	Fully-insured sponsor *Building Inc.*
End payor contracts directly with PBM	**Insurer** *Acme Health*	Insurance product or fully-insured sponsor *Acme PPO Gold*	Fully-insured sponsor (if not in account) *Manufacturers Etc.*
	Self-funded plan *Big Box Stores*	Plan type or network provider *PPO Silver*	

See SJA1010-SA1012 (Craft Reply ¶¶14-15).

Transactions involving TPAs and ASOs can also be filtered through use of codes, with the proper class members identified through straightforward database management techniques such as querying, sorting, and matching. For example, because some large ASOs are identified by recognizable codes, querying and sorting by those codes customarily confirms that the entity listed in the "client" field is an ASO, and the class member end payor is the other entity listed in the data (in the "account" or "group" fields). *See* SA1012-SA1013 (Craft Reply ¶16).

Third, after these cross-cutting and streamlined data sorting methodologies have been applied, if any transactions remain with room to doubt which named entity in the data is the actual payor (and thus the class member), a one-question form affidavit, verifiable by existing business records, could resolve such doubt. End-Payor Plaintiffs proposed using such an affidavit as a final backstop for their methodology. *See* SA997; SA1074, SA1076.

(3) Responding to challenges raised by Defendants' expert Dietz, Craft parsed 22 example transactions to demonstrate how class members could be identified assuming that the PBM had not itself already identified the end payor in its data production (the first-line option). Dietz had identified three entities listed in the "carrier" field in the sample OptumRx data where he thought it unclear if the entity was acting as a TPA/ASO or as an end-payor insurer. SA470-SA472 (Dietz Supplemental ¶46). Craft examined 16 example transactions involving the three

entities identified by Dietz and identified all of them as involving self-funded plans, establishing Dietz's three entities as TPAs and identifying the class members. SA1010-SA1011 (Craft Reply ¶14 & tbls. 2-4). For six HMO examples from the OptumRx sample data, Craft similarly classified four as involving fully-insured plans (and identified the related insurer class member) and two as involving self-funded plans. SA1012 (Craft Reply ¶15 & nn.39-40).

4. Craft's Opinions on Government Plans

In addition to describing how to handle the fully-insured plan exclusion, Craft explained several alternative (and similar) methodologies for applying the exclusion for state and federal government entities, which the district court accepted. A82-A83; A264-A268 (Craft Supplemental ¶¶35-40); SA1013-SA1019 (Craft Reply ¶¶17-23). Craft explained that PBMs track different plan types using specific codes. A265-A266 (Craft Supplemental ¶37). Just as PBMs can flag for exclusion intermediary clients when producing data, SA832-SA833 (Craft Dep. 128:1-129:17), so too can they flag state or federal government entities, A265 (Craft Supplemental ¶36). Craft also explained that commercially-available lists of government plans can be cross-referenced with the PBM data using name matching algorithms. A266-A268 (Craft Supplemental ¶¶38-39); SA892 (Craft Dep. 188:5-9).

F. District Court Decision

Without holding a hearing, the district court denied End-Payor Plaintiffs' renewed motion for class certification, despite End-Payor Plaintiffs' request for an evidentiary hearing given the array of new issues addressed in the expert opinions on ascertainability. *See, e.g.*, Renewed Mot. for Class Certification, Dkt. No. 722-1, at 25 (Sept. 4, 2020) ("Renewed Mot.").

The district court reaffirmed that End-Payor Plaintiffs satisfied Rule 23(a) requirements. A77. The court also concluded that the first ascertainability requirement—objective class definition criteria—was again met. A78. Defendants did not dispute that PBM data included all class members, arguing only that it was not feasible to apply two of the six exclusions. A79. As for the first objection involving the exclusion for state and federal entities, the district court held that End-Payor Plaintiffs had established a reliable and administratively feasible method, crediting Craft's evidence that PBMs can exclude state and federal government payors before producing data. A82-A83.

The district court nonetheless denied class certification, on the sole basis that End-Payor Plaintiffs had not established an administratively feasible methodology for applying the single (of six) remaining exclusion—for fully-insured plans.[8]

[8] The district court did not reach Defendants' arguments about predominance or superiority, or that analyzing PBM data would be too costly. A89.

Stating that End-Payor Plaintiffs "must prove that identifying class members will not require 'individualized fact-finding," A87, the district court found they had not met that standard. *See* A89 ("EPPs have not shown they can identify, without individualized inquiry, the TPP class members[.]").

In reaching this result, the district court focused on two of the twenty-two examples discussed in Craft's reply report. Specifically, Craft had identified Mitre Corporation and Target as fully-insured drug plans (and thus excluded from the class) based on OptumRx data from 2012. Defendants suggested that Craft was wrong and that both companies self-funded their drug plans (and therefore were class members), relying on public documents that either post-dated the OptumRx transactions by several years or referred only to medical and dental benefits (not prescription drugs). A86. The district court nonetheless concluded that these documents were sufficient proof that Craft's methodology would require individualized fact-finding, and therefore ascertainability was not administratively feasible. A87.

SUMMARY OF ARGUMENT

Under this Court's precedents, ascertaining membership in this class is administratively feasible and the district court abused its discretion in concluding otherwise. Readily obtainable, comprehensive, and objective data exists for every single relevant prescription drug transaction—data that includes every class member

and is maintained by neutral third parties for business purposes.

This Court's criteria for administrative feasibility is satisfied by the availability of such rich and well-organized data together with Plaintiffs' methodology that includes three mutually-reinforcing layers—(i) PBMs identify class members in the first instance when providing the data; (ii) data is cost-efficiently batch filtered and name matched with techniques that distinguish administrative intermediaries from end-payor class members; and (iii) if any lingering confusion, the option remains for a single-question form affidavit to be sent to the two already-identified potential class members to confirm which is the end-payor class member.

This overalls, belt, and suspenders approach—using far more fulsome and robust data than this Court has seen in other ascertainability cases—readily establishes administrative feasibility, the only element of ascertainability in question here.

The district court erred by adopting a bright line rule that has no grounding in common sense or this Circuit's caselaw—that *any* potential individualized inquiry defeats class certification. A89. But case after case confirms that techniques far less sophisticated, working with data far less organized or complete, demonstrate administrative feasibility even with some degree of individualized inquiry. Neither potential class size nor the possible need for limited individual file review are

reasons to deny class certification, as long as class membership can be determined by something more than the potential class member's "say so." Here, business records provide much more than "say so."

Compounding the court's legal error was its confusion as to the state of the record and misunderstanding of Plaintiffs' proposed programmatic methodology. Plaintiffs' "overalls" approach—having PBMs identify the end payors when providing the data—demands no individualized inquiry at all. And Plaintiffs' first backstop "belt" approach—systematic data sorting and name matching within a robust data set—likewise is not a transaction-by-transaction individualized query, although the district court perhaps thought it was. Finally, Plaintiffs' "suspenders" failsafe—using simple single-question form affidavits to confirm class membership for one of two already identified entities—was ignored by the district court, even though it is objectively verifiable and a far simpler use of affidavits than this Court has already accepted in other cases.

What's more, the district court applied the wrong legal standard to judge whether the inclusion of non-class-member intermediaries in the data rendered it problematically over-inclusive. Under this Court's precedents, anything less than highly over-inclusive is acceptable, but the court demanded a "de minimis" or less level of over-inclusiveness. In applying this erroneous standard, and focusing myopically on only two examples, the district court misunderstood the record, and

greatly overestimated the likelihood of confusing administrative intermediaries for end payors.

These errors (separately, or together) constitute an abuse of discretion, and require reversal of the district court's finding that the class could not be certified due to lack of administrative feasibility. No other court (inside or outside the Third Circuit) has declined to certify a similar class when presented with the same type of data, the same methodology, and the same expert. The plethora of cases going the other way shows that classes like this one can be certified in a manageable and administratively feasible fashion.

To uphold the district court's decision here would significantly raise the bar on this Court's administrative feasibility standard, which is already an outlier among the Circuits. The upshot would be to create a near-insurmountable obstacle to certifying large classes with comprehensive data—found nowhere in Rule 23—defeating the very purpose of the class action enterprise and warranting reconsideration of the Circuit's atextual ascertainability requirement.

ARGUMENT

I. STANDARD OF REVIEW

The Court reviews "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." *City Select*

Auto Sales, 867 F.3d at 438. The Court reviews de novo "the legal standard applied by the district court." *Id.*

II. THE CLASS MEETS EACH ASCERTAINABILITY CRITERION SET BY THIS COURT'S PRECEDENT.

This Circuit's "implicit" "ascertainability" requirement requires a showing "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." *Byrd*, 784 F.3d at 162, 163. Because the parties and the district court agree the class here is defined by objective criteria, A78, the only issue on appeal is administrative feasibility.

Although "rigorous," the administrative feasibility analysis must not be "too exacting" nor "essentially demand[] that [plaintiffs] identify the class members at the certification stage." *Hargrove v. Sleepy's LLC*, 974 F.3d 467, 477, 480 (3d Cir. 2020). Rather, plaintiffs need only show that it is *possible* to identify class members. *Id.* at 479-80. Specifically, plaintiffs must: (i) identify reliable evidence and (ii) explain how such evidence can be used to identify class members without resorting to "extensive and individualized fact-finding." *Id.* at 478, 480. End-Payor Plaintiffs' evidence here exceeds what Circuit law requires on both counts.

A. The Class Exceeds the Circuit's Ascertainability Criteria.

1. Comprehensive, Reliable Records Identify Class Members.

Federal law mandates a standardized record for every prescription drug

transaction. A250 (Craft Supplemental ¶11). This transaction record, together with linked PBM client data, identifies the responsible end-payor class member. A254-A255 (Craft Supplemental ¶¶17-19); SA1001-SA1003 (Craft Reply ¶¶3-5). PBMs declared that they have "readily accessible records … by which third-party payors … can be identified on every purchase of Niaspan and Generic Niaspan that [the PBM] adjudicates on behalf of its third-party payor clients." A349, A351. The district court found that PBMs possess this data and can produce it. A31 ("[T]he necessary records of brand and generic Niaspan purchases can be obtained."). And Plaintiffs produced example data. SA989-SA993 (named Plaintiffs' data); SA408-SA411, SA1079 (example claims from OptumRx data sample).

This evidence exceeds the records establishing ascertainability in other Third Circuit cases. In *Byrd*, the Court considered the ascertainability of a class of individuals who leased and used rental computers that surveilled them with spyware. 784 F.3d at 159-60 & n.3. The rental companies' business records identified each transaction and some of the class members (the lessees), but not the lessees' household members (who also used the computers). *Id.* at 169. The Court held that *unspecified* records could be used to identify the rest of the class (lessees' household members), even though plaintiffs submitted "no evidence as to them," *Hargrove*, 974 F.3d at 480 (discussing *Byrd*). In contrast to Plaintiffs here, the *Byrd* plaintiffs did not explain step by step how these unspecified records could be matched to the

lessees, and they did not supply an expert who developed an identification methodology. In *Byrd,* it was enough that the Court "could imagine the types of evidence that could be identified and used to link the existing class members to household members." *Id.*

There is no need to imagine here; as in *Hargrove*, this case is "stacks away from . . . a dearth of documents." *Id.* And the data here is even stronger than in *Hargrove*, where the records were "incomplete" but the Court nonetheless held that collating the various records "together with the affidavits" could be used to identify class members. *Id.* Here, the records are complete—they contain the identities of every class member. A254-A255 (Craft Supplemental ¶17-19). The only question is whether a small subset of those records might identify two entities, only one of whom is the class member, in a way that will cause unmanageable confusion. The answer is no. *See* pp. 32-35, *infra.*

The comprehensive dataset available here is an even further cry from the data available in cases where classes flunked ascertainability. In *Carrera* there was "no evidence that retailers even ha[d] records for the relevant period" documenting over-the-counter supplement purchases, or "that a single [class member] could be identified using records." 727 F.3d at 309. Records were similarly deficient in *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 356 (3d Cir. 2013), where "Wal-Mart lack[ed] records that are necessary to ascertain the class," and *Marcus v. BMW of N.*

Am., LLC, 687 F.3d 583, 594 (3d Cir. 2012), where "defendants' records would not indicate whether all potential class members' [tires] 'have gone flat and been replaced,' as the class definition require[d]." Here, in contrast, reliable data records each Niaspan purchase in a manner that permits health insurer and self-funded health plan end-payors to be identified. As in *Hargrove*, "the ascertainability standard [has been] satisfied in cases in which plaintiffs submitted far less evidence." 974 F.3d at 480.

2. It Is Administratively Feasible to Identify Class Members from the Available Records.

Every day, the data described above is used to ensure that prescription drug claims are paid by the responsible end-payors—health insurers and self-funded health plans—regardless of how many intermediaries are involved along the way. Craft's expert methodology confirmed how the data can feasibly be used to identify those same end-payors without "extensive and individualized fact-finding." *Hargrove*, 974 F.3d at 478.

For starters, no individual review is required because PBMs can identify the end-payors when they produce the data. SA816 (Craft Dep. 112:8-13). Under this "overalls" approach, no individual inquiry or data matching is required; like the lessees in *Byrd* whose names were listed on the defendants' rental records, 784 F.3d at 169, the class members are identified by the PBM records.

As a "belt" back-up for the manageable roughly 6% of employers where

questions might arise about which of two entities is the correct class member, Plaintiffs showed how automated data matching will identify the payor in a process significantly less individualized than approaches this Court has previously deemed feasible. In *Byrd*, the Court found ascertainable a class that required a truly individualized (as opposed to automated sorting) search of multiple different unspecified public records for each of 895 addresses to identify any "household member" residing at that address. 784 F.3d at 170. The member-by-member individual record review was even more complicated in *Hargrove*, requiring "thousands of pages of contracts, driver rosters, security gate logs, and pay statements" to be matched up for each driver to identify, in conjunction with their testimony, which drivers "work[ed] exclusively for [the defendant] full-time." 974 F.3d at 470.

In contrast, here, there is no need to manually line up several different types of records; electronic database management techniques facilitate ready class member identification. PBMs could flag the approximately 94% of employers where the payor contracts with the PBM directly. *See* p. 18, *supra*; SA832-SA833 (Craft Dep. 128:1-129:17). In those cases, the class member (self-funded plan or insurer) can be gleaned directly from the PBMs' "client" fields. In the remaining subset involving the roughly 6% of employers that use ASO and TPA intermediaries, recognizable data patterns permit the class member to be pulled from the "account"

or "group" fields. *See* p. 21, *supra*. Even if a PBM did not separately flag these ASO/TPA transactions, electronic filtering and name matching will distinguish between intermediary and non-intermediary transactions; PBMs' coding can differentiate fee-only ASOs from true end payors, SA1012-SA1013 (Craft Reply ¶16), and name matching against lists of known intermediaries can filter out non-class members, *see* A892 (Craft Dep. 188:5-9) (describing how methodology implicitly uses name matching algorithms). Either way, Craft could do this work for minimal cost in a few months. *See* A272 (Craft Supplemental ¶48).[9]

Finally, the "suspenders" back-up layer of Plaintiffs' methodology is a one-question affidavit—easily corroborated by objective records—that dispels any doubt about class membership in the handful of situations where questions might remain. It could be as simple as asking:

> Is this entity responsible for payment with respect to each of these transactions (i.e., acting as an insurer or self-funded plan sponsor), or is it acting as an intermediary (Third Party Administrator or Administrative Services Only) on behalf of the payor?
> Check one: ___ payor ___intermediary

Circuit law allows this type of simple, verifiable query. "Affidavits, in combination with records or other reliable and administratively feasible means, can meet the ascertainability standard." *City Select Auto Sales*, 867 F.3d at 441. In *City*

[9] Although Defendants' expert Dietz disputed how much it would cost to obtain the data from the PBMs, he had no basis to question Craft's estimate regarding her own analysis. SA974 (Dietz Dep. 36:4-12).

Select, affidavits were the *only* method for confirming class membership: Although a database reflecting all potential class member car dealerships existed, class membership could be verified only through affidavits confirming whether a given dealership received one of the more than 20,000 unsolicited faxes. 867 F.3d at 437, 442. Use of affidavits to confirm information, or fill gaps, within other records is also allowed. *See Hargrove*, 974 F.3d at 480 (finding class ascertainable where "multiple sets of evidence" had to be "matched with and verified by the putative class members' affidavits").

Only where plaintiffs rely "solely on unverified affidavits," such that "the only proof of class membership [is] the say-so of putative class members," does use of a form or affidavit pose "serious administrative burdens." *Byrd*, 784 F.3d at 170-71. But here the yes/no inquiry is readily verifiable by objective records. It is also much more manageable than in *Byrd* or *Hargrove* because it is more discrete and applies to only a small subset of transactions where the class member is already listed.

In sum, these three mutually reinforcing identification tools—PBM identification; database name-matching and filtering; and, where selectively needed, a simple single-question affidavit—more than satisfy this Circuit's implicit administrative feasibility requirement.

B. The District Court Abused Its Discretion in Holding the Class Was Not Ascertainable.

1. The District Court Wrongly Held that Any Individual Inquiry Was Excessive and Impermissible Individualized Fact-Finding.

The district court rejected ascertainability on the ground that End-Payor Plaintiffs "have not shown they can identify, without individualized inquiry, the … class members in Ms. Craft's examples, let alone the millions of transactions at issue in this case." A89. This ruling is both wrong on the law and "an improper application of law to fact" constituting an abuse of discretion. *City Select Auto Sales*, 867 F.3d at 438.

a. On the law, the district court misunderstood this Court's prohibition on "extensive and individualized fact-finding," *Marcus*, 687 F.3d at 593, concluding that it prohibits *any* individual inquiry. But if it were the case that "*no* level of inquiry as to the identity of class members can ever be undertaken," then "no Rule 23(b)(3) class could ever be certified." *Byrd*, 784 F.3d at 171.

As *Byrd* explained, "[t]here will always be some level of inquiry required to verify that a person is a member of a class …. Such a process of identification does not require a 'mini-trial,' nor does it amount to 'individualized fact-finding.'" 784 F.3d at 170 (quoting *Carrera*, 727 F.3d at 307). *Hargrove* approved matching multiple different record types with affidavits, driver by driver. 974 F.3d at 480. *Byrd* approved individual record searches, address by address. 784 F.3d at 170.

City Select approved individual "factual inquiry" by affidavit. 867 F.3d at 442. None of these cases required an expert methodology, let alone precise estimates of the time or cost involved, asking only for a description of what could be done. Simple steps, including those that require individual review to confirm status as a class member, are *not* impermissible individualized fact-finding.

In contrast, impermissible individualized fact-finding occurs when a defendant would be forced to either accept a class member's say so or conduct a mini-trial on complex factual issues for which no corroborating records exist, like whether a person owned particular tires that went flat and were replaced, *see Marcus*, 687 F.3d at 594, or bought a certain category of product and a service plan but did not receive any repairs from the store, *see Hayes*, 725 F.3d at 356. Asking an already-identified entity "Are you the payor or intermediary?", like "Did you receive one of these faxes?", is in a different category altogether. And, unlike the fax question, business records required by economic necessity are available to verify whether an already-identified entity is a class member or not.

b. The district court wrongly applied the law to the facts in concluding that Craft's methodology necessarily required impermissible individualized fact-finding.

First, in listing the methodologies proposed by Craft, the district court ignored or misconstrued several methods that require *no* individual review. Even though it recognized PBMs' capability to filter out government plans when they produce

records, A83, the district court ignored PBMs' similar capability to simply identify end payors. A815-A816, A831-A832 (Craft Dep. 111:14-112:18; 127:13-128:9). The district court ignored this "overalls" method altogether.

The district court further misdescribed Craft's methodology as relying solely upon the data elements PBMs exchange with pharmacies, A85, rather than complete PBM data which includes client account tables. This perhaps contributed to the court's failure to address record evidence that PBMs could systematically identify class members for each transaction.

Second, the district court wrongly classified Craft's methodology of identifying end-payors based on what "typically appears" in the data as individualized (or "ad hoc"), A86 n.8, when it is a generally-applicable programmatic methodology for identifying class members working with the typical structure of electronic PBM data. Categorizing transactions as involving TPA/ASOs (or having PBMs flag them) and then running a software program to compile a list of class members from the applicable fields (the "belt" methodology) is not an "ad hoc" individualized methodology that requires manual review of millions of transactions, as the district court suggests.

In contrast to matching up gate logs and pay stubs in *Hargrove*, for example, there is no need here to examine the drug transaction records of each potential class member individually. Rather, as Craft described, software can filter and process a

large batch of transactions encompassing multiple class members. A256-A262 (Craft Supplemental ¶¶21-29). The fact that the data follows a "typical" structure does not *detract* from feasibility; it adds to it. The "typical" nature of the available data here means the methodology is going to correctly identify class members most of the time because the data structure conforms to how Craft, based on years of experience in the industry (and successful contribution to the certification of many similar classes), knows the data can be used.

Finally, the court did not address Plaintiffs' proposal to use a simple form affidavit in the rare cases where it might be needed to confirm which of two potentials was correct. A88-A89. As described above, this discrete use of affidavits falls comfortably within the heartland of administrative feasibility. The district court wrongly described Plaintiffs as arguing "that it is sufficient for them to identify 'the only two potential class members,'" A88, when in fact Plaintiffs explained how affidavits could be used to select the single correct entity, *see* SA997, SA1074, SA1076. The district court's failure to recognize that such single-question affidavits (the "suspenders" failsafe) are an administratively feasible means to resolve the (rare) which-one-of-two question is yet another error with the court's analysis.

2. The District Court Applied the Wrong Over-Inclusiveness Standard.

Records can be over-inclusive if they include entities that are not part of the class. "While a high degree of over-inclusiveness" might prevent class certification,

"any degree of over-inclusiveness will not do so." *City Select,* 867 F.3d at 442 n.4. On the other hand, when records are *not* highly over-inclusive, the Court has suggested that ascertaining class members is necessarily administratively feasible *See id*. at 442 & n.4. What's more, so long as a method exists for identifying class members without extensive individualized fact-finding, even highly over-inclusive records do not defeat ascertainability. *See id.*

Here, the records are far from highly over-inclusive, with only about 6% of employer plans even raising the potential intermediary-confusion issue. And even if considered so, there is a three-layer methodology for identifying class members that does not require impermissible individualized fact-finding. The district court abused its discretion in implicitly concluding that over-inclusiveness defeated administrative feasibility.

a. The district court's implicit requirement that over-inclusiveness must be less than "de minimis,"—i.e., essentially nonexistent—A83, for a class to be ascertainable conflicts with Circuit law. Only a "high degree" of over-inclusiveness raises concerns for ascertainability, and even then, a class is ascertainable if there is a method of identifying class members from over-inclusive records without extensive individualized fact-finding. *See City Select*, 867 F.3d at 442. The district court got the legal standard flat wrong.

b. The district court also misjudged the degree of over-inclusiveness on the

facts. The over-inclusiveness of PBM data is de minimis *at most*, which should satisfy even the district court's erroneous over-inclusiveness standard.

Unlike *City Select*, there is no need here to sort through records that do not list any class member at all. Here, the claims data for each transaction includes the class member and identifies (at most) two entities that could possibly be the class member. The question of which of the two entities in the data is the class member arises seldomly, and if and when it does, PBMs can identify end payors, a capability the district court ignored.

Even putting aside PBMs' ability to identify end payors in their data, the potential over-inclusiveness remains extremely low. First, the intermediary-or-payor question arises only for non-Medicare group transactions, which are less than half of the transactions in the sample OptumRx data. The Medicare (and other non-group transactions) can be filtered out by plan type, a technique that the district court wrongly dismissed out of hand. A85. The court erroneously misunderstood the filtering methodology as applicable only to HMO plan transactions. *Id*. Not so. Filtering by plan type can help identify the payor in more than half the transactions, based on the OptumRx data. SA1010 (Craft Reply ¶13).[10] Within the remaining

[10] Craft initially stated that HMO plans could be categorized as fully-insured. SA857 (Craft Dep. 153:17-20). In her Reply Report, she clarified that HMOs could "support plan sponsors wanting to self-fund benefits." SA1012 (Craft Reply ¶15). The district court thus correctly found that filtering by HMO plan type does not conclusively identify fully-insured plans, A85, but that does not negate how plan-type filtering

minority of transactions, potential over-inclusiveness arises only when self-funded employers contract with TPAs and ASOs, which works out to roughly 6% of employers. *See* p. 18, *supra*.

Instead of applying the correct standard—whether there is a "high degree" of over-inclusiveness in the records and if so, whether the proposed identification methodology is highly individualized—the district court rested its erroneous too-over-inclusive holding in part on the fact that 88% of employers choose fully-insured plans. A84. But the fully-insured segment is where the intermediary confusion issue is not likely to arise. For sponsors of only fully-insured plans, insurer class members will be the PBM's readily-identifiable clients.

3. The District Court Wrongly Judged the Methodology Unreliable Based on Clearly Erroneous Conclusions About Two Examples.

The district court further abused its discretion in deeming Craft's methodology not only impermissibly individualized, but unreliable. The district court focused on two of twenty-two examples discussed by Craft: the identification of Target and Mitre as fully-insured plan sponsors, which Defendants claimed was in error. A86-A87. In concluding that these examples rendered Plaintiffs' methodology unreliable, the court both improperly applied the law and relied on clearly erroneous fact-finding. *Id.*; A88-A90.

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can be used to programmatically identify other large categories of fully-insured plans.

The district court abused its discretion by jumping to an unfounded unreliability conclusion based on two examples of transactions involving Target and Mitre prescription drug plans in 2012. Craft's analysis of the OptumRx data indicated that Target and Mitre were fully insured (and therefore not class members), with Kaiser subsidiaries as the payors. SA1012 (Craft Reply ¶15 & n.39). Defendants produced documents from 2017 (Mitre) and 2021 (Target) that they claimed showed that Target and Mitre were self-insured. SA334-SA340; SA343-SA346. But those documents said nothing about Target and Mitre's prescription drug plan funding status five or more years earlier when the 2012 transactions reviewed by Craft took place. Defendants also cited a Kaiser Self-Funded Plan Sponsor list from June 2012 and a Target 10-K from 2013, but neither document addressed prescription drug benefits (as distinct from medical). *See* SA341-SA342; SA347-SA348.

The district court also erred in effectively requiring Plaintiffs to disprove Defendants' hypothetical extrapolations *ex ante*. A86-A87. Disputes over class membership in two of twenty-two examples do not establish class-barring infeasibility. Defendants' critique shows at most that some small number of transactions may require simple, permissible individual inquiry, *e.g.*, affidavits sent to entities already identified in the data. Plaintiffs reiterated this approach when directed to respond to the examples. SA1074-SA1076. Plaintiffs did not obtain the

affidavits or subpoena other records because this Court has been clear that Plaintiffs "need not, at the class certification stage, demonstrate that a single record, or set of records, conclusively establishes class membership." *City Select*, 867 F.3d at 441. The district court abused its discretion by "essentially demand[ing] that [plaintiffs] identify the class members at the certification stage." *Hargrove*, 974 F.3d at 479.

C. District Courts Have Routinely Found Craft's Methodology Administratively Feasible.

The routine certification of end-payor pharmaceutical antitrust classes, relying on PBM data, reinforces the district court's error in rejecting administrative feasibility here. *See, e.g.*, *Sheet Metal Workers Local No. 20 Welfare & Ben. Fund v. CVS Pharmacy, Inc.*, No. 16-046 WES, 2021 U.S. Dist. LEXIS 93752, at *42 (D.R.I. May 11, 2021); *In re Suboxone*, 421 F. Supp. 3d 12, 72-73 (E.D. Pa. 2019).

In fact, multiple courts have found the *same* methodology, offered by the *same* pharmaceutical data expert, to be administratively feasible. *In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527 (S.D.N.Y. 2021), held that Craft's methodology, along with PBM data, "can be used to identify the ultimate payor of the claim." 338 F.R.D. at 549. The court explained how Craft's methodology, namely examining "the Carrier field" along with "other fields" and the transaction "identification numbers" in the PBM data, could "definitively determine the end payor." *In re Namenda Indirect Purchaser Antitrust Litig.*, No. 1:15-cv-6549 (CM) (RWL), 2020 U.S. Dist. LEXIS 247078, at *28-32 (S.D.N.Y. Dec. 18, 2020)

(*Daubert* opinion). Moreover, the court explained (as Craft did here) that PBMs knew which precise entities paid for the drug, so that "even if an individual analyzing the raw data had some difficulty analyzing the raw PBM data, the PBM itself would be able to provide the necessary information." *Id.* at *35-37.

Time and again, Craft's methodology has been deemed sufficient to certify a class. In *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294 (D. Mass. 2021), the court rejected defendants' argument that Craft could not distinguish between intermediaries (TPAs and ASOs) and "their self-funded plan clients," instead finding that Craft's proposed methodology sufficiently explained how "multiple data fields … can be used jointly to identify efficiently [] non-class members." *Id.* at 308; *see also, e.g.*, *In re Restasis (Cyclosporine Opthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1, 12-13 (E.D.N.Y. 2020). And in *In re Loestrin 24 Fe Antitrust Litig.*, 410 F. Supp. 3d 352 (D.R.I. 2019), after hearing expert testimony, the court held that Craft's methodology could show whether a plan is fully insured or self-insured. *Id.* at 399-401 & n.44. What's more, despite the district court's conclusion otherwise, A87, *Loestrin* appeared to be applying this Court's ascertainability standard. 410 F. Supp. 3d at 398-99 (citing *Carrera* and stating that the "putative class must demonstrate a methodology for distinguishing the injured from the uninjured purchasers that is … 'administratively feasible.'").

Similarly, in *In re Zetia Ezetimibe Antitrust Litig.,* No. 2:18-md-2836, 2020

U.S. Dist. LEXIS 183601 (E.D. Va. Aug. 13, 2020), the magistrate judge heard live testimony from the same experts (Craft and Dietz) and concluded that Craft's "methodology can identify and exclude fully-insured plans." *Id.* at *39-40. The court later determined that plaintiffs had shown "an administratively feasible method for identifying class members" because "Craft provided extensive and detailed testimony, which the court finds credible, regarding her ability to obtain relevant PBM data, standardize it, then identify class members and exclude non-members—all without the type of individualized inquiry that would make any proposed methodology unfeasible." *In re Zetia Ezetimibe Antitrust Litig.*, No. 2:18-md-2836, 2021 U.S. Dist. LEXIS 158073, at *27-30 (E.D. Va. Aug. 20, 2021).

It is of no matter that *Zetia* was decided in a different circuit; although the Fourth Circuit sometimes labels its "ascertainability" test differently than this Court does, they're substantively the same standard. *Byrd*, 784 F.3d at 162 n.4 (noting that the "Fourth Circuit's implicit 'readily identifiable' requirement for a proposed class is the same as our Circuit's 'ascertainability' requirement" (citing *EQT Prod. Co. v. Adair*, 764 F.3d 347, 358-60 (4th Cir. 2014))); *see also Krakauer v. Dish Network, L.L.C.*, 925 F.3d 643, 658 (4th Cir. 2019) (explaining that ascertainability requires ensuring "that there will be some administratively feasible [way] for the court to determine whether a particular individual is a member").

In fact, over the past decade, *no* other court, inside or outside this Circuit, has

declined to certify a third-party end-payor class like this one that excludes consumers when presented with PBM data and Craft's methodology. The 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. *See, e.g.*, *Zetia Ezetimibe Antitrust Litig.*, 2021 U.S. Dist. LEXIS 158073, at *20 (two-day evidentiary hearing); *In re Loestrin 24 Fe Antitrust Litig.*, 410 F. Supp. 3d at 386 (Craft testified at hearing). The district court's failure to hold the evidentiary hearing requested by End-Payor Plaintiffs, *see, e.g.*, Renewed Mot. at 25, contributed to the court's cursory and erroneous conclusion at odds with every other district court to have considered the materially same methodology and class definition.

III. DENYING CERTIFICATION HERE WOULD IMPEDE THE RIGHTFUL USE OF CLASS ACTIONS.

A. The Purposes of the Ascertainability Requirement Are Met Here.

This Circuit's ascertainability add-on to Rule 23 at no point requires Plaintiffs to be able to push a button and generate a failsafe list of class members. Rather, the ascertainability requirement aims to ensure that class members can be manageably distinguished from non-class members, for particular purposes—all of which are satisfied here.

First, ascertainability protects "absent class members' rights to opt out by facilitating the best notice practicable." *Byrd*, 784 F.3d at 175 (Rendell, J.,

concurring); *see also id.* at 165 (majority opinion). But the "best notice practicable" does not demand contacting each and every class member; it asks simply for individual notice only to "class members who can be identified through reasonable effort." *Id.* at 165.

Such notice can be "reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections." *Mullane v. Cent. Hanover Bank & Trust Co*., 339 U.S. 306, 314 (1950). It may be provided by "mail, electronic means, or other appropriate means." Fed. R. Civ. P. 23(c)(2)(B). While direct notice by mail may be the best notice practicable for those class members that are reasonably identifiable, it is not the only acceptable method. Publication, including electronic publication, is also acceptable notice. *See, e.g., In re Remeron End-Payor Antitrust Litig.*, No. 02-cv-2007, 2005 WL 2230314, at *15 (D.N.J. Sept. 13, 2005).

In pharmaceutical end-payor class actions, Plaintiffs typically retain experts who develop notice plans designed to meet the requirements of Rule 23. Such notice experts maintain proprietary databases that enable the provision of direct notice to all health insurers and self-funded health plans in the country, supplemented by notice in applicable trade publications. A293.[11] Using their own records and/or

[11] Plaintiffs are not relying on this database to establish ascertainability, only to explain how notice is often successfully accomplished.

records requested from PBMs (as named Plaintiffs did here), these end payors are able to determine their membership in the class and assess their ability to opt out or participate as absent class members. In other words, Craft's methodology is not needed to effectuate notice; notice is accomplished through a database that is distinct from any ascertainability methodology.

Second, ascertainability "ensures that a defendant's rights are protected by the class action mechanism," *City Select*, 867 F.3d at 439, by protecting a defendant's ability to "challenge the evidence used to prove class membership," *Carrera*, 727 F.3d at 308. Forcing a defendant to "accept as true absent persons' declarations that they are members of the class, without further indicia of reliability, would have serious due process implications." *Marcus*, 687 F.3d at 594. But defendants need not solely accept any absent entity's "say so" here, *id.*, because Plaintiffs are "not relying solely on unverified affidavits to establish ascertainability," *Byrd*, 784 F.3d at 171. Rather, business records for every Niaspan transaction are required under federal law, and any affidavit (if even necessary) can be "reconciled" with existing objective records. *Id.*

Third, "[a]scertainability is needed for properly enforcing the preclusive effect of final judgment," *Marcus*, 687 F.3d at 593, by ensuring "that those persons who will be bound by the final judgment are clearly identifiable," *City Select*, 867 F.3d at 439. This class is undisputedly defined by clear, objective, and verifiable

criteria. A78. If an insurer or health plan were to consider a duplicative suit, one simple question, corroborated by records—are you an intermediary or a payor for the identified set of transactions—would cleanly resolve whether that entity is part of the class and therefore bound by a final judgment.

Fourth, ascertainability "ensures that the parties can identify class members in a manner consistent with the efficiencies of a class action." *City Select*, 867 F.3d at 439. Here, End-Payor Plaintiffs' methodology is "economical," *Carrera*, 727 F.3d at 307, and efficient. PBMs can identify the class members, or automated, software-based processing of PBM data can do so. And in the handful of cases where there's still a dispute over class membership, simple affidavits can resolve it.

Finally, the ascertainability requirement is designed to provide criteria that "allow[] a trial court effectively to evaluate the explicit requirements of Rule 23" and "ensure[] that a proposed class will actually function as a class." *Byrd*, 784 F.3d at 162. Here, the class is specific enough that the district court had no trouble considering and finding numerosity, commonality, typicality, and adequacy. A77. Perhaps for a vague class, like "all consumers of aspirin who got sick," the court would have difficulties ascertaining class membership sufficiently to analyze, for instance, the size of the class or whether the named plaintiff was typical. The detailed and specific class here has none of those problems, as demonstrated by the district court's own Rule 23(a) findings.

B. If this Class Is Not Ascertainable, then Circuit Law Effectively Bars Large Class Actions Even in Data-Rich Industries.

It is nearly impossible to imagine a case with more detailed and comprehensive records of the relevant transactions than one involving the pharmaceutical industry. Extensive data on each transaction is collected and maintained by PBMs under federally-mandated standards. A248-A250 (Craft Supplemental ¶¶9-12). This systematic data, easily sortable by category and code, readily satisfies ascertainability under this Court's precedents. *See* pp. 29-35, *supra*.

The district court nonetheless evinced concern about the efficiency of identifying class members given the number of transactions. A88. But the data-rich context makes ascertainability easy for a class of this size. Modern software tools applied to comprehensive data allow class actions to function effectively to aggregate claims, as they were designed to do, and thereby remedy wrongdoing that might otherwise go undeterred and unaddressed. The same technical and econometric advances that have allowed drug companies to grow into global sellers with historic profits allows Plaintiffs to identify, with specificity, the entities harmed by the misconduct of those companies.

Reliance on a comprehensive, pre-coded dataset and automated programmatic analysis, supplemented in a subset of cases by a simple, single-question affidavit, requires substantially *less* administrative effort and individual review than the Court approved in *Hargrove* and *Byrd* for smaller classes. At worst, it is on par with *City*

Select, which contemplated sending an affidavit to as many as 31,000 auto dealerships. 867 F.3d at 442. In fact, the class here is likely smaller than *City Select*. While the district court focused on "millions" of transactions, A89, transaction numbers do not equate to class size. Class members engage in repeat transactions, and according to Defendants' estimate, the class would have around 24,000 members. *See* A55. Given the efficiencies of large batch processing and well-coded data, analysis of Niaspan transactions would take approximately two months and cost $250,000, A272 (Craft Supplemental ¶48), a minimal cost in comparison to the estimated damages suffered by the class, of at least several hundred million, and perhaps more than a billion, dollars.

More fundamentally, "the size of a potential class" cannot serve as the basis for denying class certification, because to bar large classes "would seriously undermine the purpose of a Rule 23(b)(3) class." *Byrd*, 784 F.3d at 171. "[D]efendants against whom claims of wrongful conduct have been made [should not] escape class-wide review due solely to the size of their businesses[.]" *Young v. Nationwide Mut. Ins. Co.*, 693 F.3d 532, 540 (6th Cir. 2012). If anything, "the efficiencies of a class action," *City Select*, 867 F.3d at 439, are promoted—not hindered—by adapting the administrative effort authorized to identify class members to the size of the putative class. A larger class resolves more individual claims in one fell swoop and typically seeks redress of more substantial damages.

Cases involving large classes—and thus substantial harm—where individual recoveries are not large enough to justify expenses are precisely where the class mechanism is most needed. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 617 (1997). "The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights." *Id*. Because "class action litigation [often] grows out of systemic failures …that result in small monetary losses to large numbers of people[, t]o allow that same systemic failure to defeat class certification would undermine the very purpose of class action remedies." *Young,* 693 F.3d at 540 (collecting cases and rejecting challenge to administrative feasibility based on the size of the class).

The potential aggregate class damages here far exceed the relatively small amount at stake for most individual plaintiffs. It cannot be that the very suitability of this case for the class action mechanism is also what defeats class certification under this Court's ascertainability standard. *See Hargrove*, 974 F.3d at 479 n.7 (noting that "[s]ince [2012], judges on our Court have warned that the overzealous application of the 'administratively feasible' requirement will defeat the purpose of Rule 23").

If the comprehensive and readily sorted data here—coupled with the ability to send simple form affidavits to already identified parties when necessary—is

insufficient to satisfy ascertainability, then Rule 23 (as glossed by this Circuit's atextual ascertainability standard) would "effectively thwart[]" this class action, *Byrd*, 784 F.3d at 174 (Rendell, J., concurring). This would pose an impermissible procedural barrier to a substantive right, *see Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 422-23 (2010) (controlling concurrence of Stevens, J.) ("When a federal rule appears to abridge, enlarge, or modify a substantive right, federal courts must consider whether the rule can reasonably be interpreted to avoid that impermissible result."). If the Circuit's ascertainability doctrine means that large classes cannot be certified, even in industries where every transaction is exhaustively detailed, then the doctrine has effectively abrogated Rule 23 precisely where it could be most useful.

C. The Court Should Reconsider Its Ascertainability Requirement If It Bars Certification Here.

The proposed ascertainability methodology here meets the test set out by this Court and furthers its purposes. If not, however, "[the] heightened ascertainability requirement defies clarification [and] narrows the availability of class actions in a way that the drafters of Rule 23 could not have intended." *Byrd*, 784 F.3d at 172 (Rendell, J., concurring); *see also id*. ("[T]he time has come to do away with this newly created aspect of Rule 23 in the Third Circuit."); *City Select*, 867 F.3d at 448 (Fuentes J., concurring) ("[O]ur heightened ascertainability requirement creates an unnecessary additional burden for class actions, particularly the low-value consumer

class actions that the device was designed to allow").[12]

The 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. The Seventh Circuit concluded that the "heightened ascertainability requirement …[has] the effect of barring class actions where class treatment is often most needed." *Mullins v. Direct Digital, LLC*, 795 F.3d 654, 658 (7th Cir. 2015). Similarly, the Second Circuit "decline[d] to adopt a heightened ascertainability theory" because it "would upset the careful balance of competing interests codified in the explicit requirements of Rule 23." *In re Petrobras Sec. Litig.*, 862 F.3d 250, 265 (2d Cir. 2017). These courts are not alone in holding that "[a] separate administrative feasibility prerequisite to class certification is not compatible with the language of Rule 23." *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1123 (9th Cir. 2017); *see also McKeage v. TMBC, LLC*, 847 F.3d 992, 998 (8th Cir. 2017). If ascertainability means that a class cannot be certified here, then the Court should reconsider whether its "implicit" ascertainability requirement is consistent with Rule 23.

* * * * *

The record here comfortably satisfies every parameter this Circuit has set for

[12] Appellants recognize that the panel is bound by circuit law but include these arguments to preserve them if needed for *en banc* or further review.

ascertainability. The district court misapplied the law and misunderstood the facts in concluding otherwise. For the reasons stated above the Court should reverse the district court's determination that the class is not ascertainable and remand for further proceedings.

CONCLUSION

The order denying class certification should be reversed.

January 12, 2022

Respectfully submitted,

s/Hyland Hunt

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COMBINED CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. My name appears on this brief and I am a member of the bar of this Court. *See* L.A.R 46.1.

2. The foregoing brief is in 14-point Times New Roman proportional font and contains 12,759 words, excluding the parts exempted by Fed. R. App. P. 32(f), and thus complies with the typeface requirements of Fed. R. App. P. 32(a)(5), the typestyle requirements of Fed. R. App. P. 32(a)(6), and the type-volume of Fed. R. App. P. 32(a)(7)(B).

3. On January 12, 2022, I served the foregoing brief upon all counsel of record by filing a copy of the document with the Clerk through the Court's electronic docketing system.

4. The electronic and paper versions of the foregoing brief are identical.

5. This file was scanned with Microsoft Defender Antivirus, version 1.353.675.0, and no virus was detected.

s/Hyland Hunt
Hyland Hunt

January 12, 2022

APPENDIX

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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: **NIASPAN ANTITRUST LITIGATION**	**MDL NO. 2460**
THIS DOCUMENT RELATES TO: **ALL ACTIONS**	**MASTER FILE NO. 13-MD-2460**

DuBois, J. **June 2, 2020**

M E M O R A N D U M

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I. INTRODUCTION

This multidistrict litigation involves what has come to be known as a "pay-for-delay," or "reverse payment," settlement—a practice in which a brand-name drug manufacturer brings a patent-infringement action against a generic drug manufacturer and then compensates the generic drug manufacturer for its agreement to delay entering the market with a competing generic version of the brand-name drug. In this case, two putative classes—the Direct-Purchaser Plaintiffs ("DPPs") and the End-Payor Plaintiffs ("EPPs")—aver that the brand-name manufacturer of the drug Niaspan, Kos Pharmaceuticals, Inc. ("Kos"), entered into anticompetitive settlement agreements with the generic manufacturer of that drug, Barr Pharmaceuticals, Inc. ("Barr"), in March of 2005 in order to terminate patent-infringement litigation brought by Kos against Barr in the District Court for the Southern District of New York. Kos was later acquired by defendant AbbVie Inc. ("AbbVie"), and Barr was later acquired by defendant Teva Pharmaceuticals, Inc. ("Teva").

Presently before the Court are End-Payor Plaintiffs' Motion for Class Certification, Defendants' Motion to Exclude the Expert Testimony of Laura Craft and Eric Miller Offered in Support of End-Payor Plaintiffs' Motion for Class Certification, and End-Payor Plaintiffs' Motion to Exclude the Opinions and Testimony of John F. Fritz.

For the reasons that follow, (1) Defendants' Motion to Exclude the Expert Testimony of Laura Craft and Eric Miller is denied, (2) EPPs' Motion for Class Certification is denied without prejudice, and (3) EPPs' Motion to Exclude the Opinions and Testimony of John F. Fritz is denied as moot.

II. BACKGROUND

The background of this case is set forth in detail in the Court's Memorandum and Order of September 5, 2014. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735 (E.D. Pa. 2014). This Memorandum recites only the facts and procedural history relevant to the motions presently before the Court.

Defendant AbbVie, a drug manufacturer that was spun off from Abbott Laboratories ("Abbott") in January 2013, manufactures and sells Niaspan, a brand-name prescription drug, primarily used in the treatment of lipid disorders. In the early 1990s, Kos, acquired by AbbVie in December 2006, developed a therapeutically-effective time-release version of niacin, which does not cause the side effects previously associated with niacin. Kos obtained a series of U.S. patents on time-release niacin and marketed the drug using the trademark Niaspan. Niaspan has been manufactured and sold by AbbVie (and AbbVie's predecessor corporations) since September of 1997.

In October 2001, Barr, acquired by Teva in January 2009, filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking authorization to manufacture and sell a generic equivalent of certain dosages of Niaspan. The ANDA process provides for streamlined FDA approval of a bioequivalent generic version of an FDA-approved brand-name drug. As part of the ANDA process, Barr filed certifications with the FDA stating that its generic drug did not infringe any of the patents covering Niaspan and/or that the patents were invalid or unenforceable.

In March 2002, Kos initiated the first of a series of patent-infringement lawsuits against Barr in the Southern District of New York, alleging infringement of its Niaspan patents. After three years of litigation, on April 12, 2005, Kos and Barr entered into several related settlement

agreements terminating the litigation. These agreements constitute the alleged "pay-for-delay" or "reverse payment" settlement that is the subject of this litigation.

EPPs allege that defendants' conduct violated the antitrust laws of 16 states, the consumer protection laws of 5 states, the unfair trade practices laws of 7 states, and the unjust enrichment laws of 25 states—a total of 53 state laws from 26 jurisdictions. *See* Defs.' Opp'n to EPPs' Mot. for Class Certification ("Defs.' Opp'n Class Cert") 3; Defs.' Apps. State L. Supp. Defs.' Opp'n to EPPs' Mot. for Class Certification (("Defs.' App.") A1-1–A1-4. Specifically, EPPs claim that as a result of the alleged unlawful reverse payment settlement, putative class members "were denied the opportunity to purchase generic Niaspan before September 20, 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 during the 180-day exclusivity period."[1] Mem. L. Supp. EPPs' Mot. for Class Certification ("EPPs' Mot. Class Cert") 12.

On December 19, 2018, EPPs filed a Motion for Class Certification. In their motion, EPPs seek certification of an overcharges class and an unjust enrichment class, each with two subclasses, a third party payor ("TPP") and a consumer subclass:

- Third Party Payor ("TPP") Overcharges Sub-class Definition:
  - All entities in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Arizona, California, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin for consumption by their members, employees, insureds, participants, or

[1] "[T]o encourage generic entry and to compensate ANDA filers for the expense and risk of a potential infringement lawsuit, federal law grants the first generic manufacturer to file a[n] . . . ANDA application (i.e., the "first-filer") a 180–day period of exclusive marketing rights." *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 741 (E.D. Pa. 2014). The 180–day period is exclusive only with respect to other ANDA applicants and does not prohibit the holder of an approved New Drug Application (the manufacturer of the brand-name drug) from marketing its own generic version of its drug (an authorized generic). *Id.*

beneficiaries during the period April 3, 2007 through January 31, 2018 (the "Overcharges Class Period").

- Consumer Overcharges Sub-class Definition:
  - All persons in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Arizona, California, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin for consumption by themselves or their families during the period April 3, 2007 through January 31, 2018 (the "Overcharges Class Period").
- TPP Unjust Enrichment Sub-class Definition:
  - All entities in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Alabama, Arizona, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and Wyoming for consumption by their members, employees, insureds, participants, or beneficiaries during the period April 3, 2007 through September 19, 2013 (the "Unjust Enrichment Class Period").
- Consumer Unjust Enrichment Sub-class Definition:
  - All persons in the United States and its territories who purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Alabama, Arizona, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Utah, Vermont, West Virginia, Wisconsin, and Wyoming for consumption by themselves or their families during the period April 3, 2007 through September 19, 2013 (the "Unjust Enrichment Class Period").
- Excluded from Overcharges and Unjust Enrichment Classes:
  - Defendants and their officers, directors, management, employees, subsidiaries, or affiliates;
  - All federal or state government entities other than cities, towns or municipalities with self-funded prescription drug plans;
  - All persons or entities who, after September 20, 2013, paid and/or provided reimbursement for branded Niaspan and did not pay and/or provide reimbursement for generic Niaspan;
  - All persons with a tiered co-pay plan who purchased only generic Niaspan;
  - All persons or entities who purchased Niaspan for purposes of resale or directly from Defendants or their affiliates·
  - 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);
  - Pharmacy Benefit Managers ("PBMs");

- Flat co-payers (i.e., consumers who paid the same co-payment amount for brand and generic drugs);
- The judges in this case and any members of their immediate families;
- All Counsel of Record.

End-Payor Plaintiffs' Motion for Class Certification ("EPPs' Mot. Class Cert.") 1–3.[2]

In their motion, EPPs ask the Court to appoint plaintiffs A.F. of L. – 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, and Carol Prasse (collectively, "named plaintiffs") as class representatives. *Id.* 3. EPPs also request appointment of Kenneth A. Wexler of Wexler Wallace LLP, Steve Shadowen of Hilliard Shadowen LLC, Michael Buchman of Motley Rice LLC, and Marvin Miller of Miller Law LLC as Co-Lead Counsel, and Jeffrey Kodroff of Spector Roseman & Kodroff P.C. as Liaison Counsel for the EPP class pursuant to Fed. R. Civ. P. 23(c)(1)(B) and 23(g). *Id.* 3–4.

On February 25, 2019, defendants responded to EPPs' motion for class certification and filed a motion to exclude the expert testimony of EPP class certification experts Eric Miller and Laura Craft. On March 25, 2019, EPPs filed a reply in support of their motion for class certification, responded to defendants' motion to exclude the expert testimony of Miller and Craft, and filed a motion to exclude the expert testimony of defendants' expert John Fritz. On

[2] At the Hearing on May 14 and 15, 2019, EPPs stated that the class definitions submitted with the Motion for Class Certification contained errors and submitted a slide deck correcting those errors. *See* May 14, 2019 Hr'g Tr. ("May 14 Tr.") 101:23–103:9; EPPs' Slide Deck (ECF No. 660) 51–54. The above class definitions incorporate those corrections.

April 8, 2019, defendants responded to EPPs' motion to exclude Fritz's testimony. The Court held Hearings on EPPs' class certification motion and the related motions to exclude expert testimony on May 14 and 15, 2019, and July 23, 2019.

III. MOTION TO EXCLUDE THE EXPERT TESTIMONY OF LAURA CRAFT AND ERIC MILLER

Defendants argue that the expert testimony of two EPP rebuttal experts on class ascertainability, Eric Miller and Laura Craft, should be excluded under *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993). Mem. L. Supp. Defs.' Mot. Exclude Expert Test. Laura Craft & Eric Miller Offered Supp. EPPs' Mot. Class Certification ("Mem. Exclude Craft & Miller") 1. EPPs oppose defendants' motion and argue that both experts provide admissible evidence. EPPs' Opp'n Defs.' Mot. Exclude Expert Test. Laura Craft & Eric Miller ("Opp'n Mot. Exclude Craft & Miller") 1. For the reasons that follow, the Court agrees with EPPs that Craft and Miller proffer admissible evidence. Defendants' motion to exclude the expert testimony of Craft and Miller is therefore denied.

A. *APPLICABLE LAW*

Federal Rule of Evidence 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

That rule requires the Court to act as a gatekeeper and is applicable to scientific testimony and testimony based on "technical" and "other specialized" knowledge. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 141 (1999). A court must determine whether an expert "employs in

the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." *Id.* at 152.

Courts have adopted a "liberal policy of admissibility" with respect to Rule 702. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 243 (3d Cir. 2008) (quoting *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997)). As such, the "rejection of expert testimony is the exception and not the rule." *Dorman Prods. v. PACCAR, Inc.*, 201 F. Supp. 3d 663, 686 (E.D. Pa 2016) (DuBois, J.) (quoting Fed. R. Evid. 702 Advisory Committee Note).

Courts must address a "trilogy of restrictions" before permitting the admission of expert testimony: qualification, reliability and fit. *Schneider v. Fried*, 320 F.3d 396, 404 (3d Cir. 2003); *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000). The party offering the expert must establish each requirement by a preponderance of the evidence. *In re TMI Litig.*, 193 F.3d 613, 663 (3d Cir. 1999).

i. Qualification

To qualify as an expert, "Rule 702 requires the witness to have 'specialized knowledge' regarding the area of testimony." *Betterbox Commc'ns Ltd. v. BB Techs., Inc.,* 300 F.3d 325, 335 (3d Cir. 2002). The Third Circuit has instructed courts to interpret the qualification requirement "liberally" and not to insist on a certain kind of degree or background when evaluating the qualifications of an expert. "[T]he Third Circuit noted that a witness can qualify as an expert 'under Rule 702 on the basis of practical experience alone, and a formal degree, title, or educational specialty is not required.'" *Voilas v. Gen. Motors Corp.*, 73 F. Supp. 2d 452, 457 (D.N.J. 1999) (citing *Lauria v. National R.R. Passenger Corp.*, 145 F.3d 593, 599 (3d Cir.1998)).

ii. Reliability

The reliability requirement of *Daubert* "means that the expert's opinion must be based on the 'methods and procedures of science' rather than on 'subjective belief or unsupported speculation'; the expert must have 'good grounds' for his or her belief." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994).

iii. Fit

For expert testimony to meet the *Daubert* "fit" requirement, it must "assist the trier of fact to understand the evidence or to determine a fact in issue." Fed. R. Evid. 702. "This condition goes primarily to relevance. Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Daubert*, 509 U.S. at 591.

B. *DISCUSSION*

The Court reviews defendants' challenges to Miller and Craft's proffered opinions in turn.

i. Eric Miller

In his declaration, Miller proffers two primary conclusions. First, Miller opines that through subpoenas issued to PBMs and pharmacies, EPPs will be able to obtain transactional level purchase data regarding purchases of Niaspan and its generic equivalents during the class period. Decl. Eric J. Miller ("Miller Decl.") ¶¶ 3, 20. Second, he opines that through the PBM and pharmacy transaction records obtained by the EPPs, the EPPs will be able to identify purchasers of Niaspan and its generic equivalents during the Class Period. *Id.* ¶¶ 8, 10, 20. Miller also states that he "disagrees with [defense expert, Donald] Dietz's suggestion that there is no 'reliable and administratively feasible means to identify class members in this case.'" Miller Decl. ¶ 20.

The Court concludes that Miller meets the Rule 702 requirements, but his testimony is limited to his opinions that (1) EPPs can obtain transactional level purchase data regarding purchases of Niaspan and its generic equivalents during the class period and (2) EPPs can use PBM and pharmacy transaction records to identify purchasers of Niaspan and its generic equivalents during the class period. To the extent that Miller purports to opine that class members can be identified, he has not addressed the way in which exclusions from the class can be applied and therefore he has not provided reliable grounds for any such opinion.

1. *Qualification*

EPPs claim Miller's "extensive experience obtaining and utilizing comparable data," including his direct involvement with settlement administration in over 25 indirect purchaser pharmaceutical class lawsuits, qualifies him to offer his opinions. Opp'n Mot. Exclude Craft & Miller 15.

Miller attests that he has "personally overseen the methodologies used in indirect purchaser pharmaceutical class actions to identify class members," which "utilized prescription data obtained from the records of pharmacies and PBMs to identify consumers who may be class members." Miller Decl. ¶ 9. He has 18 years of experience administering class actions settlements, including more than 25 indirect purchaser pharmaceutical class cases. Opp'n Mot. Exclude Craft & Miller 2. The Court concludes that Miller is sufficiently qualified to offer his opinions that EPPs can obtain brand and generic Niaspan transaction records for the class period and that those records can be used to identify purchasers of brand and generic Niaspan during the class period.

2. *Reliability*

Defendants argue that Miller is unreliable because he (1) did not offer a methodology to identify class members and (2) did not review any data produced in this case, address the challenges posed by the class definition, or address limitations in data availability and access in PBMs' data systems. Mem. Exclude Craft & Miller 4–9.

EPPs respond that (1) Miller need not provide a methodology to identify class members because he does not purport to provide a method for ascertaining class members, and (2) Miller was not required to review the record because his testimony is reliably based on his past industry experience and his involvement in four cases in which pharmaceutical transaction data was obtained and used. Opp'n Mot. Exclude Craft & Miller 15, 17–18.

First, the Court agrees with EPPs that Miller need not provide a methodology for identifying class members because he does not opine on such a methodology. Though EPPs' evidence of a reliable and administratively feasible methodology for identifying class members is critical to the Court's ascertainability inquiry, Miller's testimony does not address that issue—he only opines on the question whether Niaspan and generic *purchasers* can be identified. As Miller explained during his deposition, his declaration did not consider the EPPs' class definition, did not compare the EPPs' definition to the class definitions in *Relafen*, *Tricor*, *Provigil* and *Fluoride Tablets*, and did not address any of the exclusions in EPPs' class definition. Videotape Dep. Eric Miller 26:13–19, 27:13–18, 30:1–5. For those reasons, Miller will not be permitted to testify that he disagrees with defense expert Donald Dietz's opinion that there is no reliable and administratively feasible means to identify class members.

Second, the Court concludes that Miller has "good grounds" for both of his conclusions. Miller opines that EPPs can obtain brand and generic Niaspan transaction records for the class

period based on his past experience with settlement administration in pharmaceutical cases in which he was involved. Miller Decl. ¶ 10. Specifically, he relies upon his experience in the *Relafen*, *Tricor*, *Provigil* and *Fluoride Tablets* cases, in which pharmaceutical records were obtained through subpoenas to pharmacies and PBMs. *Id.* ¶¶ 10–15. Miller's past experience provides reasonable grounds for him to conclude that subpoenas to PBMs and pharmacies will result in the production of pharmaceutical records in this case. *See In re Paulsboro Derailment Cases*, 746 F. App'x 94, 98 (3d Cir. 2018) (holding that an expert may base his opinion upon personal experience).

Similarly, Miller opines that EPPs can identify purchasers of Niaspan and its generic equivalents during the class period based on his experience with similar subpoenaed data. Miller Decl. ¶ 8. Specifically, he states that in the *Relafen*, *Tricor*, *Provigil* and *Fluoride Tablets* cases, the electronic data fields enabled the plaintiffs to identify each drug purchaser. *Id.* ¶¶ 11–18. Miller's past experience in which the subpoenaed pharmaceutical data identified drug purchasers provides good grounds for his belief that the production of Niaspan pharmaceutical data would enable the identification of brand and generic Niaspan purchasers.

Because Miller has good grounds for his opinions on the identification of purchasers of brand and generic Niaspan, defendants' arguments that Miller failed to review the produced data or to address limitations in data availability and retrieval address the weight of Miller's testimony, not its admissibility. *See In re TMI Litig.*, 193 F.3d 613, 665 (3d Cir. 1999) ("[T]he judge should not exclude evidence simply because he or she thinks that there is a flaw in the expert's investigative process which renders the expert's conclusions incorrect. The judge should only exclude the evidence if the flaw is large enough that the expert lacks the "good grounds" for his or her conclusions.").

For all of the forgoing reasons, Miller will be permitted to testify that brand and generic Niaspan purchasers can be identified. He will not be permitted to testify that class members can be identified.

3. *Fit*

Defendants argue that Miller's experience with claims administration in the settlement of cases is inapposite to this case because it does not involve a settlement class. Mem. Exclude Craft & Miller 10–11. In support, they point to the fact that several courts have recognized that "the successful administration of a settlement does not necessarily mean that a litigation class could be ascertained." *Id*. at 10.

EPPs respond that the fact Miller's experience with settlement administration does not impact his opinion on the availability of the data. *See* Opp'n Mot. Exclude Craft & Miller 18–19. They contend Miller's testimony addressing the existence and availability of PBM and pharmacy transaction data is relevant to the identification of brand and generic Niaspan purchasers.

The Court rejects defendants' argument that Miller's testimony is not relevant because his experience is based on settlement claims administration. Although defendants' are correct that "[t]he successful administration of a settlement does not necessarily mean that a litigation class could be ascertained," *In re Wellbutrin XL Antitrust Litig*., 308 F.R.D. 134, 151 n.8 (E.D. Pa. 2015), EPPs correctly state that "the *fact* of data availability is the same, regardless of the context." Opp'n Mot. Exclude Craft & Miller 19. The Court thus concludes that Miller's testimony, as limited *supra*, satisfies the fit requirement under Rule 702.

4. *Conclusion*

Accordingly, that part of defendants' motion seeking to exclude all of the opinions and testimony of Miller is denied. However, Miller's testimony is limited to his opinions that (1) EPPs can obtain transactional level purchase data regarding purchases of Niaspan and its generic equivalents during the class period and (2) EPPs can use PBM and pharmacy transaction records to identify purchasers of Niaspan and its generic equivalents during the class period. However, he has not provided the required foundation to opine that class members can be identified in a reliable and administratively feasible manner.

ii. Laura Craft

In her declaration, Laura Craft attests that if provided with data from TPPs, PBMs, and pharmacies containing the identities of purchasers of Niaspan and its generic equivalents during the class period, she can compile a list reflecting the identities of the members of the proposed class in a manageable process that "can be carried out programmatically." Decl. Laura R. Craft ("Craft Decl.") ¶ 10. For the reasons below, the Court concludes that Craft's opinion is admissible under Rule 702's "liberal policy of admissibility."

1. *Qualification*

EPPs argue that Craft is qualified as president of data analytics firm OnPoint Analytics, specializes in collecting, manipulating, and analyzing pharmaceutical industry data, especially in the litigation context, and has applied her expertise to over fifty pharmaceutical cases. Opp'n Mot. Exclude Craft & Miller 5–6.

Craft's qualifications include "extensive experience [at OnPoint] working with insurance and claims processing data, including the processing of prescription drug benefits." Craft Decl. ¶ 3. She also has extensive experience using transactional data to "identify[] individual class

members in a variety of contexts . . . [including] identifying transaction dates, types, and costs, the participants in making payment, and eliminating duplicates." *Id.* ¶ 5. Craft declares that OnPoint's expertise with transactional data includes "the cleaning and transformation processes that create consistency and allow efficient programming across data obtained from multiple sources." *Id.*

The Court concludes that Craft's extensive experience working with pharmaceutical data qualifies her to opine that EPP class members can be identified in a programmatic and manageable process.[3]

2. *Reliability*

Defendants contend that Craft's testimony is unreliable because she has not reviewed the data produced in this case and has not offered a methodology for identifying class members. Mem. Exclude Craft & Miller 5–9.

EPPs respond that Craft properly based her opinions on her experience and not on the produced data because "absent a subpoena and a negotiated production process and the execution of protective orders that assure that there is a HIPAA-qualified protective order in place, one would not expect to see samples that would be, standalone, sufficient to answer all of the questions which might be implicit in defining the class." Opp'n Mot. Exclude Craft & Miller 12. They further argue that Craft justifiably relies on sworn declarations by four of the largest PBMs that they maintain their claims data in the industry standard format and that they maintain the

[3] The analysis under *Daubert* involves a preliminary assessment of admissibility and has no effect on the Court's substantive analysis of whether the admissible evidence satisfies the more rigorous Rule 23 ascertainability requirement by a preponderance of the evidence. *See, e.g.*, *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. at 144, 151 (concluding that plaintiff's witness was "sufficiently qualified to be an expert" but offered evidence that "[fell] short" of satisfying ascertainability).

types of data that would be required to identify class members and apply key exclusions. *Id*. at 10–12.

EPPs also contend that Craft explained a six-step methodology for identifying class members based on her experience manipulating pharmaceutical data, *id*. at 9, and that her methodology is particularly well-suited for drug sales in the pharmaceutical industry, "which are tracked, monitored, and recorded across a set of substantially uniform variables." Reply Mem. L. Supp. EPPs' Mot. Class Certification ("EPPs' Reply Class Cert.") 6.

The Court concludes that Craft's failure to review the data produced in this case does not render her opinion unreliable. Although Craft does not rely on actual produced data, she relies on her experience working with pharmaceutical data from PBMs, TPPs, drug manufacturers, pharmacies, and consumers. Craft Decl. ¶ 5–6. Craft reports that the data standardization process "is particularly easy in the pharmaceutical industry because the specific types of data reported are already relatively standard" and "[PBM] databases are generally able to report the same key variables." *Id*. She also relies on declarations from PBM representatives Kyle Brua (Prime Therapeutics LLC, March 28, 2018), Jonathan Stocker (Prime Therapeutics LLC, March 28, 2018), Tom Henry (Express Scripts, Inc., March 28, 2018), Robert Lahman (OptumRx, Inc. March 26, 2018), and Steven Schaper (Caremark, LLC, March 20, 2018), which detail the type of data that PBMs retain.

The Court further concludes that Craft's relatively threadbare methodology is adequate under the liberal admissibility standard of Rule 702. In her declaration, Craft asserts that "OnPoint would be able to merge the data from the various sources, identify and eliminate data errors, transform the data to standardize the fields, eliminate duplicates, and compile a list reflecting the identities of the class members contained in the data." Craft Decl. ¶ 10.

Defendants are correct that Craft does not explain how any of these steps would be carried out and "did not describe a specific method" to identify payors who meet the class definitions in this case. Mem. Exclude Craft & Miller 6. However, Craft reviewed the class exclusions, and declared that "OnPoint has extensive experience applying these types of exclusions to pharmaceutical data." Craft Decl. ¶ 9. As such, Craft's opinion that she can create a list of class members and apply the class exclusions in this case is based on her experience applying these types of exclusions to similar data in other cases. The Court determines that Craft's reliance upon her past experience applying "these types of exclusions" provides sufficient grounds for her belief that she can do so again in this instance. Defendants' objections to Craft's assurances that she can apply the class exclusions go to the weight of her testimony and not its admissibility. *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 596 (1993) ("Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence.").

3. *Fit*

Defendants argue that Craft has not shown her experience is sufficiently analogous because "Craft's declaration did not identify a single case that showed she had applied her (unspecified) methodology in a comparable setting." Mem. Exclude Craft & Miller 10. However, as explained above, Craft states that she has "extensive experience applying these types of exclusions to pharmaceutical data." Craft Decl. ¶ 9. Craft's declaration rebuts defense expert Dietz's opinion by explaining that she and OnPoint "routinely perform[] precisely th[e] type of work" that Dietz incorrectly (in her view) identifies as 'difficult' and 'cumbersome.'" Opp'n Mot. Exclude Craft & Miller 8. Thus, Craft's testimony assists the Court in understanding the evidence relating to whether EPPs have provided a reliable and

administratively feasible mechanism for identifying class members, which is relevant to the Court's determination of class ascertainability.

4. *Conclusion*

The Court thus concludes that Craft's expert opinion is admissible. That part of defendants' motion seeking to exclude the opinion and testimony of Laura Craft is denied.

IV. EPPS' MOTION FOR CLASS CERTIFICATION

A. *LEGAL STANDARD*

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 248 (3d Cir. 2016). Subsection (a) of Federal Rule of Civil Procedure 23 sets out four prerequisites for a class action—numerosity, commonality, typicality, and adequacy. Subsection (b) provides additional requirements for each type of class action. To obtain certification under Rule 23(b)(3), as EPPs seek to do in this case, the moving party must also show "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." These requirements are referred to, respectively, as predominance and superiority. Rule 23(b)(3) also contains an implied, judicially-created requirement that the identities of class members are ascertainable. *Byrd v. Aaron's Inc.*, 784 F.3d 154, 162 n.5 (3d Cir. 2015).

"The party seeking certification bears the burden of establishing each element of Rule 23." *In re Modafinil Antitrust Litig.*, 837 F.3d at 248. "[T]rial 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) (citing *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 316–25 (3d Cir. 2008)). The Rule 23 analysis also requires courts to "determine the nature of the evidence, and how plaintiffs would present this evidence at trial." *In re Domestic Drywall Antitrust Litig.*, 322 F.R.D. at 221. However, "a court should not address merits-related issues 'beyond what is necessary to determine preliminarily whether certain elements will necessitate individual or common proof.'" *Harnish*, 833 F.3d at 305.

The Third Circuit has "repeatedly emphasize[d] that [a]ctual, not presumed conformance with Rule 23 requirements is essential." *Gonzalez v. Corning*, 885 F.3d 186, 192 (3d Cir. 2018) (internal quotations omitted). "When courts harbor doubt as to whether a plaintiff has carried her burden under Rule 23, the class should not be certified." *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 483 (3d Cir. 2018).

B. *DISCUSSION*

EPPs contend that they meet the four requirements under Rule 23(a) and the three requirements under Rule 23(b)(3). The Court addresses each such requirement in turn.

C. *RULE 23(A) REQUIREMENTS*

EPPs must initially satisfy the four prerequisites detailed in Rule 23(a): numerosity, commonality, typicality, and adequacy. The Court concludes that each requirement is satisfied.

i. Numerosity

Rule 23(a)(1) requires that the class be "so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a)(1).

EPPs assert that "Niaspan prescriptions peaked at nearly 600,000 per month in 2011," and argue that joinder is impracticable for such a large class. Mem. L. Supp. EPPs' Mot. Class

Certification ("EPPs' Class Cert. Mem.") 8. The Court agrees with EPPs and concludes that the numerosity requirement is satisfied.

ii. Commonality

To satisfy Rule 23(a)(2), there must be "questions of law or fact common to the class." Satisfaction of the commonality requirement requires that plaintiffs demonstrate that their claims "depend upon a common contention," the resolution of which "will resolve an issue that is central to the validity of each one of the claims in one stroke." *Wal–Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 350 (2011). "Commonality does not require an identity of claims or facts among class members; instead, [t]he commonality requirement will be satisfied if the named plaintiffs share at least one question of fact or law with the grievances of the prospective class." *Johnston v. HBO Film Mgmt., Inc.*, 265 F.3d 178, 184 (3d Cir. 2011).

The Court agrees with EPPs that most of the "central questions in this case focus entirely on Defendants' conduct" and involve common questions. EPPs' Class Cert. Mem. 9. These common questions include, *inter alia*, (1) whether Kos entered into a contract, combination, and/or conspiracy with Barr to restrain trade; (2) whether Kos paid cash and/or other valuable consideration to Barr in exchange for a promise to delay the launch of generic Niaspan; (3) whether defendants had pro-competitive justifications for their conduct; and (4) whether defendants possessed market power in the relevant market. The commonality requirement is satisfied.

iii. Typicality

Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." The Third Circuit has a "low threshold" for satisfying typicality. *See In re Nat'l Football League Players Concussion Injury Litig.*, 821 F.3d 410, 428 (3d Cir. 2016). To conduct the typicality inquiry, the Court must examine "whether the named plaintiffs' claims are typical, in common-sense terms, of the class, thus suggesting that the

incentives of the plaintiffs are aligned with those of the class." *In re Blood Reagents Antitrust Litig.*, No. 09-2081, 2015 WL 6123211, at *26 (E.D. Pa. Oct. 19, 2015) (DuBois, J.).

EPPs argue that typicality is satisfied because "named Plaintiffs' claims arise out of the same facts and legal theories that give rise to the claims of all EPP Class members: Kos and Barr entered into a reverse-payment settlement that unlawfully extended Kos' monopoly over the Niaspan market and delayed the onset of generic competition." EPPs' Class Cert. Mem. 11. Defendants do not contest that EPPs have satisfied the typicality requirement. The Court concludes that the typicality requirement is satisfied.

iv. Adequacy

Rule 23(a)(4) requires plaintiffs to show that "the representative parties will fairly and adequately protect the interests of the class." "Whether adequacy has been satisfied 'depends on two factors: (a) the plaintiff's attorney must be qualified, experienced, and generally able to conduct the proposed litigation, and (b) the plaintiff must not have interests antagonistic to those of the class.'" *McDonough v. Toys R Us, Inc.*, 638 F. Supp. 2d 461, 477 (E.D. Pa. 2009). "Only a fundamental conflict will defeat adequacy of representation." *In re K-Dur Antitrust Litig.*, 686 F.3d 197, 223 (3d Cir. 2012), *judgment vacated on other grounds*, 570 U.S. 913 (2013).

EPPs contend that "plaintiffs are represented by experienced counsel thoroughly familiar with litigating complex class actions" and "there is no likelihood of a conflict of interest among class members." EPPs' Class Cert. Mem. 11–12. Defendants make no argument to the contrary, and the Court agrees with EPPs that the adequacy requirement is satisfied.

D. *RULE 23(B)(3) REQUIREMENTS*

EPPs must also satisfy the predominance and superiority requirements of Rule 23(b)(3) and the ascertainability requirement. *See In re: Domestic Drywall Antitrust Litig.*, 322 F.R.D.

188, 200 (E.D. Pa. 2017). Defendants argue that EPPs fail their burden of proving each of these requirements. The Court addresses each such requirement in turn, beginning with ascertainability.

i. Ascertainability

The ascertainability "inquiry is two–fold, requiring a plaintiff to 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.'" *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015). "Plaintiff has the burden of making this showing by a preponderance of the evidence, and the district court must 'undertake a rigorous analysis of the evidence to determine if the standard is met.'" *City Select Auto Sales Inc. v. BMW Bank of N. Am. Inc.*, 867 F.3d 434, 439 (3d Cir. 2017) (internal citations omitted). "However, 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.* (internal citations omitted).

The Third Circuit has articulated three principal rationales for the ascertainability standard:

> First, ascertainability and a clear class definition allow potential class members to identify themselves for purposes of opting out of a class. Second, it ensures that a defendant's rights are protected by the class action mechanism, and that those persons who will be bound by the final judgment are clearly identifiable. Finally, it ensures that the parties can identify class members in a manner consistent with the efficiencies of a class action.

City Select Auto Sales Inc., 867 F.3d at 439 (internal quotations and citations omitted).

"The predominance and ascertainability inquiries are distinct . . . because the ascertainability requirement focuses on whether individuals fitting the class definition may be identified without resort[ing] to mini-trials, whereas the predominance requirement focuses on

whether essential elements of the class's claims can be proven at trial with common, as opposed to individualized, evidence." *Byrd*, 784 F.3d at 164.

EPPs argue that under the governing Third Circuit law, plaintiffs can satisfy ascertainability with "almost zero evidence." EPPs' Class Cert. Mem. 17. In support, EPPs rely heavily on *Byrd*, for the proposition that EPPs need not show "how the records would be obtained, who would obtain them, or who would do the matching of records." EPPs' Class Cert. Mem. 18.

Defendants' respond that EPPs "offer a gross misreading of *Byrd* and the Third Circuit's ascertainability jurisprudence." Defs.' Opp'n Class Cert. 37.

The Court agrees with defendants that EPPs mischaracterize the Third Circuit ascertainability standard. Contrary to EPPs' assertion, *Byrd* does not stand for the proposition that ascertainability requires less than a rigorous showing of administrative feasibility. In *Byrd*, the Third Circuit reversed a denial of class certification in a case in which the district court "summarily adopted the Magistrate Judge's Report and Recommendation, and no oral argument was held on the class-certification motion," notwithstanding the fact that the plaintiffs had filed an objection to the Report and Recommendation that addressed class ascertainability. *Byrd*, 784 F.3d at 169–170. As such, the Third Circuit ruled that the district court erred in failing to conduct a rigorous analysis of the evidence presented.

Although Judge Rendell filed a concurring opinion in *Byrd* in which she opined that "the time has come to do away with [the ascertainability requirement]," that position has not been adopted by this Circuit. *See Byrd*, 784 F.3d at 172 (Rendell, J., concurring). As the Third Circuit recently reiterated, plaintiffs have the burden of showing ascertainability "by a preponderance of the evidence, and the district court must 'undertake a rigorous analysis of the

evidence to determine if the standard is met.'" *City Select Auto Sales Inc.*, 867 F.3d at 439. Courts in this district have consistently rejected EPPs' argument that *Byrd* lowered the Third Circuit ascertainability standard, and this Court agrees with those decisions. *See, e.g.*, *In re Domestic Drywall Antitrust Litig.*, No. 13-2437, 2017 WL 3700999, at *8 (E.D. Pa. Aug. 24, 2017) ("[In *City Select*,] the court reaffirmed its prior precedent and did not take the opportunity to retreat from the "heightened" ascertainability standard that has been developed in this Circuit, as urged by Judge Rendell in her *Byrd* concurrence."); *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *11 (E.D. Pa. June 10, 2015) ("[P]lans to create a methodology at a later date do not satisfy the rigorous analysis insisted upon by the Third Circuit and I do not read *Byrd* to alter these requirements.").

Thus, the Court will rigorously analyze EPPs' evidence of ascertainability. While EPPs need only show at class certification that class members can be identified, *City Select*, 867 F.3d at 439, "actual, not presumed[,] conformance with [the ascertainability] requirement[] is essential." *Gonzalez v. Corning*, 885 F.3d 186, 192 (3d Cir. 2018) (internal quotations and alterations omitted). The Court next considers whether EPPs' class definition is defined with objective criteria.

1. *Defining Class with Reference to Objective Criteria*

EPPs argue that the provided class definitions are defined with reference to objective criteria. EPPs' Class Cert. Mem. 13. Defendants disagree, arguing that "given the complex flow of payments and reimbursements in the pharmaceutical distribution chain, it is far from clear exactly who is in the class and who is not." Defs.' Opp'n Class Cert. 29. Defendants also claim that there is an ambiguity in the class definition regarding whether a payor includes any entity that bears risk for drug costs. *Id.* at 29–31.

EPPs respond that "[t]he ambiguities that Defendants assert do not appear on the face of the class definitions, which is the standard by which to determine class membership." EPPs' Reply Class Cert. 3.

The Court agrees with EPPs that the class definition is defined with reference to objective criteria and satisfies the first prong of the ascertainability analysis. Defendants' arguments do not challenge the objective nature of the class criteria. *Cf. City Select Auto Sales Inc.*, 867 F.3d at 439 ("Under the objective criteria requirement, '[a] class definition that depends on subjective criteria, such as class members' state of mind, will fail for lack of definiteness.'"). The Court next turns to the evidence submitted by EPPs to establish that they have a reliable and administratively feasible mechanism for identifying class members.

2. *Reliable and Administratively Feasible Mechanism for Determining Whether Putative Class Members Fall Within the Class Definition*

EPPs assert that they have "submitted evidence that an administratively feasible methodology exists to allow for the determination of whether a TPP or consumer falls within the definitions of the Proposed Classes." EPPs' Class Cert. Mem. 14. Defendants respond that EPPs have not met their burden of proving a reliable and administratively feasible methodology by a preponderance of the evidence. Defs.' Opp'n Class Cert. 34.

Upon a rigorous analysis of the evidence, the Court determines that EPPs have failed to carry their burden of showing a reliable and administratively feasible mechanism for identifying class members by a preponderance of the evidence.

a. EPPs' Evidence of a Reliable and Administratively Feasible Mechanism

EPPs face an uphill battle in carrying their burden of proving they have a reliable and administratively feasible mechanism for identifying class members. Courts in this district have

held in similar pay-for-delay cases that end-payor plaintiffs have failed to provide adequate evidence of an administratively feasible mechanism for identifying class members. *See, e.g.*, *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 4737288, at *11 (E.D. Pa. Aug. 4, 2015) ("Plaintiffs have . . . not met their burden of establishing that any methodology for identifying class members would be administratively feasible."); *see also In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 149–50 (E.D. Pa. 2015) ("[Plaintiffs ha[ve] not shown by a preponderance of the evidence that there is a reliable and administratively feasible mechanism for determining which PBMs and individual consumers are members of the class.").

EPPs argue in this case, they "have provided the [evidentiary] record that the courts in *Wellbutrin* and *Vista* [Healthplan] lacked." EPPs' Reply Class Cert. 3. They argue that their evidence demonstrates "that obtaining, standardizing, and merging data from multiple sources with the goal of ascertaining class members is . . . common practice in antitrust litigation, [and] is especially well-suited to the pharmaceutical industry." EPPs' Reply Class Cert. 4. The Court reviews EPPs' evidence below.

First, EPPs proffer evidence that the relevant pharmaceutical transaction data exists. EPPs' expert, Myron Winkelman, asserts that "[e]very prescription drug transaction in the United States is well-documented and records of those transactions are maintained so that TPPs and consumers can identify, at a minimum, the prescriptions drugs they purchased, the date on which they were purchased, and the price they each paid for the medication." Decl. Myron Winkelman ("Winkelman Decl.") ¶ 18. Winkelman also claims that "PBMs are obligated by their contractual agreements with the TPPs to maintain records in connection to the processing, payment and denial of claims," *id.* ¶ 35, and "mail order and retail pharmacies maintain extensive records of each consumer's prescription purchase." *Id.* ¶ 36. Finally, Winkelman

opines that pharmaceutical data is "maintained in standardized accepted industry format." *Id.* ¶ 32.

In support of EPPs' claim that the data exists, they have presented short declarations by several PBM representatives. For example, Jonathan Stocker, Vice President of PBM Operations at Prime Therapeutics LLC, declared "Prime has readily accessible records, in an industry standard format created by the National Council for Prescription Drug Program, by which third party payors and consumer can be identified on every purchase of Niaspan and Generic Niaspan that Prime adjudicates on behalf of its third-party payor clients." Decl. Non-Party Prime Therapeutics LLC ("Stocker Decl.") ¶ 7. Similarly, Robert Lahman, Senior Vice President of Industry Relations at Optum Rx, Inc., attested that "OptumRx has readily accessible records, in an industry standard format created by the National Council for Prescription Drug Program, by which third party payors and consumers can be identified on every purchase of Niaspan and Generic Niaspan that OptumRx adjudicates on behalf of its third-party payor clients." Decl. Non-Party OptumRx ("Lahman Decl.") ¶ 5. Both PBM declarants stated that they maintain the records of transaction details in its regular course of business. Stocker Decl. 9; Lahman Decl. ¶ 7.

Second, EPPs proffer evidence that the data is obtainable. They rely on Miller's expert opinions, discussed above, in which Miller states that through subpoenas issued to PBMs and pharmacies, EPPs will be able to obtain transactional level purchase data regarding purchases of Niaspan and its generic equivalents during the class period, which will enable EPPs to identify purchasers of Niaspan and its generic equivalents during the class period. Miller Decl. ¶¶ 3, 8, 10, 20. As set forth in greater detail above, Miller bases his opinions on his experience in claims administration for settlement classes.

Third, EPPs assert that identifying class members from the obtained pharmaceutical data is administratively feasible. In support, they rely on Craft's declaration, discussed above, in which she states that she can compile a list reflecting the identities of the members of the proposed class in a manageable process that "can be carried out programmatically" and that she has "extensive experience applying these types of exclusions to pharmaceutical data." Craft Decl. ¶¶ 9–10.

EPPs also present a declaration by EPP Interim Co-Lead Counsel, Kenneth Wexler, which synthesizes EPPs' "evidence that an administratively feasible methodology exists to allow for the determination of whether a TPP or consumer falls within the definitions of the Proposed EPP Classes." EPPs' Class Cert. Mem. 14. First, Wexler states that Winkelman has provided evidence that "PBMs, TPPs, pharmacies, and individual consumers have records reflecting what TPPs and consumers purchased Niaspan or its generic versions during the class periods." Decl. Kenneth A. Wexler Supp. EPPs' Mot. for Class Certification ("Wexler Decl.") ¶ 26. Second, Wexler says that EPPs would serve HIPAA-compliant court-issued subpoenas to "the top six Pharmacy Benefit Managers (in terms of market share), the ten largest Third-Party Payors, the top ten chain store pharmacies, and the top five mail order pharmacies" for the production of purchase records for brand and generic Niaspan during the class period. *Id.* ¶¶ 27–28. Third, he says EPPs would retain OnPoint Analytics, transfer the obtained records to OnPoint, which "could then process the data and identify those persons and entities in the data who fit the class definitions." *Id.* ¶¶ 29–30. Finally, Wexler states that the remainder of unidentified class members can obtain records of their relevant purchases and prove their class membership. *Id.* ¶ 31.

Defendants argue that EPPs' evidence does not show that the class is ascertainable, and EPPs' "offer only vague assurances that they will somehow be able to ascertain class members in the future." Defs.' Opp'n Class Cert. 32. They claim that EPPs failed to present a methodology "specific to this case" or provide "evidentiary support that the method will be successful." *Id.* at 33 (citing *Carrera v. Bayer Corp.*, 727 F.3d 300, 306, 310 (3d Cir. 2013)). Defendants also raise specific challenges to EPPs' evidence that they can obtain the necessary data and identify class members using pharmaceutical data.

For the reasons below, the Court agrees with defendants that EPPs have not satisfied their burden of proving a reliable and administratively feasible mechanism for identifying class members.

b. Data Obtainability

Defendants contend that EPPs have not shown that the records necessary to identify class members are obtainable and raise several challenges to EPPs' evidence. Defs.' Opp'n Class Cert. 39. Defendants note that EPPs have faced difficulties obtaining data in this case, as evidenced by the fact that when EPPs served deposition and document subpoenas on four PBMs, three PBMs served formal objections, and only two PBMs produced requested data—one of which produced an extremely limited report relating only to the transactions involving named plaintiff AF of L. *Id.* at 22. According to defendants, EPPs' declarations from the PBM representatives are inadequate because they "merely describe in non-specific terms the type of information generated in the claim adjudication process." *Id.* at 20.

Defendants' also challenge Miller's opinion that data of brand and generic Niaspan purchases can be feasibly obtained. They highlight that Miller did not account for data limitations that arose in past cases in which he was involved. Specifically, defendants present

affidavits originally filed in *Relafen*, one of the four cases upon which Miller primarily relies in his report, in which two PBMs, Express Scripts and Medco, attested to the difficulties of data retrieval. *Id.* at 20–21.

EPPs' reply that defendants' objections to data obtainability rely on "outdated" declarations from PBMs and that PBMs' reluctance to produce data "merely underscores the importance of implementing a HIPAA-compliant protective order (which has been done in this case) and, if necessary, the routine matter of enforcing subpoenas." EPPs' Reply Class Cert. 14–15. EPPs also note that "[m]ost of the named Plaintiffs in this litigation were able to provide data for the complete set of relevant transactions going back to around the beginning of the class period." *Id.* at 14.

The Court concludes that, notwithstanding defendants' objections, EPPs have demonstrated by a preponderance of the evidence that the necessary records of brand and generic Niaspan purchases can be obtained. In addition to EPPs' evidence above, the Court notes that the Vice President of Knowledge Solutions and Chief Data Officer for PBM Express Scripts submitted a declaration in this case that "Express Scripts maintains records of claims that can be provided to its Clients, although certain additional fees, costs, or expenses may be associated with this service." Decl. Non-Party Express Scripts, Inc. ("Henry Decl."). Although the failure of several PBMs to provide any record evidence "heightens the Court's concern that such pharmaceutical records may not be obtainable for use in the ascertainability inquiry," *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 150 (E.D. Pa. 2015), the Court is satisfied that through Court-issued subpoenas, records of brand and generic Niaspan transactions can be obtained. However, the Court is concerned about the economic feasibility of obtaining such

information and the ability of EPPs to identify class members in a reliable and administratively feasible manner, issues that the Court addresses below.

c. Methodology for Determining Class Membership

In this case, EPPs have proffered a complex class definition with multiple exclusions. As such, the inquiry as to the ascertainability of class members does not end merely by noting the existence of obtainable records of brand and generic Niaspan purchasers. EPPs "must also demonstrate an administratively feasible method for [applying the exclusions], as required by the class definition." *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *21 (D.N.J. Oct. 30, 2018); *see also City Select*, 867 F.3d at 441–442 (remanding for an inquiry as to whether plaintiffs could use existing database as part of a reliable and administratively feasible means to determine class membership); *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 4737288, at *2 (E.D. Pa. Aug. 4, 2015) ("However, by choosing to define its class with eight specific exclusions, Plaintiffs have created the need for a structured, multi-stepped, individualized fact-finding process in order to determine which individuals would fall within the class definition and which would fall within one of the eight exclusions.").

Defendants contend that EPPs' "experts have affirmatively conceded that they have no methodology for determining class membership in this case." Defs.' Opp'n Class Cert. 1. They assert EPPs failed to provide a feasible methodology for identifying and removing brand and generic Niaspan purchases that fall within class exclusions. *Id.* at 41. Defendants specifically argue that EPPs failed to provide any method for identifying the exclusions of brand-only payors after actual generic entry, generic-only payors on tiered plans, consumers with the same co-

payment for brand and generic drugs, fully insured plans, and state and federal agencies with self-funded prescription drug plans. *Id*. at 41–46.

EPPs respond that Craft proffers a six-step methodology for identifying class members based on her experience manipulating pharmaceutical data, and that her methodology is particularly well-suited for the pharmaceutical industry, "which are tracked, monitored, and recorded across a set of substantially uniform variables." EPPs' Reply Class Cert. 6. EPPs also argue defendants' challenges to feasibility address "tiny subgroups of consumers" and "each argument can be addressed reliably and programmatically through Plaintiffs' proposed methodology." *Id*. at 20.

The Court agrees with defendants on this issue. It is not persuaded that EPPs have an administratively feasible mechanism for identifying class members which involves applying all class exclusions. Craft's six-step methodology that "OnPoint would be able to merge the data from the various sources, identify and eliminate data errors, transform the data to standardize the fields, eliminate duplicates, and compile a list reflecting the identities of the class members contained in the data," Craft Decl. ¶ 10, does not offer a methodology "specific to this case." *See Carrera*, 727 F.3d at 306, 311. Without more information about the process through which Craft claims she will "compile a list reflecting the identities of the class members," defendants lack the ability to meaningfully test the reliability of EPPs' proposed method of identifying class members. *See Carrera*, 727 F.3d at 307. As defendants persuasively stated at oral argument, EPPs have the burden "to develop the methodology and bring it to the Court . . . for [defendants] to be able to evaluate and . . . to present [to the Court any] opposing positions." July 23, 2019 Hr'g Tr. ("July 23 Tr.") 137:5–10.

Craft's expert report assures the Court that she can "programmatically" through a "manageable process" identify a list of class members based on the fact that she has "extensive experience applying these types of exclusions." While Craft's report constitutes admissible evidence, the Court does not find that her report establishes by a preponderance of the evidence that EPPs have an administratively feasible methodology for identifying class members. The Court is particularly concerned by Craft's failure to provide any explanation as to how she can apply all of the exclusions required by plaintiffs' complex class definition in an administratively feasible manner. Mere assurances that a model will be effective to ascertain class members is insufficient. *Carrera*, 727 F.3d at 311–312. Accordingly, plaintiffs must provide more than Craft's *ipse dixit* to prevail under a rigorous ascertainability analysis.[4]

A review of EPPs' evidence belies their claim that all exclusions can be "addressed reliably and programmatically through Plaintiffs' proposed methodology." EPPs' Reply Class Cert. 20. EPPs submitted numerous short declarations that omitted critical supporting details necessary to satisfy the Court. EPPs present an individualized, *ad hoc* approach that does not adequately establish a feasible methodology to address the many class exclusions.

For example, defendants argue that EPPs have proposed no methodology for identifying federal and state entities with self-funded plans—one of the many class exclusions. Defs.' Opp'n Class Cert. 45; May 14 Tr. 175:23–177:15. EPPs respond that federal and government agencies are facially obvious. EPPs' Reply Class Cert. 17. However, defendants provided evidence that such plans are not necessarily facially obvious. May 14 Tr. 176:7–177:6.

[4] EPPs provided the Court with notice of the decision in *In re Restasis (Cyclosporine Cphthalmic Emulsion) Antitrust Litig.*, No. 18-md-2819, (E.D.N.Y. May 5, 2020), in which Judge Gershon of the Eastern District of New York certified an end payor class, relying in part on evidence provided by Craft (Document No. 706, filed May 15, 2020). The Court concludes that this precedent is unpersuasive because the Second Circuit applies a less rigorous standard for analyzing ascertainability.

Moreover, even if such plans were facially obvious, EPPs have not explained how they intend to programmatically apply that exclusion to a putative class estimated at over 600,000 members.

The District of Rhode Island's recent decision on the ascertainability of TPPs is not persuasive on this issue. *See In re Loestrin 24 FE Antitrust Litig.*, No. 1:13-md-2472, 2019 WL 5406077 (D.R.I. Sept. 17, 2019) (Smith, J.). The *Loestrin* court approved of end payor plaintiffs' proposed methodology for identifying class members in part by dismissing concerns regarding the exclusion of federal and state entities with self-funded plans. *Id.* at *30. However, EPPs in that case made specific assurances that self-funded government plans would be removed from the data by PBMs rather than merely identified by name. *Id.* As discussed above, EPPs in this case have only said that such plans would be facially obvious—a contention that defendants have rebutted.

Additionally, defendants contend that plaintiffs have no methodology to identify and exclude "[f]ully insured plans (i.e. plans that purchased insurance from another third party covering 100% of the Plan's reimbursement obligations to its members)." Defs.' Opp'n Class Cert. 44. In her deposition, Craft asserted for the first time that Form 5500s, an IRS form filed by health benefit plans, could be used to identify fully insured plans. *Id.* at 44–45. However, defendants identify inconsistencies on the Form 5500 of named plaintiff AF of L as exemplary of the difficulties in ascertaining fully insured health plans in that manner. *Id.* at 45.

EPPs respond that defendants can only point to "a single Form 5500," which they contend does not rebut Craft's deposition testimony. EPPs' Reply Class Cert. 18. They also note that Winkelman testified that PBMs typically maintain data that can be used to identify and exclude fully-insured plans. *Id.* However, Winkelman acknowledged that no such data has been produced in this case. Defs.' Opp'n Class Cert. 45. In their Reply, EPPs proffer that "even to

the extent that Form 5500 and PBM records do not capture the funding status of a small number of plans, those plans can be presumed to be fully-insured (and thus excluded from the subclasses) unless they are able to supply proof of their self-insured status." EPPs' Reply Class Cert. 19. It is possible that such a methodology, if adopted, could address this challenge. However, the above exchange further illustrates the extent of EPPs' *ad hoc* approach to applying class exclusions and the lack of a comprehensive methodology for systematically applying exclusions in this case.

For some exclusions, EPPs have simply not provided the Court with satisfactory evidence that the exclusions can be systematically applied. For example, the class definition excludes consumers with the same co-payment for brand and generic drugs ("flat co-payors"). Exclusion of these flat co-payers requires a determination of what purchasers would have paid for their brand Niaspan prescription as well as what they would have paid for generic Niaspan they never purchased, a task further complicated by the fact that a health plan co-payment structure can change over time. Defs.' Opp'n Class Cert. 42. EPPs provide evidence that at least some PBMs maintain this information. Jonathan Stocker of Prime Therapeutics stated that "Prime's database houses member plan design details, including, but not limited to, information regarding copayment structure (*i.e.* flat co-payment or percentage co-payment), to the extent applicable." Stocker Decl. ¶ 10. Kyle Brua, also of Prime Therapeutics, declared that "Prime can . . . provide purchase records that exclude purchases made by members with a flat co-payment benefit plan." Decl. Non-Party Prime Therapeutics LLC ("Brua Decl.") ¶ 6. However, as defendants' ascertainability expert, Donald Dietz, explains, in the pharmaceutical industry, the term "flat co-pay" refers to "a co-pay that is set in dollar amounts, as opposed to a percentage of the drug cost . . . and not a single-tier plan design that has the same co-pay for brand and generic drugs."

Expert Rep. Donald J. Dietz ("Dietz Rep.") ¶ 68. Based on the evidence before the Court, EPPs' have not established that PBMs can provide purchase records that exclude consumers with the same co-payment for brand and generic drugs, or that transactional records stored by PBMs and other record holders contain information related to plan details in a way that could be programmatically and feasibly applied in order to exclude "flat co-payors" from the class.

The Court is further concerned about the possibility that even if identification of class members is technically possible, EPPs' proposed methodology would be prohibitively expensive and thus infeasible. At oral argument, EPPs claimed that an administratively feasible mechanism for identifying class members is not required for facilitating the best class notice practicable pursuant to Rule 23(c)(2).[5] *See* May 15, 2019 Hr'g Tr. ("May 15 Tr.") 44:15–46:3. Moreover, EPPs predicted that they may never have to utilize their methodology for identifying class members. *Id.* at 45:8-21. In fact, counsel for EPPs reported that in a similar pay-for-delay case before Judge Saris,[6] when plaintiffs sought to subpoena the relevant pharmaceutical records, they learned it would cost $18 million to obtain the requested information. July 23 Tr. 181:20–182:1. In that case, Judge Saris rejected that approach as "too expensive because it [would] come[] out of the class's recovery," and pursued publication notice instead. *Id.* at 181:20–182–14. In view of these statements, the Court is concerned that EPPs' claimed ascertainability methodology is not reasonably practicable.

The Court harbors significant doubt as to whether EPPs have met their burden of showing

[5] The Court notes that EPPs' interpretation of the ascertainability requirement is not supported by Third Circuit precedent. *See, e.g.*, *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593 (3d Cir. 2012) ("[The ascertainability requirement] protects absent class members by facilitating the 'best notice practicable' under Rule 23(c)(2) in a Rule 23(b)(3) action."); *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013) ("First, at the commencement of a class action, ascertainability and a clear class definition allow potential class members to identify themselves for purposes of opting out of a class.").

[6] Judge, former Chief Judge, U.S. District Court for the District of Massachusetts. *In re Pharmaceutical Industry Average Wholesale Price Litigation*, No. 01-12257, (D. Mass. filed Dec. 19, 2001).

they can identify class members through a reliable and administratively feasible mechanism. "When courts harbor doubt as to whether a plaintiff has carried her burden under Rule 23, the class should not be certified." *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 483 (3d Cir. 2018). Accordingly, the Court declines to certify the EPP class as ascertainable on the state of the present record. As detailed below, the EPP proposed class also fails the predominance and superiority requirements of Rule 23(b)(3).

ii. Predominance

Rule 23(b)(3) requires that "the questions of law or fact common to class members predominate over any questions affecting only individual members." "Rule 23(b)(3), however, does *not* require a plaintiff seeking class certification to prove that each 'elemen[t] of [her] claim [is] susceptible to classwide proof.' What the rule does require is that common questions '*predominate* over any questions affecting only individual [class] members.'" *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 568 U.S. 455, 469 (2013) (emphasis in original).

"An individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a prima facie showing [or] the issue is susceptible to generalized, class-wide proof." *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016) (internal quotations and citations omitted).

"The aim of the predominance inquiry is to test whether any dissimilarity among the claims of class members can be dealt with in a manner that is not 'inefficient or unfair.'" *In re Asacol Antitrust Litig.*, 907 F.3d 42, 51 (1st Cir. 2018). "Inefficiency can be pictured as a line of thousands of class members waiting their turn to offer testimony and evidence on individual issues." *Id.* "Unfairness is equally well pictured as an attempt to eliminate inefficiency by

presuming to do away with the rights a party would customarily have to raise plausible individual challenges on those issues." *Id.* at 51–52.

EPPs' argue that common issues predominate across their antitrust claims and unjust enrichment claims, and that aggregate damages can be calculated on a classwide basis. EPPs' Class Cert. Mem. 20–28. Specifically, EPPs claim they will be able to prove their antitrust claims with common evidence that there was an unlawful restraint of trade through an unjustified reverse payment from Kos to Barr, that the reverse payment had anticompetitive effects in the relevant market, that the anticompetitive effects outweighed any pro-competitive justifications, and that EPPs sustained class-wide impact, or injury, caused by defendants' actions. *Id.* at 20–25. They also assert that their unjust enrichment claims can be proven by the same common evidence used to prove that unlawful delay in generic entry produced monopoly profits at the expense of EPPs. *Id.* at 26; EPPs' Reply Class Cert. 65.

Defendants respond that individual questions predominate because EPPs lack common evidence of antitrust injury and cannot establish that class members were injured without resorting to individualized evidence that would overwhelm common questions. They argue that EPPs improperly apply the federal overcharge standard for antitrust injury, but even under that injury standard, EPPs have no common proof of antitrust injury.[7] They further contend that EPPs' evidence of classwide injury relies on averages that impermissibly conceal uninjured class members and identify specific subsets of the class that are potentially uninjured. Defendants also raise challenges to EPPs' aggregate damages model, and contend that many state antitrust laws, unjust enrichment laws, and unfair trade practices and consumer protection laws require proof of

[7] Under federal antitrust law, antitrust injury occurs the moment that a purchaser incurs an overcharge. *See Adams v. Mills*, 286 U.S. 397, 407 (1932). Antitrust injury is also referred to as "antitrust impact." *See In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d at 311.

actual damages and that variations between the state laws raise individualized questions that overwhelm the common issues.

The Court considers each of defendants' challenges in turn.

1. *The Impact of Individual Questions for Antitrust Injury and Impact*

EPPs argue that defendants' predominance challenges focus on proof of injury, and that common questions predominate based on EPPs' "common proof to establish the [other] essential substantive elements of their antitrust claims, including the presence of a 'large, unjustified reverse-payment,' market power, anti competitive effects, and causation." EPPs' Reply Class Cert. 30.

The Court rejects EPPs' argument on this issue. It is well established that the lack of common evidence of antitrust injury or impact alone can cause individual questions to predominate. *See, e.g.*, *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 262 (3d Cir. 2016) ("In an antitrust class action, 'impact often is critically important for the purpose of evaluating Rule 23(b)(3)'s predominance requirement because it is an element of the claim that may call for individual, as opposed to common, proof.'").

2. *Antitrust Injury and Impact Standard for State Law Claims*

It is undisputed that under longstanding federal antitrust law, antitrust injury occurs the moment that a purchaser incurs an overcharge. *See e.g., Adams v. Mills*, 286 U.S. 397, 407 (1932) ("In contemplation of law the claim for damages arose at the time the extra charge was paid."). However, the parties disagree as to whether that same injury standard should apply to EPPs' state law antitrust claims. EPPs contend that the federal antitrust standard, under which injury occurs the moment of overcharge, applies to the state law claims. EPPs' Class Cert. Mem. 24. Defendants disagree, asserting that the Court has an obligation to determine whether each

state would apply an actual economic harm standard, and that under the correct state law standards for injury, EPPs are required to prove that they suffered actual economic harm from the overcharge, and did not pass on that overcharge to others. Defs.' Opp'n Class Cert. 66–68.

In order to assess the antitrust injury standard for state law claims, it is important to first review the jurisprudential backdrop against which EPPs bring their antitrust claims.

In *Hanover Shoe*, the Supreme Court held that antitrust plaintiffs could recover the full amount of their overcharge damages, and antitrust defendants could not raise the defense that plaintiffs were unharmed because plaintiffs passed to others any overcharges that they had paid. *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 491–93 (1968). The Supreme Court chose to abolish this pass-on defense because "establishing the applicability of the passing-on defense would require a convincing showing of each of these virtually unascertainable figures [and] the task would normally prove insurmountable . . . Treble-damage actions would often require additional long and complicated proceedings involving massive evidence and complicated theories." *Id.* at 493.

In *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), the Supreme Court "made the symmetrical decision, consistent with *Hanover* [*Shoe*], to disallow an offensive use of the [pass-on] theory." *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1164 n.10 (3d Cir. 1993). "[J]ust as *Hanover Shoe* wanted to avoid burdening antitrust plaintiffs from nearly-impossible evidentiary challenges, *Illinois Brick* reflected the Supreme Court's 'perception of the uncertainties and difficulties in analyzing price and out-put decisions in the real economic world . . . and of the costs to the judicial system and the efficient enforcement of the antitrust laws of attempting to reconstruct those decisions in the courtroom.'" *In re Processed Egg Prod. Antitrust Litig.*, 881 F.3d 262, 270 (3d Cir. 2018). Under *Illinois Brick*, federal antitrust claims

by indirect purchasers were barred. However, *Illinois Brick* did not preempt indirect purchasers from bringing antitrust actions under state antitrust laws. *California v. ARC Am. Corp.*, 490 U.S. 93, 105–06 (1989). In the present action, EPPs bring their antitrust claims under laws by "*Illinois Brick* repealer states" that have passed statutes enabling indirect purchasers to bring antitrust claims under state law. EPPs' Reply Class Cert. 35; *see generally In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 214 n.9 (E.D. Pa. 2012) (describing "*Illinois Brick* repealers").

Defendants argue that "[t]he federal overcharge measure of injury that EPPs rely upon is a legal construct that, for reasons grounded in federal antitrust policy, permit direct purchasers to recover the entire overcharge even if they 'passed on' the overcharge to others and suffered no actual economic harm." Defs.' Opp'n Class Cert. 67 (citing *Hanover Shoe, Inc. v. United Shoe Mach. Corp.*, 392 U.S. 481, 494 (1968)). They state that "EPPs just assume, without any analysis of specific state laws, that the federal measure of injury for direct purchaser claims applies to their indirect purchaser claims [and that EPPs'] assumption makes no sense, as a matter of law or policy." Defs.' Opp'n Class Cert. 67. Defendants argue to the contrary that the Court must assess each state statute, and absent "a definitive ruling by a state's highest court, [this Court] must predict how that court would rule if faced with the issue." *Id.* at 68 (citing *Covington v. Cont'l Gen. Tire, Inc.*, 381 F.3d 216, 218 (3d Cir. 2004)).

EPPs respond that "[t]he class states repealed *Illinois Brick Co. v. Illinois*'s prohibition against indirect purchaser antitrust actions, but they did not repeal the century of federal antitrust law preceding *Illinois Brick*[,] . . . includ[ing] the well established principle that 'antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset.'" EPPs' Reply Class Cert. 35 n. 55.

The Court agrees with EPPs that *Illinois Brick* repealer states have applied the federal overcharge injury standard. Defendants' argument conflates the policy that the Supreme Court articulated with respect to treatment of the pass-on defense in *Hanover Shoe* and the offensive use of the pass-on theory in *Illinois Brick* with the longstanding antitrust principle that injury occurs at the moment of overcharge. *See, e.g.*, *Adams v. Mills*, 286 U.S. 397, 407 (1932); *S. Pac. Co. v. Darnell-Taenzer Lumber Co.*, 245 U.S. 531, 534 (1918). The "federal" overcharge standard of antitrust injury is distinct from the policy judgments implicated by *Hanover Shoe* and *Illinois Brick* and the subsequent passage of the state statutes repealing *Illinois Brick*.

EPPs contend that defendants' argument "is based on the faulty legal premise that injury and damages are synonymous." EPPs' Class Cert. Mot. 34. The Court agrees with EPPs on that issue.

Proof of antitrust injury or impact is analytically distinct from proof of antitrust damages. *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d 184, 194 (3d Cir. 2020) ("We have consistently distinguished injury from damages."); *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 188 (3d Cir. 2001) ("Proof of injury (whether or not an injury occurred at all) must be distinguished from calculation of damages (which determines the actual value of the injury)."). "[T]he purpose of the antitrust injury requirement is to prove that the theory of unlawful conduct, i.e. the theory of liability, was in fact responsible for causing harm to plaintiffs." *In re Niaspan Antitrust Litig.*, No. 13-2460, 2019 WL 3816829, at *14 (E.D. Pa. Aug. 14, 2019). The availability of a pass-on defense has no bearing on proof that a plaintiff sustained "some harm traceable to the defendant's conduct." *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 305 (3d Cir. 2016). To the extent that pass-on defense is available, it relates to the calculation of damages, not the standard of antitrust injury. *See In re Cardizem CD*

Antitrust Litig., 200 F.R.D. 297, 317 (E.D. Mich. 2001) ("Defendants' by-pass and offsetting benefits arguments relate to the quantum of damages; not the fact of injury."); *see also In re Vitamins Antitrust Litig.*, 259 F. Supp. 2d 1, 8–9 (D.D.C. 2003) (permitting a pass-on defense as a challenge to "plaintiff's damage estimates").

The Court concludes that EPP class members sustained antitrust injury at the moment they were overcharged. This decision is consistent with the approach adopted by other courts considering state law claims in similar antitrust actions by indirect purchasers. *See In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015) ("[A]ntitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset."); *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *14 (D.N.J. Oct. 30, 2018) (holding that subsequently recovered damages are "irrelevant to the question of impact"); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, No. 14-02503, 2017 WL 4621777, at *15 (D. Mass. Oct. 16, 2017) ("[E]ven if putative class members were reimbursed for overcharges through insurance plans or coupons, they still experienced antitrust injury in the form of an overcharge, although the amount of damages may require adjustment."); *In re Lidoderm Antitrust Litig.*, No. 14-02521, 2017 WL 679367, at *21 (N.D. Cal. Feb. 21, 2017) ("[T]he Court concludes that a person suffers a cognizable injury and is impacted by a price-fixing conspiracy at the moment he pays an antitrust overcharge, even if the anticompetitive conduct at issue also results in offsetting benefits.").

Thus, for purposes of the predominance inquiry, EPPs may satisfy their burden of showing common evidence of antitrust injury by establishing that each class member paid an overcharge, regardless of whether that overcharge was subsequently passed on to others.

3. *EPPs' Common Proof of Injury*

EPPs present an expert report from Dr. Meredith Rosenthal to support their claim that they have common proof of antitrust injury arising from the delay in generic entry. Dr. Rosenthal relies on extensive evidence, including a Federal Trade Commission ("FTC") study finding that "generic price discounts with respect to the pre-launch branded price reach 17% after 6 months," at which point generics hold 83.7% of the market share. Expert Rep. Meredith Rosenthal, Ph.D. ("Rosenthal Rep.") ¶ 37. According to Dr. Rosenthal, the actual launch of generic Niaspan resulted in a 33% price discount after 6 months, at which point generic Niaspan garnered 79% of the market share. *Id.* Dr. Rosenthal also notes that defendant AbbVie's internal analyses anticipated results similar to the FTC study, namely, "a generic penetration rate starting at 30% in the first month and reaching nearly 90% assuming two generic products." *Id.*

Based on this research, Dr. Rosenthal employs a "yardstick model," which compares the actual prices and quantities in the market of interest to the prices and quantities that occur in a similar market untainted by the delay of generic entry and foreclosure of lower prices. *Id.* ¶ 27. She bases her yardstick calculations on AbbVie's internal analysis and the FTC study results, and assumes an average rate of generic substitution of 87.8% from Kos' own internal forecasting. *Id.* ¶ 38.

Dr. Rosenthal concludes that "the likelihood that a consumer who paid for Niaspan during the Class Period would not have paid for at least one prescription of the generic in the but-for world is small – 100 minus 87.8 or 12.2%. Moreover, because Niaspan is a maintenance drug most potential Class members will have many prescriptions and thus repeated opportunities to be offered and try the generic." *Id.* ¶ 39. With respect to TTPs, Dr. Rosenthal opines that, assuming a TPP pays for at least ten independent Niaspan claims, "the likelihood that a payer

with only 10 claims for Niaspan in the actual world had no generic claims in the but-for world is approximately 0.000000001 or 1 in 1 billion." *Id.* ¶ 38.

According to EPPs, "the analysis conducted by Dr. Rosenthal demonstrates that virtually all class members were injured on at least one transaction by the unlawful delay in generic Niaspan competition."[8] EPPs' Class Cert. Mem. 33.

4. *Defendants' Challenges to EPPs' Common Proof of Injury*

Defendants argue that contrary to EPPs' assertions, Dr. Rosenthal's report does not provide common evidence of antitrust injury. Defs.' Opp'n Class Cert. 51–55. Defendants highlight Dr. Rosenthal's deposition testimony in which she conceded she does not opine that all class members were injured, and that her aggregate damages analysis does not show which individual class members were uninjured. *Id.* at 52. As defendants' expert, Professor James Hughes, opines, "if [Dr. Rosenthal's] damages model were reliable, which it is not, at best she could establish the average 'overcharge' per prescription paid by the class. But this average overcharge simply does not speak to whether any or all individual class members were injured." Expert Rep. Prof. James W. Hughes, Ph.D. ("Hughes Rep.") ¶ 119. Defendants contend that Dr. Rosenthal's reliance on averages impermissibly hides uninjured class members. In support, they rely on Professor Hughes' analysis of transactional data produced by ten EPP named plaintiffs. Defs.' Opp'n Class Cert. 54. After reviewing the data, Professor Hughes concluded that "there is wide heterogeneity across Named Plaintiffs in total prescription costs for Niaspan, ranging from $0 to over $1,000 per prescription," and that "[p]ayments made by consumers of Niaspan and

[8] EPPs argue that they are entitled to a presumption of causation that the class sustained classwide injury. EPPs' Class Cert. Mem. 24–25. They claim that "an antitrust plaintiff may be entitled to a presumption of causation where the anticompetitive conduct 'is deemed wrongful because it is believed significantly to increase the risk of a particular injury' and that injury occurred." *Id.* at 24 (citing *In re Actos End-Payor Antitrust Litig.*, 848 F.3d 89, 101 (2d Cir. 2017)). The Court agrees with defendants that *Actos* does not diminish EPPs' burden of proving classwide antitrust injury. *See* Defs.' Opp'n Class Cert. 56.

generic niacin also vary considerably across consumers and also deviate substantially from Professor Rosenthal's calculated average, ranging from $0 to over $250." Hughes Rep. ¶ 122. Defendants argue that Dr. Rosenthal's assertion that Niaspan users will likely make at least one generic purchase "ignores studies that showed more than 40 percent of patients stopped taking Niaspan after the first three months, and only 16 percent continued to take Niaspan after one year." Defs.' Opp'n Class Cert. 26.

Defendants further argue that "there are numerous examples of circumstances in which potential class members would not have suffered any injury from the alleged delay in generic entry, and for which there is no way to identify those class members without individualized inquiries." Defs.' Opp'n Class Cert. 57. These groups include (1) consumers and TPPs who still would have paid for brand Niaspan after generic Niaspan was introduced (brand loyalists), (2) uninjured consumers due to copay assistance, (3) consumers fully reimbursed by health reimbursement accounts ("HRAs"), (4) flat co-payors, (5) consumers who filled all Niaspan prescriptions in the Medicare Part D coverage gap, (6) TPPs that would have paid the same or more for generic Niaspan than brand Niaspan, and (7) rebates.

The Court first considers defendants' challenges to EPPs' use of averages to prove classwide injury, and then addresses the defendants' claims regarding specific subgroups of uninjured class members.

a. EPPs' Use of Averages To Prove Classwide Injury

The Court must determine whether Dr. Rosenthal's use of averages in her yardstick model masks uninjured class members or can be used to prove common classwide injury. The answer: Dr. Rosenthal does not provide common evidence of classwide injury; proof of injury

would involve individualized inquiries that defeats predominance. Dr. Rosenthal's use of averages to determine classwide injury thus masks uninjured class members.

"The use of averages in a common impact analysis is controversial, and courts have come down on both sides of the issue at the class certification stage . . . Essentially, the case law seems to compel the court to view averages as at least somewhat suspect, but not as fatally flawed so long as (1) the differentiation among the data being averaged is not so great as to make the use of averages misleading; and (2) there are other indicia that the averages are not concealing the true story of the data." *In re Blood Reagents Antitrust Litig.*, No. 09-2081, 2015 WL 6123211, at *18 (E.D. Pa. Oct. 19, 2015) (DuBois, J.) (citing *In re Processed Egg Prod. Antitrust Litig.*, 81 F. Supp. 3d 412, 428 (E.D. Pa. 2015)). "Averages are also more of a problem when plaintiffs seek to certify a class of indirect purchasers." *In re Lamictal Indirect Purchaser & Antitrust Consumer Litig.*, No. 12-00995, 2018 WL 6567709, at *7 (D.N.J. Dec. 12, 2018), *rev'd on other grounds* 957 F.3d 184 (3d Cir. 2020). On this issue, the Third Circuit recently cautioned that courts should not assume, "absent a rigorous analysis, that averages are acceptable." *In re Lamictal Direct Purchaser Antitrust Litig.*, 957 F.3d at 194.

EPPs contend that Dr. Rosenthal's proposed damages model uses common evidence to show class-wide injury, and "is constructed by reference to the well-researched and accepted understanding in the scholarly literature of the impact of generic competition on drug prices, real world data reflecting the prices and volume of brand and generic Niaspan, in addition to the prices and quantities sold for 'yardstick' products." EPPs' Reply Class Cert. 44. They argue that the variation is not so wide as to mask uninjured members. *Id.* According to EPPs, this case is similar to *Flonase*, another pay-for-delay case, in which plaintiffs submitted expert evidence of common injury based on a yardstick analysis. *Id.* at 44 n.66 (citing *In re Flonase Antitrust*

Litig., 284 F.R.D. 207, 222 (E.D. Pa. 2012). In that case, the court was "satisfied that the data variation in this case [was] not so extreme as to mask the absence of injury for a significant number of class members." *Id.* at 229.

Defendants argue that *Flonase* is inapposite. May 14 Tr. 191:7–15. In *Flonase*, plaintiffs' expert conducted a sensitivity analysis, which assured the court that the averages did not mask significant variation. *Id.*; *In re Flonase Antitrust Litig.*, 284 F.R.D. at 228–229. In addition, defendants correctly note that the *Flonase* court was only satisfied that the averages did not mask significant variation after excluding several groups of potentially uninjured plaintiffs, including (1) uninsured consumers who purchased brand Flonase after generic entry; (2) all consumers who purchased brand Flonase prior to generic entry and did not purchase brand or generic Flonase after generic entry; and (3) TPPs that only purchased and/or reimbursed brand Flonase but never generic Flonase during the Class Period. *In re Flonase Antitrust Litig.*, 284 F.R.D. at 230–232. Significantly, *Flonase* was decided prior to the Third Circuit adoption of the ascertainability requirement, so the court was able to exclude potentially uninjured purchasers without considering whether purchasers falling within those exclusions were reasonably ascertainable. *Id.*; May 14 Tr. 192:4–6. Thus, *Flonase* is distinguishable from this case.

EPPs correctly state that evidence of delay in generic entry that results in overcharges can in some cases suffice to show classwide evidence of injury. EPPs' Reply Class Cert. 44, 52–53. However, the substantial variation in prices reported by Dr. Hughes among the sliver of data produced by named plaintiffs—$0 to over $1,000 per prescription for TPPs, and $0 to over $250 for consumers—raises cause for concern in this case. *See* Hughes Rep. ¶ 122. EPPs do not contest Dr. Hughes' analysis, but instead observe that "most transaction prices clustered around

[Dr. Rosenthal's] average prices, and that any variations follow a discernable trend alongside the average prices." EPPs' Reply Class Cert. 52 n.75.

The Court concludes that the averages in Dr. Rosenthal's yardstick model do not suffice to prove classwide injury for EPPs in this case. Critically, Dr. Rosenthal conceded that her yardstick model does not purport to show that all class members were injured. Defs.' Opp'n Class Cert. 52 (citing Rosenthal Dep. 62:21–63:5). The Court finds this case analogous to *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, in which plaintiffs also relied on the expert testimony of Dr. Rosenthal. In that case, Judge Stengel conducted "[a] 'rigorous analysis' of Dr. Rosenthal's reports and testimony" and concluded "it does not show that *all* class members paid supra-competitive prices for generic or branded sustained release bupropion, or that this determination can be made with common proof." No. 04-5898, 2010 WL 3855552, at *26 (E.D. Pa. Sept. 30, 2010). In *GlaxoSmithKline*, Dr. Rosenthal admitted that certain class members may be uninjured, and that her analysis would be unable to identify them, leading the court there to conclude that the proffered yardstick model masked groups of uninjured class members. *Id.* at *30. As Judge Stengel noted in rejecting the proposed yardstick methodology, "the issue is not whether [the] techniques are generally accepted; it is whether they are appropriate when applied to the facts and data *in this case*." *Id.* (internal quotations omitted and emphasis in original). In this case, the Court concludes that the use of averages hides several groups of uninjured class members who cannot be easily identified.

b. Means of Removing Uninjured Class Members

Defendants argue that EPPs further fail the predominance requirement because there are large categories of uninjured class members that EPPs have not identified and cannot identify without individualized inquiry. Defs.' Opp'n Class Cert. 57. Specifically, defendants point to

brand loyalists, consumers who are uninjured due to co-payment assistance, health reimbursement accounts ("HRAs"), flat co-payors, consumers who filled all Niaspan prescriptions during a Medicare Part D coverage gap, TPPs paying the same or more for generic Niaspan than for brand Niaspan, and TPPs that received brand rebates. In response, EPPs assert that "virtually all class members were injured on at least one transaction by the unlawful delay in generic Niaspan competition." EPPs' Reply Class Cert. 33.

To the extent that a proposed class contains uninjured class members, plaintiffs must provide a reasonable and workable method for differentiating between uninjured class members and injured class members so that uninjured class members do not recover damages. *In re Asacol Antitrust Litig.*, 907 F.3d 42, 58 (1st Cir. 2018). Such a method must be protective of a defendant's constitutional rights and not cause individual inquiries to overwhelm common issues. *Id.*; *see also Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *21 (E.D. Pa. June 10, 2015) ("Without a means of identifying these uninjured persons using common evidence, every class member would need to be reviewed on an individualized basis to see if they were impacted by Defendants' alleged anticompetitive actions."). Moreover, for purposes of the predominance analysis, the number of potentially uninjured class members is a relevant consideration. While it is perfectly reasonable for the Court to address challenges to a small number of uninjured class members, "it would be far more difficult for a court to 'weed out' over 2,000 uninjured class members—or some subset of that number—from a class of over 16,000." *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 292 F. Supp. 3d 14, 137–38 (D.D.C. 2017); *see also In re Intuniv Antitrust Litig.*, No. 16-12396, 2019 WL 3947262, at *8 (D. Mass. Aug. 21, 2019). In this case, there are an estimated 600,000 class members, any of whom may

be uninjured, and according to defendants, there are thousands who in fact suffered no injury. *See In re Asacol Antitrust Litig.*, 907 F.3d at 53–54.

The Court next addresses defendants' arguments on the issue of uninjured class members.

i. Brand Loyalists

The first and most significant group of uninjured, unidentified class members are consumer brand loyalists, who were unharmed by delayed generic entry because they would have continued buying brand Niaspan regardless of any price difference between brand and generic Niaspan. Dr. Rosenthal calculated that 12.2% of purchases after generic entry would remain brand purchases. Rosenthal Rep. ¶ 39.

Defendants contend that "there is simply no mechanism to determine which prescriptions [the 12.2% of continued brand purchases after generic entry] would have been, and who would have paid for them, without class-member-specific and even transaction-specific inquiries." Defs.' Opp'n 57.

EPPs first respond that "[d]ue to state automatic substitution laws, all or virtually all Niaspan consumers would try generic Niaspan at least once, even if they ultimately chose to return to the brand at a higher price." EPPs' Reply Class Cert. 49 (citing *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27–30 (1st Cir. 2015). EPPs have provided no evidence regarding the specific terms of such state laws. This omission is significant because, while all states have such laws, not all states make substitution mandatory.

EPPs also argue that they have accounted for brand loyalists by excluding consumers who purchased only brand Niaspan after generic entry on September 20, 2013, and argue that such purchasers can be identified. EPPs' Reply Class Cert. 23. They assure the Court that they can create a database by which they can systematically apply the brand loyalist exclusion. *Id.*

For the reasons discussed when analyzing class ascertainability, the Court doubts whether EPPs can feasibly produce such a database and systematically apply the brand loyalist exclusion.

Even assuming *arguendo* that EPPs could identify the brand loyalists that purchased only brand Niaspan after generic entry, EPPs have no means of identifying brand loyalists who purchased brand Niaspan prior to generic entry but made no purchases of brand or generic Niaspan after generic entry. EPPs respond with three arguments. The Court rejects EPPs' arguments.

First, EPPs argue that "such consumers cannot properly be considered brand loyalists because generic Niaspan was not yet available on the market, they lacked an opportunity to demonstrate any preference for or 'loyalty' to branded or generic Niaspan." EPPs' Reply Class Cert. 25. This response fundamentally misconceives the objective of the inquiry, which is to assess whether a purchaser *would have* purchased cheaper generic Niaspan had that option been available. This Court is aware of no court that has adopted this unfounded argument, and it declines to do so in this case.

Second, EPPs argue that the presence of unidentified, uninjured brand loyalists in the class does not prejudice defendants. EPPs' Reply Class Cert. 25. Specifically, they assert that Dr. Rosenthal factored in the presence of brand loyalists and calculated damages only for those class members who would have switched to generic Niaspan or who purchased the generic at inflated prices so "defendants have no interest tied to the exclusion of purported brand loyalist class members." *Id*. at 26.

EPPs' argument that defendants have no interest in the exclusion of uninjured class members has been rejected by the Third Circuit. *See Carrera v. Bayer Corp.*, 727 F.3d 300, 310 (3d Cir. 2013) ("[Defendant] has an interest in ensuring it pays only legitimate claims. If

fraudulent or inaccurate claims materially reduce true class members' relief, these class members could argue the named plaintiff did not adequately represent them [and they are not bound by the judgment."); *see also In re Asacol Antitrust Litig.*, 907 F.3d 42, 56 (1st Cir. 2018) ("Once one accepts plaintiffs' 'no harm, no foul' position there would be no logical reason to prevent a named plaintiff from bringing suit on behalf of a large class of people, forty-nine percent or even ninety-nine percent of whom were not injured, so long as aggregate damages on behalf of 'the class' were reduced proportionately. Such a result would fly in the face of the core principle that class actions are the aggregation of individual claims, and do not create a class entity or re-apportion substantive claims.").

Finally, EPPs argue "it would be inappropriate to exclude from the classes individuals who purchased Niaspan solely prior to generic entry because it would permit Defendants to benefit from their own illegal conduct." EPPs' Reply Class Cert. 26. However, this argument is unavailing, as under Rule 23, it is EPPs who bear the burden of proof. "The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only," *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 248 (3d Cir. 2016), and for EPPs to take advantage of the class action device, EPPs must limit their class to an operational definition. *See, e.g.*, *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 232 (E.D. Pa. 2012) (excluding class members who did not make any purchases of brand or generic Flonase after generic entry to avoid potential brand loyalists).

The Court concludes that there are a substantial number of brand loyalists in the class, and EPPs have the burden of showing that excluding them can be accomplished without extensive individualized inquiry. EPPs have provided no "reasonable and workable plan for how [the opportunity to press at trial genuine challenges to allegations of injury-in-fact] will be

provided in a manner that is protective of the defendant's constitutional rights and does not cause individual inquiries to overwhelm common issues." *Thalomid*, 2018 WL 6573118, at *12. Accordingly, the Court concludes that identification of consumer brand loyalists would require extensive individualized inquiries and defeat predominance. *See Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 4737288, at *19 (E.D. Pa. Aug. 4, 2015);[9] *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, No. 04-5898, 2010 WL 3855552, at *25 (E.D. Pa. Sept. 30, 2010).

Thus far, the brand loyalist discussion has focused on consumer purchasers. With respect to TPP brand loyalists, Dr. Rosenthal opined that the likelihood that a payor with only 10 independent claims for Niaspan had no generic claims is approximately 1 in 1 billion. Rosenthal Rep. ¶ 38. As a result, EPPs state there is no brand loyalist concern for TPPs with many independent claims. In response, defendants point out that there are over 20,000 self-insured health plans and over 4,000 mixed health plans, many of which are very small and would have made only a few purchases, thereby rendering it more likely that at least some of the TPPs are uninjured. May 14 Tr. 188:7–15. For example, defendants point to the fact that from 2014 to 2016, named TPP plaintiff AF of L paid for only 31 months of Niaspan for only three beneficiaries. *Id.* at 188:16–23.

Even if a TPP reimbursed only three beneficiaries, it would remain unlikely that all the TPP's reimbursements were for brand loyalists. On the current state of the record, the Court concludes that the number of any TPP brand loyalists is *de minimis*.

[9] EPPs provided notice to the Court that Judge Goldberg recently certified a settlement class in *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 2:06-cv-01833, slip op. at 1 (E.D. Pa. Apr. 21, 2020). However, Judge Goldberg made clear that the prospect of settlement impacted his analysis of both ascertainability and predominance. *Id.* at 24-25, 28. Indeed, many of the concerns at issue in certifying a litigation class are alleviated after settlement. *See In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. at 151 n.8 ("In certifying a litigation class, the Court must be mindful of a defendant's due process rights. Such a concern is not present when administering a settlement class.").

ii. Uninjured Consumers Due to Co-payment Assistance

Defendants argue that EPPs have made no attempt to determine whether there are uninjured class members due to coupon use—that involvement in a coupon co-payment assistance program resulted in some purchasers paying less for branded Niaspan than they would have paid for generic Niaspan had it been available. Defs.' Opp'n Class Cert. 61–62. Dr. Hughes estimates that 3–4% of brand Niaspan purchases were made with co-payment assistance coupons that included $0 co-payment coupons, $50 off co-payment coupons, and $25 maximum co-payment coupons, *id.* at 61, whereas Dr. Rosenthal estimates that 2.4% of prescription purchases involved coupon use. *Id.* at 62 n.27.

Defendants claim that they "are entitled to defend against individual claims by testing whether class members used copay assistance and did not pay an overcharge, necessitating individualized inquiries." *Id.* at 62. Defendants further contend that given the drug's low persistency rate, there were likely many consumers who used coupons for all of their purchases. *Id.* at 61–62.

EPPs respond that defendants concede that coupons apply to less than 4% of transactions and would affect "only a handful of customers." EPPs' Reply Class Cert. 22. However, even if only a small percentage of consumers were uninjured due to coupon use, the sheer class size creates significant difficulties for manageably addressing defendants' challenges. *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 292 F. Supp. 3d 14, 137–38 (D.D.C. 2017).

EPPs also state that "even if there were a small substantiated subset of uninjured 'all-coupon' consumers—and there is not—these consumers can be identified and programmatically

excluded from the subclasses" because "pharmacies track coupon usage on a transactional basis, including the coupon value, prescription fill date, and identity of the consumer." EPPs' Reply Class Cert. 22. Assuming *arguendo* that adequate records tracking coupon use on all Niaspan purchases could be produced prior to trial, defendants have the right to present evidence to the jury that a subset of class members did not suffer antitrust injury because of their coupon use. *See In re Asacol Antitrust Litig.*, 907 F.3d 42, 58 (1st Cir. 2018) ("[C]ertainly where injury-in-fact is a required element of a claim, as it is in an antitrust action, a class cannot be certified based on an expectation that the defendant will have no opportunity to press at trial genuine challenges to allegations of injury-in-fact." (internal citations omitted)). EPPs have offered no means of manageably addressing such challenges in a manner that would not defeat predominance. EPPs' failure to identify a non-individualized means of addressing uninjured consumers due to coupon use weighs against class certification.

iii. Health Reimbursement Accounts

Defendants argue that consumers who were subsequently fully reimbursed by HRAs for their Niaspan and generic Niaspan payments had no damages and are therefore uninjured. Defs.' Opp'n Class Cert. 62. EPPs respond that "[t]hird-party reimbursements under HRAs—to the unsubstantiated extent they occur at all for Niaspan—are irrelevant to the issue of whether consumers were injured" because the purchasers were injured as soon as they paid the overcharge. EPPs' Reply Class Cert. 23. The Court agrees with EPPs that injury occurs at the time of an unlawful overcharge, and any subsequent reimbursement is irrelevant.

Defendants raise the possibility that some purchasers may be uninjured because they paid for brand Niaspan with debit cards issued and paid for by their employer. Defs.' Opp'n Class Cert. 10 n.2; May 14 Tr. 195:20–196:1. Defendants do not even attempt to estimate the

prevalence of such uninjured class members. On this issue the Court concludes that, to the extent that the class contains such uninjured members, that number is *de minimis* and does not preclude certification.

iv. Flat Co-Payors

Defendants further argue that 4–9% of consumers had flat co-pays during the class period and would have paid the same for generic as brand Niaspan and therefore are uninjured. Defs.' Opp'n Class Cert. 58–59, 64.

EPPs respond that they "have established that records exist to identify plans by copayment structure, which can then be sorted by a data analytics firm to exclude transactions associated with a flat copay." EPPs' Reply Class Cert. 49–50.

To the extent that the identification of flat co-payors, which are excluded from the class definition, cannot be differentiated from other class members without extensive individualized inquiry, flat co-payors pose a predominance problem in addition to an ascertainability problem. As the Court discussed with respect to ascertainability, the Court is not convinced that EPPs have a method of differentiating flat co-payors from other class members through a means that avoids extensive individualized inquiries. Absent a systematic means of excluding flat co-payors, defendants would be entitled to present individualized evidence to a jury that certain Niaspan purchasers are uninjured due to a flat co-pay structure and are therefore excluded from the class definition. *See Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *19 (E.D. Pa. June 10, 2015) ("When the identification and exclusion of these consumers cannot be managed without considering the highly individualized purchasing history of individuals and their specific insurance plans, simply stating that they are excluded from the class definition is not sufficient to show that common issues will predominate.").

v. Consumers Who Filled all Niaspan Prescriptions After Reaching a Medicare Part D Coverage Gap

Defendants assert that consumers who filled Niaspan prescriptions in a Medicare Part D coverage gap may not have incurred an overcharge because their coinsurance rates were lower for branded than generic drugs. Defs.' Opp'n Class Cert. 59.

EPPs contend that defendants' hypothetical is highly speculative, so "it is no surprise that neither Defendants nor Dr. Hughes identify a single consumer who meets these criteria nor attempt to estimate their prevalence." EPPs' Reply Class Cert. 50. They note that in order to reach the coverage gap,

> a Part D consumer must first reach their out-of-pocket deductible and then pay a copayment or coinsurance on their prescriptions until reaching their initial coverage limit. Only after surpassing these two coverage thresholds does a Part D consumer enter the coverage gap and allegedly pay less for brand Niaspan-and even then, only through the end of that policy period. A consumer would need to fill all of their Niaspan prescriptions only after entering the Part D coverage gap in every period during which they were prescribed Niaspan to be uninjured.

Id. The Court agrees with EPPs that defendants' argument rests on an unfounded hypothetical and "defendants' speculation cannot defeat certification." *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *23 (D.N.J. Oct. 30, 2018).

vi. TPPs Paying the Same or More for Generic Niaspan than Brand Niaspan

Defendants assert that there are multiple scenarios in which TPPs would not have paid an overcharge because they would have paid the same or more for generic Niaspan than for brand Niaspan. Defs.' Opp'n Class Cert. 59. Dr. Hughes hypothesizes that "if the retail price of the brand drug is $100 and $83 for the generic, and the consumer's copayment is $30 for a preferred brand drug and the generic copayment is $10 (as was the case for certain City of Providence plans), then the TPP would pay $70 for the brand but $73 for the generic." *Id.* Defendants also

highlight that Dr. Hughes found that, for two named TPP plaintiffs, "the effective cost to TPPs for Niaspan just before actual generic entry [was] often lower than for generic niacin after actual generic entry." *Id.* at 54.

EPPs argue that the TPPs would have to have an unfavorable co-pay on every single payment, and note that in Hughes' two examples, for one insurer, twelve of the fifteen claims for generic Niaspan were less than the brand, and for the other, generic Niaspan claims were less in five out of eight transactions. EPPs' Reply Class Cert. 50. EPPs also persuasively note that Hughes not only failed "to identify a single Plaintiff that would have paid more on every generic Niaspan transaction for even one insured member in a competitive world, [he also failed to] even estimate the likelihood of that situation actually occurring for any TPP across all its members." *Id.*

The Court is convinced by EPPs' argument; given Dr. Hughes' failure to even estimate the prevalence of uninjured TPPs, the Court concludes that the number of TPPs in this hypothetical category is *de minimis*.

vii. Rebates

Defendants also argue that TPPs may have received brand rebates, which would further lower the costs of brand Niaspan and could result in generic Niaspan being more expensive. Defs.' Opp'n Class Cert. 60–61. Plaintiffs respond that there is no legal basis to argue that rebates negate antitrust injury, and instead would act as a "damages set-off." EPPs' Reply Class Cert. 48.

The Court agrees with EPPs. *See In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *14 ("[A]s Plaintiffs correctly argue, any amounts that such Plan Sponsors received in coverage or in the form of rebates is irrelevant to the question of impact.").

Defendants argue that some rebates are different in that they do not operate as reimbursements but rather are credited towards the cost of prescriptions at the time of the invoicing. Defs.' Opp'n Class Cert. 61 n.26. This latter type of rebate could negate antitrust impact, or injury. *See In re Nexium Antitrust Litig.*, 777 F.3d 9, 28 (1st Cir. 2015). However, defendants do not even attempt to quantify the prevalence of such rebates, and on the present state of the record, the Court concludes that such rebates are *de minimis*.

viii. Conclusion: Uninjured Class Members

In sum, the Court is concerned that the class contains, at minimum, substantial numbers of uninjured consumer brand loyalists, coupon users, and flat co-payers.[10] The Court is not satisfied that EPPs have a non-individualized means of identifying these uninjured class members in a way that protects defendants' constitutional rights. *See, e.g.*, *In re Intuniv Antitrust Litig.*, No. 16-12396, 2019 WL 3947262, at *8 (D. Mass. Aug. 21, 2019) (holding predominance not satisfied because plaintiffs "have not put forth a reasonable and workable plan to weed out uninjured class members"); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 53–54 (1st Cir. 2018) ("The need to identify those [uninjured] individuals will predominate and render an adjudication unmanageable absent evidence . . . [of] some . . . mechanism that can manageably remove uninjured persons from the class in a manner that protects the parties' rights."). The Court concludes that EPPs lack common evidence of antitrust injury, and cannot satisfy the Rule 23(b)(3) predominance requirement.

[10] EPPs' contention that "[d]efendants have not rebutted Plaintiffs' common evidence of injury with any substantiated example of a specific uninjured class member in the record," EPPs' Reply Class Cert. 34, is unpersuasive in light of the expert testimony discussed above and the extremely limited data production in the case.

5. *Defendants' Challenge to EPPs' Aggregate Damages Model*

Defendants also challenge EPPs' classwide aggregate damages model. At class certification, "a model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to that theory." *In re Niaspan Antitrust Litig.*, No. 13-2460, 2019 WL 3816829, at *14 (E.D. Pa. Aug. 14, 2019) (citing *Comcast v. Behrend*, 569 U.S. 27, 35 (2013).

Defendants argue that "there is a mismatch between the EPPs' aggregate damages model and their exclusion of PBMs from . . . class membership," because "PBMs sometimes end up paying for part of the cost of prescriptions charged by pharmacies." Defs.' Opp'n Class Cert. 64–65. In support of their position, defendants assert that "the record contains documentary evidence of Caremark, a PBM, making a $333,906 payment to the City of Providence in order to perform a price guarantee. On this issue, Mr. Winkelman acknowledged that, in his experience auditing PBM contracts, around half of the time the PBM ended up having to make a payment to perform on price guarantees." *Id.* at 65.

EPPs respond that "[t]here is no merit to Defendants' argument that the role of PBMs—intermediary service providers who do not insure or pay for beneficiary purchases— somehow fatally wounds EPPs' damages model under *Comcast*." EPPs' Reply Class Cert. 44–45. They contend that "[d]efendants have completely failed to substantiate their argument that PBMs actually suffer losses on Niaspan purchases through the mechanics of their price negotiations on behalf of TPPs. Indeed, the PBMs themselves disavow this theory." *Id.* at 45. As Robert Lahman of OptumRx stated,

> As a PBM, OptumRx does not consider itself to be paying for its Clients' prescription drug purchases. While OptumRx may retain, in certain cases, compensation through spread pricing, rebates, or administrative fees, that compensation is payment for services that OptumRx provides and not payment for

> prescription drugs that are dispensed to health plan members and which are the financial responsibility of the health plan.

Lahman Decl. ¶ 11. EPPs further note that defendants' Caremark example does not show that any of the repayment in question was attributable to Niaspan purchases. EPPs' Reply Class Cert. 45.

Courts considering this argument in similar cases have recognized that a PBM's payment of part or all of the overcharge for the cost of prescriptions charged by pharmacies, "would create issues either with ascertainability or, if PBMs are excluded, with the classwide damages model." *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *23 (D.N.J. Oct. 30, 2018); *see also In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 149 (E.D. Pa. 2015) (noting if PBMs were excluded from the class definition, "[plaintiffs'] current damages model would potentially include damages suffered by non-class members, and may therefore overstate the amount of damages suffered by the [class]."). However, courts have rejected this challenge in cases in which the defendants did not provide evidence that PBMs may have paid pharmacies more for a drug than the payment they received from a TPP, and therefore dismissed the challenge as a "general, theoretical risk." *In re Thalomid & Revlimid Antitrust Litig.*, 2018 WL 6573118, at *23; *In re Lidoderm Antitrust Litig.*, No. 14-02521, 2017 WL 679367, at *25 (N.D. Cal. Feb. 21, 2017).

In this case, the Court agrees with EPPs that defendants have not provided evidence that any PBM payments based on price guarantees resulted in a loss on Niaspan purchases, and further credits the statement by OptumRx that any such PBM payments are "not payment for prescription drugs." The Court thus concludes that EPPs' aggregate damages model is consistent with the exclusion of PBMs from class membership.

6. *Availability of Pass-On Defense Under State Law*

Defendants contend that individualized issues predominate because, unlike federal law, some states allow antitrust defendants to raise a pass-on defense, which requires individualized analysis as to whether any particular plaintiff sustained actual economic harm. Defs.' Opp'n Class Cert. 68–70. They rely on the opinion of their expert, John Fritz, to argue that many EPPs did not suffer actual economic harm because those EPPs passed on any overcharge incurred through increased insurance or contribution premiums. *Id.* at 72–75.

EPPs respond that the pass-on defense is not available under most state statutes, and when it is available, it is limited to transactions within the chain of distribution and does not include premium payments. EPPs' Reply Class Cert. 36. EPPs also filed a Motion to Exclude the Opinions and Testimony of Fritz.

As explained *supra*, to the extent that state laws do permit a pass-on defense,[11] that defense relates to the quantum of damages, not antitrust injury. Unlike antitrust injury, a "relaxed measure of proof" is applied to antitrust damages calculations and "the actual amount of damages may result from a 'reasonable estimate.'" *In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1176 (3d Cir. 1993); *Eastman Kodak Co. of New York v. S. Photo Materials Co.*, 273 U.S. 359, 379 (1927) ("[A] defendant whose wrongful conduct has rendered

[11] EPPs have failed to provide to the Court with an adequate analysis of which state antitrust laws permit a pass-on defense to damages. EPPs summarily contend that the pass-on defense is not permitted under state law because "the relevant antitrust statutes have language mirroring federal antitrust laws, contain a federal harmonization provision, and/or have been interpreted in harmony with federal law." EPPs' Class Cert. Mot. 20 (citing App. A). However, as defendants persuasively argue, "[i]n permitting indirect purchaser actions at all, the [*Illinois Brick* repealer] state has already determined that its laws will not follow, but rather will deviate significantly, from federal antitrust law." Defs.' Opp'n Class Cert. 70; May 15, 2019 Hr'g Tr. 20:6–19. These statutory deviations specifically repeal *Illinois Brick*'s bar against indirect purchaser actions, the symmetrical counterpart to *Hanover Shoe* which eliminated the pass-on defense under federal law. *See In re Lower Lake Erie Iron Ore Antitrust Litig.*, 998 F.2d 1144, 1164 n.10 (3d Cir. 1993). As such, EPPs' references to generic federal antitrust harmonization provisions does not provide the Court with the individualized analysis of the applicable states' laws to determine whether each state would permit a pass-on defense, and "the Court will decline to undertake the 'back-breaking labor involved in deciphering the state of antitrust [pass-on defense] in each of those states.'" *See In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. 124, 148–149 (E.D. Pa. 2015).

difficult the ascertainment of the precise damages suffered by the plaintiff, is not entitled to complain that they cannot be measured with the same exactness and precision as would otherwise be possible."). Any adjustment to damages calculations for pass-on defenses arising under state laws would not affect the fact of antitrust injury, and does not preclude class certification.

As a result, the availability of the pass-on defense involves "merits-related issues 'beyond what is necessary to determine preliminarily whether certain elements will necessitate individual or common proof.'" *See Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 305 (3d Cir. 2016). Accordingly, the Court does not address defendants' argument that certain class members did not suffer actual economic harm based on the pass-on defense or EPPs' motion to exclude Fritz's opinion addressing that issue.

7. *Consumer Protection and Unfair Trade Practices Claims and Unjust Enrichment Claims*

EPPs assert that their claims arising under state consumer protection and unfair trade practices laws "all recognize that satisfaction of antitrust elements constitute liability." EPPs' Reply Class Cert. 2. EPPs have asserted no other theory of liability under the state consumer protection laws. Because the Court concludes that common issues do not predominate as to EPPs' antitrust claims, the Court likewise rejects EPPs' argument with respect to the state consumer protection claims. *See In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. 124, 163 (E.D. Pa. 2015).

EPPs also argue that "all invoked unjust enrichment claims include essentially the same equitable elements" as the antitrust claims. EPPs' Reply Class Cert. 2. However, because EPPs have failed to demonstrate that common issues predominate as to their antitrust claims, and because EPPs assert no other theory of unjust enrichment, the Court rejects EPPs' argument as to

EPPs' unjust enrichment claims. *See In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. at 163.

For these reasons, the Court concludes that EPPs' claims arising under consumer protection and unfair trade practices statutes and EPPs' unjust enrichment claims fail the Rule 23(b)(3) predominance requirement.

8. *Variations in States Laws*

Defendants further argue that the variations between the various state laws under which EPPs bring their claims defeat predominance.[12] Defs.' Opp'n Class Cert. 77–88.

EPPs' burden of demonstrating that common questions of law or fact predominate "includes providing the Court with an extensive analysis which demonstrates that the variations in the applicable state laws do not defeat predominance."[13] *Vista Healthplan, Inc. v. Cephalon, Inc.*, 2015 WL 3623005, at *33 (E.D. Pa. June 10, 2015). Under the Third Circuit standard, courts may "certify nationwide classes where differences in state law f[a]ll 'into a limited number of predictable patterns,' and any deviations 'could be overcome at trial by grouping similar state laws together and applying them as a unit.'" *Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 183 (3d Cir. 2014). However, "plaintiffs face a significant burden to demonstrate that grouping is a workable solution." *Id*; *see also In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *16 (D.N.J. Oct. 30, 2018) ("In a motion for class

[12] Defendants also claim that EPPs failed to properly conduct a choice of law analysis. Defs.' Opp'n Class Cert. 77–81. The Court is not persuaded by this argument and agrees with EPPs that "[u]nder proper choice of law principles, the law of the state where the drug was purchased from a pharmacy governs because the injury (i. e., overcharge) occurs at the point of sale." EPPs' Reply Class Cert. 54. *See In re Flonase Antitrust Litig.*, 815 F. Supp. 2d 867, 883-84 (E.D. Pa. 2011); *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 134–136 (E.D. Pa. 2011); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 391 (E.D. Pa. 2010).

[13] The inquiry into whether variations in state laws can be manageably addressed implicates both the predominance and superiority requirements. *See Vista Healthplan, Inc.*, No. 06-1833, 2015 WL 3623005, at *35. The Court considers this issue under the predominance standard. *See, e.g.*, *In re Thalomid & Revlimid Antitrust Litig.*, No. 14-6997, 2018 WL 6573118, at *11.

certification, plaintiff bears the burden of providing an extensive analysis of state law variations to determine whether there are insuperable obstacles to class certification.").

Defendants contend that "[f]or this case to proceed as a class action, this Court would need to analyze the specific elements and issues that may arise under 53 state laws, decide critical and unsettled legal issues regarding how those laws would apply to the allegations in this case, and determine how the case will be adjudicated and tried under the 53 state laws." Defs.' Opp'n Class Cert. 77. They further assert that "EPPs provide no analysis of the state laws, no explanation of how they plan to prove the necessary elements of the 53 state laws, no proposed jury instructions nor any plan to address and manage these issues." *Id.*; May 15 Tr. 33:9–35:23. In addition, defendants raise numerous putative differences between the various state laws. Defs.' Opp'n Class Cert. 81–88.

EPPs reply that "'variations' in applicable state laws do not exist or are minor and manageable." EPPs' Reply Class Cert. 54. They assure the Court that any variations between the various statutes "can be handled via a special verdict form or by separating the purported variations into grouped categories." *Id.* at 58. They also note that some courts have held that differences between state consumer protection and unjust enrichment laws do not defeat predominance and address many of the alleged specific variations raised by defendants. *Id.* at 56–68.

The Court is not persuaded by EPPs' *ipse dixit* that there are no significant variations between the various state laws. The Third Circuit's *Grandalski* opinion is instructive in this regard. In that case, the plaintiffs "failed to provide a sufficient, or virtually any, analysis describing how the grouped state laws might apply to the facts of this case. They assert[ed] only that the differences between the state laws within each group are 'insignificant or non-existent.'"

Grandalski v. Quest Diagnostics Inc., 767 F.3d at 184. The *Grandalski* court explained that "[plaintiffs] must do more than provide their own *ipse dixit*, citation to a similar case, and a generic assessment of state consumer fraud statutes, to justify grouping." *Id.*

In this case, EPPs have provided no analysis of any variations between the various state laws other than to assure the Court that such differences are minor and manageable. Without an extensive analysis of the applicable state laws and any variation in state law, EPPs cannot meet their burden of proving predominance under Rule 23. *See Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *34 (E.D. Pa. June 10, 2015) (concluding that "Plaintiffs' accounting of the state variations [was] not comprehensive and glosses over important differences."); *see also In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. 124, 164 (E.D. Pa. 2015) ("Plaintiffs have provided charts seeking to demonstrate what the requirements of each state are with respect to the claims at issue[], but Plaintiffs have not proposed how those state claims would be grouped and managed at trial.").

Moreover, in other indirect purchaser antitrust actions proceeding under a wide array of state laws, plaintiffs have proposed trial plans, jury instructions or verdict sheets to assist the Court in understanding how any variations could be managed at trial. *See, e.g.*, *Vista Healthplan, Inc.*, No. 06-1833, 2015 WL 3623005, at *34 (evaluating plaintiffs' "proposed jury instructions [to] organize the state laws into a limited number of permutations"); *In re Processed Egg Prod. Antitrust Litig.*, 312 F.R.D. at 165 (considering plaintiffs' "Suggested Trial Options" memorandum); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2017 WL 4621777, at *20 (D. Mass. Oct. 16, 2017) (addressing plaintiffs' proposed multiple phase trial plan). EPPs have not presented any such proposals in this case. Any renewed motion for class certification by EPPs should include, at minimum, charts identifying the substantive elements of each state

law claim, an analysis of all variations between the state law claims, and a proposed trial plan through which these variations may be manageably addressed.

For all of the above reasons, the Court concludes that EPPs have not satisfied the predominance requirement.

iii. Superiority

The superiority requirement "asks the court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication." *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 533–34 (3d Cir. 2004). "[S]uperiority, unlike numerosity, considers alternatives to class actions other than joinder." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 253 n.11 (3d Cir. 2016).

In considering whether superiority is established, the Court must consider "whether variations in state laws present the types of insuperable obstacles which render class litigation unmanageable." *Vista Healthplan, Inc.*, No. 06-1833, 2015 WL 3623005, at *35 (citing *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 529 (3d Cir. 2004)). For the reasons stated above, EPPs have not provided a record sufficient for the Court to conclude that variations in applicable state laws are manageable in a single trial. They have not demonstrated by a preponderance of the evidence that a single class action proceeding under the 53 state laws arising from 26 jurisdictions would be superior to alternative available methods of adjudication. The Court thus concludes that EPPs have not established superiority on the current state of the record.

iv. Conclusion

In sum, EPPs have not satisfied their burden of establishing ascertainability, predominance, or superiority by a preponderance of the evidence. For these reasons, EPPs'

motion for class certification is denied. This decision is without prejudice to EPPs' right to file an amended motion for class certification if warranted by the facts and applicable law as set forth in this Memorandum.

V. EPPS' MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF JOHN F. FRITZ

EPPs filed a motion to exclude the opinions and testimony of defendants' expert witness, John Fritz, who opines that certain EPP class members passed on the costs of any overcharge and therefore did not sustain actual economic harm. Mem. L. Supp. EPPs' Mot. Exclude Opinions & Test. John F. Fritz 1. As explained above, the issue of whether recoverable damages are limited to a class members' actual economic harm does not impact class certification, and the Court need not address this issue at this stage in the litigation. In light of the Court's denial of EPPs' motion for class certification, EPP's motion to exclude Fritz's opinions and testimony is denied as moot. This decision is without prejudice to plaintiffs' right to challenge Fritz's expert testimony, if warranted, at a later stage in this litigation.

VI. CONCLUSION

For the reasons set forth above, (1) defendants' Motion to Exclude the Expert Testimony of Laura Craft and Eric Miller is denied, (2) EPPs' Motion for Class Certification is denied without prejudice to EPPs' right to file an amended motion if warranted by the facts and applicable law as set forth in this Memorandum, and (3) EPPs' Motion to Exclude the Opinions and Testimony of John F. Fritz is denied as moot.

An appropriate Order follows.

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: **NIASPAN ANTITRUST LITIGATION**	**MDL NO. 2460**
THIS DOCUMENT RELATES TO: **ALL ACTIONS**	**MASTER FILE NO. 13-MD-2460**

DuBOIS, J. **August 17, 2021**

M E M O R A N D U M

I. INTRODUCTION

This multidistrict litigation involves what has come to be known as a "pay-for-delay," or "reverse payment," settlement—a practice in which a brand-name drug manufacturer brings a patent-infringement action against a generic drug manufacturer and then compensates the generic drug manufacturer for its agreement to delay entering the market with a competing generic version of the brand-name drug. In this case, End-Payor Plaintiffs ("EPPs") aver that the brand-name manufacturer of the drug Niaspan, Kos Pharmaceuticals, Inc. ("Kos"), entered into anticompetitive settlement agreements with the generic manufacturer of that drug, Barr Pharmaceuticals, Inc. ("Barr"), in March of 2005 in order to terminate patent-infringement litigation brought by Kos against Barr in the District Court for the Southern District of New York.

Presently before the Court is EPPs' Renewed Motion for Class Certification. For the reasons stated below, the Renewed Motion is denied on the ground that EPPs failed to satisfy the ascertainability requirement of Federal Rule Civil Procedure 23(b)(3) that they provide a reliable and administratively feasible mechanism for distinguishing between class members and intermediaries in drug transactions which are excluded from the class.

II. BACKGROUND

The background of this case is set forth in detail in the Court's Memorandum and Order dated September 5, 2014. *See In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735 (E.D. Pa. 2014). This Memorandum recites only the facts and procedural history relevant to the motion presently before the Court.

Defendant AbbVie, a drug manufacturer that was spun off from Abbott Laboratories ("Abbott") in January 2013, manufactures and sells Niaspan, a brand-name prescription drug, primarily used to treat lipid disorders. In the early 1990s, Kos, acquired by AbbVie in December 2006, developed a therapeutically-effective time-release version of niacin, which does not cause the side effects previously associated with niacin. Kos obtained a series of U.S. patents on time-release niacin and marketed the drug under the trademark Niaspan. Niaspan has been manufactured and sold by AbbVie (and AbbVie's predecessor corporations) since September of 1997.

In October 2001, Barr, acquired by Teva in January 2009, filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") seeking authorization to manufacture and sell a generic equivalent of certain dosages of Niaspan. The ANDA process provides for streamlined FDA approval of a generic version of an FDA-approved brand-name drug. As part of the ANDA process, Barr filed certifications with the FDA stating that its generic drug did not infringe any of the patents covering Niaspan and/or that the patents were invalid or unenforceable.

In March 2002, Kos initiated the first of a series of patent-infringement lawsuits against Barr in the Southern District of New York, alleging infringement of its Niaspan patents. After three years of litigation, on April 12, 2005, Kos and Barr entered into several related settlement agreements terminating the litigation. EPPs allege that, under the settlement agreements, Kos

paid Barr not to launch a generic equivalent of Niaspan until 2013. These agreements constitute the alleged "pay-for-delay" or "reverse payment" settlement that is the subject of this litigation.

A. Prior Class Certification Motion

On December 19, 2018, EPPs filed a motion to certify classes of consumers and third-party payors ("TPPs") which paid for brand or generic Niaspan. That motion alleged that defendants' conduct "violated the antitrust laws of 16 states, the consumer protection laws of 5 states, the unfair trade practices laws of 7 states, and the unjust enrichment laws of 25 states—a total of 53 state laws from 26 jurisdictions." *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 689 (E.D. Pa. 2020).

On June 2, 2020, the Court denied EPPs' motion for class certification on a number of grounds. *Id.* at 725. First, the Court concluded that EPPs had not satisfied the ascertainability requirement of Federal Rule of Civil Procedure 23, stating that it was "concerned about the economic feasibility of obtaining [the necessary] information and the ability of EPPs to identify class members in a reliable and administratively feasible manner." *Id.* at 704. Second, the Court determined that EPPs failed to demonstrate they could show by common proof that all class members were injured. On that issue, the Court stated that "the use of average[] [prices]" in a model presented by EPPs' expert, Dr. Meredith Rosenthal, "hides several groups of uninjured class members who cannot easily be identified." *Id.* at 714. Finally, the Court concluded that EPPs failed to provide the "extensive analysis of the applicable state laws and any variation in state law" necessary to "assure the Court that such differences are minor and manageable." *Id.* at 724.

B. Renewed Class Certification Motion

On September 4, 2020, EPPs filed the pending Renewed Motion for Class Certification ("Renewed Motion"). In their Renewed Motion, EPPs seek certification of a class under Federal Rule of Civil Procedure 23(b)(3), defined as follows:

> All entities in the United States and its territories who [sic] purchased, paid, and/or provided reimbursement for some or all of the purchase price for Niaspan and/or generic versions of Niaspan in Arizona, California, Florida, Iowa, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New York, North Carolina, North Dakota, Oregon, Rhode Island, Tennessee, Vermont, West Virginia, and Wisconsin for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries during the period April 3, 2007 through January 31, 2018.

Mot. at 4–5. The proposed class excludes the following entities:

a. Defendants and their subsidiaries, or affiliates;

b. All federal or state government entities other than cities, towns or municipalities with self-funded prescription drug plans;

c. 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;

d. All entities who [sic] purchased Niaspan for purposes of resale or directly from Defendants or their affiliates;

e. 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

f. Pharmacy Benefit Managers.

Id. The proposed class in EPPs' Renewed Motion "differs from [the] previous proposed class" by (1) "omitting 'persons' (*i.e.*, consumers) from the class definition," and (2) "invok[ing] only

23 state laws."[1] *Id.* at 4, 8. In support of their Renewed Motion, EPPs submitted a chart of state law claims, a proposed trial plan, and a model verdict form. Document No. 722, Exs. 1, 3, 4.[2]

Defendants filed their Opposition to EPPs' Renewed Motion and Supplemental Opposition to EPPs' Renewed Motion on November 6, 2020, and December 4, 2020, respectively. EPPs filed a reply on December 18, 2020. Thereafter, the parties submitted numerous documents related to the Renewed Motion, including EPPs' Motion for Leave to File the Expert Reply Report of Ms. Laura Craft ("Motion for Leave to File") (Document No. 735, filed December 19, 2020), which was granted by Order dated February 24, 2021.[3] The last of these documents was not filed until May 27, 2021. The motion is now ripe for decision.

III. LEGAL STANDARD

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 248 (3d Cir. 2016). The United States Court of Appeals for the Third Circuit has directed district

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1 In their Renewed Motion, EPPs "incorporate all evidence and argument" submitted in support of their prior motion for class certification. Mot. at 1 n.1.

2 The parties also submitted reports from a number of experts in connection with EPPs' Renewed Motion. EPPs presented a report dated August 25, 2020 from Dr. Meredith Rosenthal in support of their claim that they have common proof of antitrust injury. In her report, Dr. Rosenthal considers whether TPPs paying average monthly prices for Niaspan would be overcharged in a number of hypothetical scenarios. She concludes that, in each scenario, "there were many months in which the hypothetical TPP experienced an overcharge." Rosenthal Rep. ¶ 21. In response to Dr. Rosenthal's report, defendants presented the report of Dr. James Hughes dated November 6, 2020. Dr. Hughes concludes that Dr. Rosenthal's use of averages "conceal[s] considerable diversity in the prices paid by class members." Hughes Rep. ¶ 27. With respect to the issue of ascertainability, the parties submitted reports from Laura Craft, Eric Miller, and Donald Dietz. The Court discusses the reports of Ms. Craft, Mr. Miller, and Mr. Dietz in § III.B. of this Memorandum, *infra*.

3 After EPPs filed the Motion for Leave to File, the parties submitted the following documents: defendants' Response in Opposition to EPPs' Motion for Leave to File (Document No. 739, filed January 4, 2021); defendants' Additional Opposition to EPPs' Motion for Leave to File (Document No. 740, filed January 6, 2021); EPPs' Notice of Supplemental Authority (Document No. 748, filed February 12, 2021); defendants' Response to EPPs' Notice of Supplemental Authority (Document No. 749, filed February 23, 2021); EPPs' Amended Reply Memorandum of Law in Further Support of Their Renewed Motion (Document No. 752, filed March 4, 2021); defendants' Response to Reply Declaration of Laura Craft (Document No. 754, filed March 10, 2021); EPPs' Reply to Defendants' Response to Reply Declaration of Laura Craft (Document No. 759, filed May 7, 2021); EPPs' Supplemental Authority Regarding Renewed Motion (Document No. 760, filed May 19, 2021); and defendants' Response to EPPs' Supplemental Authority (Document No. 761, filed May 27, 2021). The Court considers these filings as well.

courts to "treat renewed motions like any other for class certification, and to apply the usual Rule 23 standard." *Hargrove v. Sleepy's LLC*, 974 F.3d 467, 477 (3d Cir. 2020).

Subsection (a) of Federal Rule of Civil Procedure 23 sets out four prerequisites for a class action—numerosity, commonality, typicality, and adequacy. Subsection (b) provides additional requirements for class actions—the moving party must show "that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." These requirements are referred to, respectively, as predominance and superiority. Rule 23(b)(3) also contains an implied, judicially-created requirement that the identities of class members be ascertainable. *Hargrove*, 974 F.3d at 477.

"The party seeking certification bears the burden of establishing each element of Rule 23." *In re Modafinil Antitrust Litig.*, 837 F.3d at 248. "[T]rial 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) (citing *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 316–25 (3d Cir. 2008)). The Rule 23 analysis also requires courts to "determine the nature of the evidence, and how plaintiffs would present this evidence at trial." *In re Domestic Drywall Antitrust Litig.*, 322 F.R.D. 188, 221 (E.D. Pa. 2017). However, "a court should not address merits-related issues beyond what is necessary to determine preliminarily whether certain elements will necessitate individual or common proof." *Harnish*, 833 F.3d at 305.

The Third Circuit has "repeatedly emphasize[d] that [a]ctual, not presumed conformance with Rule 23 requirements is essential." *Gonzalez v. Corning*, 885 F.3d 186, 192 (3d Cir. 2018).

"When courts harbor doubt as to whether a plaintiff has carried her burden under Rule 23, the class should not be certified." *Mielo v. Steak 'n Shake Operations, Inc.*, 897 F.3d 467, 483 (3d Cir. 2018).

A. Rule 23(a) Requirements

Rule 23(a) provides that a class may not be certified unless:

> (1) the class is so numerous the joinder of all members is impractical, (2) there are questions of law or fact common to the class, (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class, and (4) the representative parties will fairly and adequately protect the interests of the class.

Defendants do not dispute, and the Court agrees, that EPPs have met their burden with respect to Rule 23(a)'s four requirements. First, joinder of all members is impracticable because "Niaspan prescriptions peaked at nearly 600,000 per month in 2011." *Niaspan*, 464 F. Supp. at 698. Second, common questions of law or fact exist in this case, including "whether Kos entered into a contract, combination, and/or conspiracy with Barr to restrain trade." *Id.* Third, the typicality requirement is satisfied in that named plaintiffs claim "Kos and Barr entered into a reverse-payment settlement that unlawfully extended Kos's monopoly over the Niaspan market and delayed the onset of generic competition." *Id.* at 699. Fourth, EPPs contend that "plaintiffs are represented by experienced counsel thoroughly familiar with litigating complex class actions" and "there is no likelihood of a conflict of interest among class members." Mot. at 7.

B. Ascertainability

"In addition to all the other requirements for class actions in Federal Rule of Civil Procedure 23," the Third Circuit requires that a Rule 23(b)(3) class be currently and readily ascertainable. *Hargrove*, 974 F.3d at 469. The Third Circuit has articulated three principal rationales for the ascertainability requirement:

> First, ascertainability and a clear class definition allow potential class members to identify themselves for purposes of opting out of a class. Second, it ensures that a defendant's rights are protected by the class action mechanism, and that those persons who will be bound by the final judgment are clearly identifiable. Finally, it ensures that the parties can identify class members in a manner consistent with the efficiencies of a class action.

City Select Auto Sales, Inc. v. BMW Bank of N. Am. Inc., 867 F.3d 434, 439 (3d Cir. 2017).

To satisfy the ascertainability 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.'" *Hargrove*, 974 F.3d at 469–70 (quoting *Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d Cir. 2015)). "Plaintiff has the burden of making this showing by a preponderance of the evidence, and the district court must undertake a rigorous analysis of the evidence to determine if the standard is met." *City Select*, 867 F.3d at 439. "However, 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.*

1. Objective Criteria

EPPs contend that they have "provided a readily discernible, clear, and precise statement of the parameters" defining the class, and defendants do not argue to the contrary. Mot. at 8. The Court agrees with EPPs on this issue.

The Court concludes that EPPs' class is defined with reference to objective criteria and satisfies the first prong of the ascertainability analysis. The Court next turns to the evidence submitted by EPPs to establish that they have a reliable and administratively feasible mechanism for identifying class members as required by the Third Circuit's ascertainability jurisprudence.

2. Reliable and Administratively Feasible Mechanism

EPPs assert that they have presented "a reliable an administratively feasible mechanism for determining whether putative class members fall within the class definition." Mot. at 7–8. Defendants argue that EPPs' proposed ascertainability methodology is insufficient because they fail to distinguish between class members and (1) government plans or (2) mere intermediaries, such as fully insured plans,[4] in drug transactions, both of which are excluded from the class. The Court considers each of defendants' challenges in turn.

"The method of determining whether someone is in the class must be administratively feasible." *Carrera*, 727 F.3d at 307. "Administrative feasibility means that identifying class members is a manageable process that does not require much, if any, individual factual inquiry." *Id*. at 307–08. "A plaintiff does not satisfy the ascertainability requirement if individualized fact-finding or mini-trials will be required to prove class membership." *Id*. at 308.

In this case, EPPs have proffered a complex class definition with six specific exclusions. Therefore, EPPs must present an administratively feasible method for applying each exclusion. *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 4737288, at *2 (E.D. Pa. Aug. 4, 2015) ("[B]y choosing to define its class with eight specific exclusions, [p]laintiffs have created the need for a structured, multi-stepped, individualized fact-finding process in order to determine which individuals would fall within the class definition and which would fall within one of the eight exclusions.").

[4] EPPs defined a fully insured health plan in their class definition as a health plan that purchases insurance from a third-party payor covering 100% of the plan's reimbursement obligations to its members. Mot. at 5.

a. Expert Reports

EPPs presented reports from Laura Craft and Eric Miller in support of their claim that the proposed class is ascertainable. In response to the opinions provided by Ms. Craft, defendants presented the supplemental expert report of Donald Dietz.[5]

Laura Craft: In support of their Renewed Motion, EPPs presented Laura Craft's supplemental declaration and reply report dated August 25, 2020, and January 6, 2021, respectively. Ms. Craft's opinions rely in part on the "[s]tandards published by the National Council for Prescription Drug Programs ("NCPDP") and the implementation of those [] standards, pursuant to federal law, by PBMs and pharmacies throughout the United States." Craft Rep. ¶ 5. She asserts that, "[s]ince 2003, regulations enacted pursuant to HIPAA (the Health Insurance Portability and Accountability Act of 1996) have required the use of the NCPDP [standards] for electronic submission and processing of prescriptions." *Id.* ¶ 11. EPPs argue that "NCPDP standards mandate[] the use of fields that identify the TPP associated with each transaction." Mot. at 13.

In her supplemental declaration and reply report dated August 25, 2020 and January 6, 2021, respectively, Ms. Craft provides the following four opinions: (1) the identity of and transaction details for TPPs are recorded by Pharmacy Benefit Managers ("PBMs"); (2) the methodology for identifying TPPs from available data is administratively feasible; (3) excluded entities can be removed from the data; and (4) "the cost of processing and analyzing the PBM data once collected would not exceed $250,000." Craft Rep. ¶ 8. Ms. Craft asserts that, "[i]f

[5] Laura Craft and Eric Miller submitted reports in support of EPPs' prior motion for class certification on October 19, 2018, and October 22, 2018, respectively. Document No. 578, Exs. 5, 6. On August 27, 2018, Donald Dietz submitted a report in opposition to EPPs' prior motion. Document No. 610-1. These reports are not otherwise referenced in this opinion.

PBM claims records were obtained for analysis, [she] would expect there to be approximately 20 million class transactions . . . ." Craft Rep., App. 1.

Donald Dietz: In response to Ms. Craft's supplemental declaration, defendants presented the supplemental expert report of Donald Dietz dated November 6, 2020. Mr. Dietz's report criticizes Ms. Craft's supplemental declaration on three grounds.

First, Mr. Dietz contends that Ms. Craft understates the complexity of identifying class members and excluding non-class members. For example, he states that Ms. Craft relies on NCPDP data fields which do not distinguish between class members and intermediaries in drug transactions, such as administrative-service-only organizations ("ASOs") and third-party administrators ("TPAs"), both of which are excluded from the class. Dietz Rep. ¶ 20. Mr. Dietz concludes that NCPDP standards identify the PBM's client, but Ms. Craft "fails to recognize" that the PBM's client is often an intermediary, such as an ASO, "in which case it is not a Class Member." *Id.* ¶¶ 27, 30.

Second, he claims that Ms. Craft fails to address whether it is administratively feasible to obtain the necessary data to identify class members. For example, he states that Ms. Craft failed to address why—in this case, where the class period spans from 2007 through 2018—one large PBM, OptumRx, produced "virtually no data for transactions prior to April 2010." Defs.' Resp. at 8 (citing Dietz Rep. ¶¶ 67–69).

Finally, Mr. Dietz contends that "Ms. Craft did not attempt [to] estimate how long or how much it would cost for the PBMs to compile the necessary data." Dietz Rep. ¶ 77.

Eric Miller: EPPs also presented the supplemental declaration of Eric Miller dated August 24, 2020, in support of their claim that the proposed class is ascertainable. In his supplemental declaration, Mr. Miller states that, "[i]n his experience, with the exception of one

recent $1,800 fee, PBMs do not charge for the collection or production of their data, and that data can generally be produced within approximately three months." Miller Rep. ¶ 4.

b. Government Plans

Defendants argue that EPPs failed to present an administratively feasible methodology "to identify federal and state government plans for exclusion." Defs.' Resp. at 12. EPPs respond that they have presented a number of approaches for applying this exclusion:

> (1) PBMs can identify and exclude federal and state government-funded plans prior to producing data; (2) Managed Markets Insight & Technology ("MMIT") data can be used to identify and exclude federal and state government-funded plans; (3) the 31 class states can provide a historical list of their state-funded plans; and (4) Milliman, Inc. ("Milliman") data can be used to identify and exclude state-funded plans.

EPPs' Reply at 10.[6]

Ms. Craft claims that PBMs' websites "confirm . . . that they have the capability to tailor their programs to the needs of federal and state government entities and they aggressively market this capability." Craft Rep. ¶ 37. She further asserts that PBMs "must (and do) maintain . . . data that identifies government payors" because "[f]ederal law prohibits enrollees in federal health programs from participating in pharmacy incentive programs." *Id.* & n.84. On this issue Mr. Dietz agreed that PBMs "need to interpret [information received from pharmacies] and know whether it is a government-funded piece of business or whether it is commercial . . . ." Dietz Tr. 194:20–195:15. Finally, Ms. Craft states that "[t]he major PBMs" participated in developing

[6] MMIT is "the recognized industry leader tracking the formulary status of specific drugs across plans of all types, nationwide." Craft Rep. ¶ 4. Milliman is a "premier global consulting and actuarial firm." *Id.* ¶ 39.

"Field A28-ZR"—a data field which PBMs may use "to track and categorize their government payor clients."[7] Craft Rep. ¶ 37.

Ms. Craft concludes that, "[g]iven that PBMs can exclude state and government payors prior to producing data, . . . the[] other approaches are not necessary." *Id.* ¶ 40. She adds that "each [approach] provides an alternative mechanism" for applying this exclusion. *Id.*

Based on the foregoing evidence presented by EPPs, including Ms. Craft's detailed representations with respect to this issue, the Court concludes that EPPs have made a sufficient showing that "PBMs can exclude state and government payors prior to producing data." *Id.* EPPs have presented an administratively feasible methodology to identify federal and state government plans which are excluded from the class.

c. Fully Insured Plans and Other Intermediaries

Defendants argue that EPPs failed to present an administratively feasible methodology "for determining whom the ultimate payor actually was" in transactions involving fully insured plans, or other intermediaries, such as TPAs or ASOs. EPPs' proposed class definition expressly excludes fully insured plans. EPPs do not dispute that ASOs and TPAs are not in the proposed class. EPPs' Reply at 8 n.27 (ASOs "are not class members"); Craft Tr. 113:13–114:14 ("ASOs and TPAs [are] fundamentally performing the same role").

At the outset, the Court notes that the issue of whether EPPs have presented a sufficient methodology for distinguishing between class members and mere intermediaries, such as fully insured plans and TPAs, is not *de minimis*. According to Mr. Dietz, "survey results from the

[7] In his supplemental expert report dated November 6, 2020, Mr. Dietz states that NCPDP standards do not require PBMs to use "Field A28-ZR." Dietz Rep. ¶ 21. Ms. Craft acknowledged at her October 14, 2020 deposition that Mr. Dietz is correct with respect to this issue: NCPDP standards do not require PBMs to use this field. Craft Tr. at 183:2–22. She further testified that PBMs "absolutely" use a "plan-type field" to identify government plans, but she did not know whether the field "would be called A28-ZR." *Id.* at 169:7–170:1.

Pharmacy Benefit Management Institute found that between 38 and 55 percent of employers' contractual relationships with their PBM was through a TPA each year from 2013 to 2017." Dietz Rep. ¶ 32. Similarly, Ms. Craft states that fully insured plans are "extremely common," and "approximately 88% of all employment-based prescription drug plans are fully insured." Craft Rep. ¶ 31.

Vista Healthplan is instructive on this issue. In *Vista Healthplan*, the court declined to certify a proposed class of end-payors which alleged that defendants engaged in reverse-payment settlements. *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 06-1833, 2015 WL 3623005, at *2 (E.D. Pa. June 10, 2015). Similar to this case, the proposed class in *Vista Healthplan* excluded fully insured health plans. *Id.* at *4. The *Vista Healthplan* court stated that, "[u]ntil proceeding through each transaction and resolving factual disputes about who 'bears the burden' of the price in that transaction, the Court 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 (quoting *In re Skelaxin Antitrust Litig.*, 299 F.R.D. 555, 571 (E.D. Tenn. 2014)). Continuing, that court concluded that the proposed class was not ascertainable, stating that identification of class members "required consideration of the individual contractual relationships underlying each transaction." *Id.*

In this case, the Court shares the concerns stated in *Vista Healthplan*—EPPs 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." *Id.* EPPs have presented a number of different methodologies to address this issue, none of which is sufficient.

First, in support of their prior motion for class certification dated December 19, 2018, EPPs argued that "Form 5500s, an IRS form filed by health benefit plans, could be used to identify fully insured plans." *Niaspan*, 464 F. Supp. 3d at 706. "However, defendants

identif[ied] inconsistencies on the Form 5500 of named plaintiff AF of L [sic] as exemplary of the difficulties in ascertaining fully insured health plans in that manner." *Id.* By Memorandum and Order dated June 2, 2020, the Court rejected that proposed ascertainability methodology. As defendants correctly state in their present opposition, EPPs "change course" in their Renewed Motion, and no longer discuss Form 5500. Defs.' Resp. at 20.

Second, in their Renewed Motion dated September 4, 2020, EPPs argue that "data collected by the PBM pursuant to NCPDP standards mandates the use of fields that identify the TPP associated with each transaction . . . ." Mot. at 13. In a report dated January 6, 2021, Ms. Craft admitted that NCPDP data merely contains "code numbers"—not "names or descriptions." Craft Reply ¶ 3. Ms. Craft also testified at her deposition on October 14, 2020 that NCPDP data "is not designed to identify the ASO or TPA relationships." Craft Tr. at 155:16–17.

Third, during her deposition, Ms. Craft testified that EPPs may be able to identify fully insured plans based on "the nature of the plan." *Id.* at 153:17–20. On this issue, she stated that "if it's an HMO," "we know categorically . . . it's a fully funded plan." *Id.* In their response, defendants argue "Ms. Craft is wrong: in reality an HMO plan can be either self-funded or fully insured." Defs.' Resp. at 21. Ten days after defendants' response was filed, Ms. Craft submitted a deposition errata, deleting the word "categorically" and changing her testimony as follows: "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," and paying for the prescription drugs. Document No. 729, Ex. B.

Fourth, in her January 6, 2021 reply report, Ms. Craft selected four examples from PBM data produced in this case in which she purported to identify fully insured plans in the "Account" field, not class members, and TPP class members in the "Carrier" field. Craft Reply ¶ 15 n.39. She identifies the entities in those fields as follows: (1) "Carrier: Pacificare of Colorado with

Account: Colorado HMO Commercial"; (2) "Carrier: UHC of TX (Pacificare) with Account: Commercial HMO Dallas"; (3) "Carrier: Kaiser Colorado with Account: Mitre Corporation"; and (4) "Carrier: Kaiser-California North with Account: Target." *Id.*[8]

Defendants argue that "it clearly appears from public documents that [Ms. Craft] is wrong about two" of her four examples—the examples involving Mitre Corporation and Target. Document No. 755 at 2. Defendants contend that publicly available documents show that Mitre Corporation and Target's plans are self-funded, and therefore within the class definition—not, as Ms. Craft claims, fully insured and excluded. Document No. 755, Ex. A ("Plan benefits are self-insured by The MITRE Corporation, which is responsible for their payment."); Document No. 755, Ex. D (Target "retain[s] a substantial portion of the risk related to . . . team member medical and dental claims.").[9]

By Order dated May 4, 2021, the Court directed EPPs to respond to defendants' argument that Ms. Craft is "wrong about two" of her four examples. Document No. 758. On May 7, 2021, EPPs responded that it is "legally irrelevant" which entity in each example is a class member and

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[8] In her reply report dated January 6, 2021, Ms. Craft included a few additional examples in which she purported to identify mere intermediaries in the PBM data. *See, e.g.,* Craft Reply ¶ 14. Her discussion of those additional examples does not alter the Court's analysis in this case. Ms. Craft does 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, including the four examples discussed in greater detail above, Ms. Craft relied on what she "would normally expect to see" in a particular situation (*id.* ¶ 14), what "typically appears" in a particular situation (*id.* ¶ 15), and how certain code letters ("UMR") that appear in transactions involving one ASO "indicate[] a self-funded plan" (*id.* ¶ 16). 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.

[9] EPPs argue that Exhibit A to Document No. 755, a 2017 Mitre Benefit Booklet, is irrelevant. They claim the Booklet is irrelevant because defendants' assertion that Ms. Craft "is wrong about two [examples]" was based, in part, on defendants' citation to "relevant transactions" involving Mitre Corporation in 2012—five years before the date of the Booklet. Document No. 755 at 3 n.1. EPPs' argument is rejected. The 2017 Mitre Benefit Booklet is relevant to whether Mitre Corporation was a TPP during the class period, which concluded in 2018. Further, EPPs have not presented a Mitre Benefit Booklet from 2012, the year EPPs claim is at issue. *See In re Actiq Sales & Mktg. Practices Litig.*, No. 07-4492, 2014 WL 3572932, at *6–7 (E.D. Pa. July 21, 2014) (concluding that Dr. Meredith Rosenthal appropriately used a "report [which] relates to a period of time after the Proposed Class Period" because "there has been no suggestion . . . that better data was available").

which is not. Document No. 759 at 1. The Court disagrees with EPPs on this issue. Although EPPs "need not be able to identify all class members at class certification," they must prove that identifying class members will not require "individualized fact-finding." *City Select*, 867 F.3d at 439; *Carrera*, 727 F.3d at 308. Significantly, EPPs refer to all of the entities in Ms. Craft's examples, including entities Ms. Craft purported to identify as fully insured, as "potential class members," and they are not. Document No. 759 at 1. It is clear that fully insured plans are included in Ms. Craft's examples, and they cannot be class members. This fact, coupled with the evidence presented by defendants in challenging the examples involving Mitre Corporation and Target, supports the conclusion that identifying class members will require "individualized fact-finding." *Carrera*, 727 F.3d at 308.

EPPs' reliance on the following four decisions is not persuasive with respect to the exclusion of fully insured plans: (1) *In re Loestrin 24 Fe Antitrust Litig.*, 410 F. Supp. 3d 352 (D.R.I. 2019); (2) *In re Zetia Ezetimibe Antitrust Litig.*, No. 18-2836, 2020 WL 5778756 (E.D. Va. Aug. 14, 2020); (3) *In re Namenda Indirect Purchaser Antitrust Litig.*, No. 15-6549, 2021 WL 509988 (S.D.N.Y. Feb. 11, 2021); and (4) *In re Ranbaxy Generic Drug Application Antitrust Litig.*, No. 19-2878, 2021 WL 1947982 (D. Mass. May 14, 2021). In each of those cases, the court concluded that end-payor plaintiffs demonstrated they could exclude fully insured plans from the proposed class. However, those cases were decided by courts in the First, Second, and Fourth Circuits—not by any court in the Third Circuit, which has adopted the unique requirement that a class be "administratively feasible." *See Carrera*, 727 F.3d at 307–08.

Courts in the First and Second Circuits have rejected the administrative feasibility requirement adopted by the Third Circuit in *Carrera*. In *Dial Complete Marketing & Sales Practices Litigation*, the District of New Hampshire (in the First Circuit) stated that "the court is not persuaded by the reasoning of *Carrera* and its progeny." 312 F.R.D. 36, 51 (D.N.H. 2015).

Likewise, the Second Circuit "decline[ed] to adopt a heightened ascertainability theory that requires a showing of administrative feasibility at the class certification stage." *In re Petrobras Sec. Litig.*, 862 F.3d 250, 265 (2d Cir. 2017) ("In declining to adopt an administrative feasibility requirement, we join a growing consensus that now includes the Sixth, Seventh, Eighth, and Ninth Circuits."). With respect to the Third Circuit's administrative feasibility requirement, Judge Julio M. Fuentes (of the Third Circuit) recently stated in a concurring opinion in *City Select* that "circuits that have carefully considered whether to adopt our new requirement have declined to do so." *See City Select*, 867 F.3d at 443 & n.3 (Fuentes, J., concurring); *see also* 5 Moore's Federal Practice § 23.21 (3d ed. 2021) ("Other circuits to consider the Third Circuit's approach have rejected it.").

Further, unlike the courts in *Zetia* and *Ranbaxy*, this Court is not persuaded that EPPs can identify fully insured plans in a "ready" or "efficient" manner. In *Zetia*, the court determined that "PBM data alone can readily identify fully-insured plans." 2020 WL 5778756, at *12. Similarly, in *Ranbaxy*, the court concluded that PBM data can "efficiently" identify fully insured plans. 2021 WL 1947982, at *12. The evidence presented in this case is to the contrary.

As stated *supra*, Ms. Craft selected four examples from the PBM data in which she purported to identify a fully insured plan, which is excluded from the class, and a TPP class member. In response to an Order dated May 4, 2021, directing EPPs to address two of these examples, EPPs responded that it is sufficient for them to identify "the only two potential class members for these particular transactions"—a fully insured plan, not a class member, and a TPP class member. Document No. 759 at 2. They declined to identify which entity in each example is a TPP class member and which is a fully insured plan. Given that fully insured plans are extremely common and EPPs expect PBM data to include "approximately 20 million class transactions," it is insufficient for EPPs to narrow the identification of "potential class members"

to one of two entities as in the examples selected by Ms. Craft. Craft Rep., App. 1. EPPs have not shown they can identify, without individualized inquiry, the TPP class members in Ms. Craft's examples, let alone the millions of transactions at issue in this case.

The Court concludes that EPPs have not presented an administratively feasible mechanism to distinguish between class members and mere intermediaries such as fully insured plans. EPPs may not adopt a methodology that changes as defendants test its reliability and, in the end, fails to accomplish what is required. In its June 2, 2020 Memorandum denying class certification, the Court stated that EPPs failed to provide "a comprehensive methodology for systematically applying exclusions in this case." *Niaspan*, 464 F. Supp. 3d at 706. The Court remains of the view that EPPs have failed to provide a methodology to systematically apply the class exclusion for fully insured health plans. Accordingly, the Court concludes that EPPs have not satisfied the ascertainability requirement of Rule 23(b)(3).[10]

The Court having ruled that EPPs have not satisfied the ascertainability requirement, it need not address whether EPPs have satisfied the requirements of superiority and predominance. *In re Wellbutrin XL Antitrust Litig.*, 308 F.R.D. 134, 149–50 (E.D. Pa. 2015) (concluding ascertainability was not satisfied and declining to address superiority and predominance); *Afzal v. BMW of N. Am., LLC*, No. 15-8009, 2020 WL 2786926, at *8 (D.N.J. May 29, 2020) (concluding ascertainability was not satisfied and declining to "reach the questions of superiority and predominance").

[10] In addition to arguing EPPs failed to provide a sufficient methodology to apply their class exclusions, defendants claim the proposed class is not ascertainable for a number of reasons. They argue that EPPs failed to: (1) provide a case-specific methodology; (2) identify the records that would enable them to ascertain class membership; (3) identify thousands of class members; and (4) show that their methodology can be implemented without excessive cost. In light of the Court's conclusion that EPPs failed to provide a sufficient methodology to apply their class exclusions, the Court need not reach these additional arguments.

IV. CONCLUSION

For the foregoing reasons, EPPs' Renewed Motion for Class Certification is denied. An appropriate order follows.

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

CCO-121

No. 21-8042

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,
Petitioners

(E.D. Pa. No. 2-13-md-02460)

Present: RESTREPO, MATEY and SCIRICA, Circuit Judges

1. Petition for Leave to Appeal pursuant to Fed. R. Civ. P. 23(f) filed by Petitioners A.F. of L.- 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 132 Health & Welfare Fund, International Union of Operating Engineers Local 49 Health and Welfare Fund, New England Electrical Workers Benefits Fund, Carol Prasse, United Food & Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund and Miles Wallis;

2. Motion filed by Respondents Abbott Laboratories, Abbott Respiratory LLC, AbbVie Inc, Barr Pharmaceuticals LLC, Duramed Pharmaceuticals Sales Corp, Teva Pharmaceutical Industries Ltd, Teva Pharmaceuticals USA Inc and Teva Womens Health Inc to Seal Exhibits 6-13 to Their Response in Opposition to Petition for Permission to Appeal Pursuant to Fed. R. Civ. P. 23(f);

3. Response filed by Respondents Abbott Laboratories, Abbott Respiratory LLC, AbbVie Inc, Barr Pharmaceuticals LLC, Duramed Pharmaceuticals Sales Corp, Teva Pharmaceutical Industries Ltd, Teva Pharmaceuticals USA Inc and Teva Womens Health Inc. to Petition Pursuant to Fed. R. Civ. P. 23(f);

4. Exhibits 1 Through 5 In Support of Response;

5. Exhibits 6 Through 13 Filed Under Seal In Support of Response;

6. Motion by Petitioners for Leave to File Reply In Support of Petition for Permission to Appeal Pursuant to Fed. R. Civ. P. 23(f);

7. Reply In Support of Petition for Permission to Appeal Pursuant to Fed. R. Civ. P. 23(f);

8. Exhibit A to Petitioners Reply In Support of Permission to Appeal Pursuant to Fed. R. Civ. P. 23(f);

9. SEALED Exhibits B-D to Petitioners Reply in Support of the Petition for Permission to Appeal Pursuant to Fed. R. Civ. P. 23(f);

10. Motion filed by Petitioners to Seal Exhibits B-D to Petitioners Reply In Support of the Petition for Permission to Appeal Pursuant to Fed. R. Civ. P. 23(f);

11. Response by Respondents to Motion for Leave to File Reply In Support of Petition for Permission to Appeal.

Respectfully,
Clerk/tmm

ORDER

The petition for leave to appeal pursuant to Fed. R. Civ. P. 23(f) is granted. The motions to seal exhibits and to file reply in support of petition are granted.

By the Court,

s/Anthony J. Scirica
Circuit Judge

Dated: October 7, 2021
Tmm/cc: All Counsel of Record

A True Copy:

Patricia S. Dodszuweit, Clerk

UNITED STATES COURT OF APPEALS FOR THE THIRD CIRCUIT

NOTICE

GRANT OF PERMISSION FOR LEAVE TO APPEAL

The Court of Appeals has granted a petition for leave to appeal in this matter.

The $505.00 docketing and filing fee must be paid in the district court within 14 days after the entry of the order granting permission for leave to appeal, unless the petitioner is the United States government. Fed. R. App. P. 5. In addition, a cost bond must be filed if one is required under Fed. R. App. P. 7.

A notice of appeal does not need to be filed as a copy of the Court's order granting permission for leave to appeal which has been forwarded to the district court will serve as the notice of appeal.

The entry date of the order granting permission to appeal serves as the date of the filing of the notice of appeal for calculating time under the Federal Rules of Appellate Procedure. **Petitioner should notify the Court of Appeals in writing that the filing fee has been paid.**

Upon receipt of the notice from petitioner, the appeal will be opened on the general docket. All future filings regarding the appeal will be entered under the new docket number.

Very truly yours,
Patricia S. Dodszuweit, Clerk

By: Timothy McIntyre
Timothy McIntyre, Case Manager
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Dated: October 7, 2021

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