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

---

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

---

[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.