UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE LIPITOR ANTITRUST LITIGATION	MDL No. 2332
This Document Relates To:	Master Docket No.: 3:12-cv-2389 (PGS/JBD)
All End-Payer Class Actions	**MEMORANDUM**

This case is before the Court on End-Payor Plaintiffs' Motion for Class Certification. (ECF No. 1251). In this motion, End-Payor Plaintiffs (hereinafter, "EPPs") seek class certification on the basis that Defendant Ranbaxy Inc., Ranbaxy Laboratories Limited, and Ranbaxy Pharmaceuticals, Inc. (hereinafter, "Ranbaxy" or "Defendant") engaged in an alleged "reverse payment settlement" with Pfizer Inc., Pfizer Ireland Pharmaceuticals, Warner-Lambert Company, and Warner-Lambert Company LLC (hereinafter, "Pfizer")[1] which led to the delayed entry of generic Lipitor. EPPs claim that the effect of Ranbaxy's agreement is that it blocked generic drug manufacturers from entering the market earlier, causing EPPs to pay for Lipitor at an inflated cost for a period of time. EPPs seek monetary damages.

[1] This Motion was originally filed by both Pfizer and Ranbaxy. In August 2023, when oral argument was tentatively scheduled, DPPs and EPPs announced their tentative settlement with Pfizer. As such, Pfizer no longer participated in the motion practice surrounding this motion. Herein, the Court refers only to the remaining Defendant Ranbaxy although initial briefing was filed by both Pfizer and Ranbaxy.

On June 20, 2023, EPPs filed a motion to certify two classes of end payors: a Third-Party Payor (hereinafter, "TPP") Class and a Consumer Class which has two class periods: the total generic exclusion period (June 28, 2011 to November 29, 2011) and the Generic Overcharge Period (November 30, 2010 to December 31, 2012). Accompanying this motion, EPPs present the reports of two experts: their ascertainability expert, Ms. Laura Craft (ECF No. 1252-2 (hereinafter, "Craft Rep.") and ECF No. 1252-13 (hereinafter, "Craft Reply Rep.")) and their damages and antitrust injury expert, Dr. Hal Singer (ECF No. 1252-1 (hereinafter, "Singer Rep.").

Ranbaxy opposes class certification on several grounds, focusing primarily on ascertainability and predominance. In support of their opposition, Ranbaxy presents the report of their expert, Dr. James Hughes (ECF No. 1252-12 (hereinafter, "Hughes Rep.")). In addition to these motions, EPPs filed a Motion to Strike the proposed findings of fact and conclusions of law by Ranbaxy, or in the alternative, to allow EPPs to file supplemental responses. (ECF No. 1348).[2] While Ranbaxy opposed class certification on multiple grounds, because the Court finds that the

[2] EPPs moved to strike a multitude of Ranbaxy's proposed findings of fact or conclusions of law or alternatively to allow EPPs to supplement their own findings of fact and conclusions of law. At oral argument, I denied the motion to strike, but granted the motion to supplement out of an abundance of caution in undertaking the rigorous analysis required to determine this motion. (*See* ECF Nos. 1382, 1387, 1388).

ascertainability requirement of 23(b)(3) is not met, the Court limits its analysis to the ascertainability prong of Rule 23.[3]

EPPs' proposed classes are vast, encompassing "hundreds of thousands, if not millions, of consumers, and thousands of third-party payors" across over ten million brand and generic Lipitor prescriptions written during the class period. (*See* ECF No. 815 at ¶ 488; Singer Rep. at Table 3). EPPs define their two classes as follows:

The Third-Party Payor ("TPP") Class:

> All entities that, for consumption by their members, employees, insureds, participants or beneficiaries, purchased, paid and/or provided reimbursement for some or all of the purchase price of branded Lipitor or generic atorvastatin calcium, in the Class States, other than for resale, at any time during the period from June 28, 2011 through and until December 31, 2012.
>
> The TPP Class excludes:
>
> a. Defendants and their subsidiaries and affiliates;
>
> b. Federal and state governmental entities;
>
> c. Medicare Part D Plans; and
>
> d. Medicaid Plans.

The Consumer Class:

> Total Generic Exclusion Period (June 28, 2011 through November 29, 2011). All individuals who purchased, paid and/or provided reimbursement for some or all of the

[3] Nothing herein means that the other class certification requirements have been satisfied.

purchase price of branded Lipitor, in the Class States, without the use of a Pfizer co-pay card.

Generic Overcharge Period (November 30, 2011 through December 31, 2012). All individuals who purchased, paid and/or provided reimbursement for some or all of the purchase price of generic atorvastatin calcium, in the Class States.

The Consumer Class excludes:

a. Judges assigned to this case and their chambers' staff and any members of the judges' or chambers staff's immediate family;

b. Defendants' officers, directors and employees;
c. Individuals who only purchased through a Medicare Part D or Medicaid Plan;

d. Individuals who only purchased branded Lipitor after November 30, 2022, and did not purchase generic atorvastatin calcium; and

e. Any "flat copay" consumers who purchased Lipitor only via a fixed dollar copayment that does not vary on the basis of the drug's status as brand or generic.

There are two principal reasons why this motion for class certification must be denied. First, the Court granted summary judgment, finding that there was no genuine issue of material fact as to an essential element of the cause of action: causation. (ECF No. 1415). Causation—which is inextricably linked with antitrust injury—prevents the Court from certifying a class where causation cannot be shown. There is no cause of action, and accordingly, there is no class. Second, even if summary judgment had been denied and the Court had found that there was a

genuine issue of material fact, class certification would still be inappropriate because EPPs have failed to show the ascertainability of their proposed class under Federal Rule of Civil Procedure 23(b)(3).

Ascertainability is discussed below.

I.

"The class action is 'an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only.'" *Wal-Mart Stores v. Dukes*, 564 U.S. 338, 131 (2011) (quoting *Califano v. Yamasaki*, 442 U.S. 682, 700–01 (1979)). The party seeking certification must establish each element of Rule 23 by a preponderance of the evidence. *In re Hydrogen Peroxide,* 552 F.3d 305, 307 (3d Cir. 2009). "'[A]ctual, not presumed, conformance' with Rule 23 is essential." *Id.* at 326 (internal citations omitted). To determine whether actual conformance with Rule 23 has been met, the Court is obligated to conduct a "'rigorous analysis'" of the evidence and arguments presented. *Id.* at 316. In performing this analysis, courts must resolve all factual or legal disputes relevant to class certification even if they overlap with merits issues. *Id.* at 307.

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 citations 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) (citing *In re Hydrogen Peroxide,* 552 F.3d at 321)).

In our Circuit, where the parties seek certification on the basis of Rule 23(b)(3), EPPs must satisfy the requirements of ascertainability, predominance, and superiority. *See In re Niaspan Antitrust Litig.*, 67 F.4th 118, 133 (3d Cir. 2023). With respect to ascertainability, the class must be "'currently and readily ascertainable based on objective criteria.'" *Hargrove v. Sleepy's LLC*, 974 F.3d 467, 477 (3d Cir. 2020).

This ascertainability requirement is two-fold: "'(1) the class is defined with reference to objective criteria; and (2) there is a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.'" *Id.* at 469–70 (internal citation omitted). As the Third Circuit has explained, the ascertainability requirement is:

> grounded in the nature of the class-action device itself. In endeavoring to further explain this concept, we adhere to the precise boundaries of ascertainability previously iterated in the quartet of cases we discuss below. The ascertainability requirement as to a Rule 23(b)(3) class is consistent with the general understanding that the class-action device deviates from the normal course of litigation in large part to achieve judicial economy.

Byrd v. Aaron's Inc., 784 F.3d 154, 162 (3d Cir. 2015) (internal citations omitted). Indeed, the ascertainability requirement provides due process "by requiring a defendant to test the reliability of the evidence submitted to prove class

membership." *Carrera v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013). As such, a defendant has a due process right to raise challenges to the proof proffered to demonstrate class membership. *See id.* (citing *Marcus*, 687 F.3d at 594).

To satisfy the ascertainability requirement, a plaintiff must present a methodology to identify class members and prove by a preponderance of the evidence that such methodology will not require extensive and individualized inquiry or mini-trials. *Marcus*, 687 F.3d at 593; *see also Byrd v. Aaron's Inc.*, 784 F.3d 154, 163 (3d. Cir. 2015) ("We explained, 'If class members are impossible to identify without extensive and individualized fact-finding or 'mini-trials,' then a class action is inappropriate.'"). Importantly, identification in this context does not mean that "a plaintiff must be able to identify all class members at class certification—instead, a plaintiff need only show that 'class members *can* be identified.'" *Byrd*, 784 F.3d at 163 (internal citations omitted) (emphasis in the original).

"'Administrative feasibility means that identifying class members is a manageable process that does not require much, if any, individual factual inquiry.'" *Carrera*, 727 F.3d at 306 (internal citations omitted). A "plaintiff must propose a classification method with evidentiary support . . . ." *In re Niaspan Antitrust Litig.*, 67 F.4th 118, 130 (3d Cir. 2023) (hereinafter, "*Niaspan III*"). The Third Circuit has made clear that "[a]ffidavits, in combination with records or other reliable and

administratively feasible means, can meet the ascertainability standard." *City Select Auto Sales Inc. v. BMW of N. Am. Inc.*, 867 F.3d 434, 441 (3d Cir. 2017) (internal citations omitted); *see also Byrd*, 784 F.3d at 171.

II.

A fulsome discussion of the facts underlying this litigation is recited in the Court's Memorandum on Summary Judgment. (ECF No. 1415). For the purposes of this motion, the Court discusses the facts as related to EPPs' proposed methodology within its analysis of the ascertainability prongs below.

i. EPPs' Proposed Methodology

To determine whether ascertainability under 23(b)(3) is satisfied, the Court must analyze the EPPs' methodology to ascertain the class, eliminate exclusions, and see if the methodology is administratively feasible—*i.e.*, if it is "manageable process that does not require much, if any, individual factual inquiry." *Carrera*, 727 F.3d at 306 (internal citations omitted). To answer this question, one must understand the prescription pharmaceutical payment flow.

This flow is complex. TPPs are entities that may pay for part or all of the cost of members' prescription drug. Insurers, self-funded plans, fully-insured plans, and union health and welfare funds are most often considered TPPs.

The flow of payments for prescription pharmaceuticals often involves multiple parties, including manufacturers, wholesalers, retail and mail-order pharmacies, consumers, federal and state payors, aid organizations, insurers, health plans, Pharmacy Benefit Managers (hereinafter, "PBMs"), Third-Party Administrators (hereinafter, "TPAs"), and Administrative Services Only providers (hereinafter, "ASOs"). (Hughes Rep. at ¶ 33). The final purchase in this distribution chain is called the "end purchase;" this is the final sale of a drug to the ultimate consumer who will use the prescribed drug. (*See* Nov. 28, 2023 Tr. at 27:9–16).

Before a pharmacy dispenses a prescription drug to a consumer, the pharmacy determines, among other things, who the end-payor is, whether the drug is covered by the consumer's prescription drug benefits, and how much will be paid by the consumer and the TPP. (*See* Craft Rep. at ¶ 28; *see also* Nov. 28, 2023 Tr. at T27:9–T28:10). The cost of a prescription drug depends on whether the consumer is a cash payor or whether the consumer has prescription drug benefits that pay for a portion of the drug's cost. (Craft Rep. at ¶¶ 13, 28–29; Nov. 28, 2023 Tr. at T27:18–21; T31:23–T32:10).

The consumer and the pharmacy need to know on a real-time basis who is paying for a drug and, if applicable, the amount a consumer will co-pay. As such, pharmacies communicate with PBMs. PBMs play a central role in the pharmaceutical distribution chain by acting as intermediaries between drug

manufacturers, pharmacies, health plans and commercial insurers. (Hughes Rep. at ¶ 44). PBMs do not pay for the purchase of a prescription drug. (*See* Nov. 28, 2023 Tr. at T31:23–T32:10). Rather, "PBMs are intermediaries who operate on behalf of their clients in transferring funds. They are not payors." (*See* ECF No. 1259-2 (hereinafter, "Craft Dep.") at T35:22–T36:18). Overall, PBMs manage the large volume of pharmacy claims by processing and adjudicating claims on behalf of health plans and payors in a process known as "claims adjudication." (Nov. 28, 2023 Tr. at T28:15–20; Hughes Rep. at ¶ 44).

ASOs and TPAs are intermediaries that facilitate the claims adjudication process for TPPs. ASOs and TPAs provide no payment towards pharmaceutical purchases. (Craft Rep. at ¶¶ 36–39; *see also* Nov. 28, 2023 Tr. at T33:3–14; T38:19–22). ASOs are also "insurance companies that provide administrative services for clients that prefer to self-fund their benefits," and TPAs are "non-insurers that provide similar services for self-funded clients." (Craft Rep. at ¶ 36; *see also* ECF No. 1252-5 (hereinafter, "Fridberg Declaration") at ¶ 15). By their nature, ASOs and TPAs are not end-payors because they do not contribute any amount to the ultimate purchase of the prescription drug. (Nov. 28, 2023 Tr. at T38:19–22).

Working against this backdrop and to account for the prescriptions issued, there are federal laws and regulations, including the Health Insurance Portability and Accountability Act (hereinafter, "HIPAA"), that require record keeping. These laws

and regulations mandate that prescription data be transmitted and retained in a standardized format pursuant to National Council for Prescription Drug Programs (hereinafter, "NCPDP") standards. (*See* Nov. 28, 2023 Tr. at T29:7–T30:8, 35:8–12; Craft Rep. at ¶¶ 20–24, 28–29). It is the data protected by HIPAA and these regulations that is the basis for the methodology in this case.

This methodology was elaborated by EPPs' ascertainability expert, Ms. Laura Craft. She opined that the members of the class could be identified and that individuals could be excluded from the class through the data produced from the above prescription process. Overall, she reached the following conclusions. First, industry practices and legal mandates result in the creation, standardization, and retention of detailed data for prescription drug dispensing. (Craft Rep. at ¶ 16). Second, this data is centralized by PBMs. (Craft Rep. at ¶ 17). Third, TPP and consumer data can also confirm class membership. (Craft Rep. at ¶ 18). Fourth, class exclusions can be applied using multiple information sources. (Craft Rep. at ¶ 19). To support these conclusions, Ms. Craft analyzed a quantity of information. Ms. Craft analyzed data and documents from PBMs, TPPs, and consumers specific to purchase of Lipitor and generic Lipitor. PBM data was sourced from three PBMs—Prime Therapeutics, LLC, Humana Pharmacy Solutions, and Express Scripts, Inc. (Craft Rep. at ¶ 11). TPP data was also sourced from one insurer, Blue Cross Blue Shield of Louisiana, and seven self-funded plan sponsors (A.F. of L. –

A.G.C. Building Trades Welfare & Pension Plans; Bakers Local 433 Health Fund; the Mayor and City of Baltimore, Maryland; the Fraternal Order of Police, Fort Lauderdale Lodge 31; the United Food and Commercial Workers & Employers Arizona Health & Welfare Trust; the Twin Cities Bakery Workers Health and Welfare Fund, and the City of Providence). For the Consumer Class, Ms. Craft analyzed data supplied by five consumers (Edward Czarnecki, Emilie Heinle, Andrew Livezey, Jean Dougan, and Nancy Billington). (*Id.*). With respect to the Pfizer co-pay program, Ms. Craft "was given access to and reviewed documents pertaining to the copay card program for branded Lipitor offered by Defendant." (*Id.*). She also reviewed depositions of some of these plaintiffs and Declarations of executives from PBMs as well as a claims administrator. (*See id.* at Ex. 3). Before reviewing Ms. Craft's findings, the data provided by these entities and individuals is examined.

As previously stated, the claims adjudication process was detailed by Declarations provided by several PBM executives. For example, the PBMs described the scope of their coverage. Deb Fridberg, AVP of PBM Operations for Prime Therapeutics (hereinafter, "Prime"), explained that Prime provides PBM to 33 million people including Blue Cross and Blue Shield. (*See* ECF No. 1252-5, (hereinafter, "Fridberg Declaration") at ¶ 4). Similarly, Edward Devaney, Senior Vice-President of Caremark, L.L.C. (hereinafter, "Caremark"), another PBM, noted

that Caremark managed approximately 2.2 billion prescriptions in 2021. (*See* ECF No. 1252-6 (hereinafter, "Devaney Declaration") at ¶ 3).

Also detailed in Ms. Fridberg's and Mr. Devaney's Declarations is the actual flow of the claims adjudication process—specifically, that the claims adjudication process involves detailed information that is electronically exchanged between a pharmacy and PBM. This information includes who made the purchase, what product was purchased, when the purchase occurred, where the drug was purchased (*i.e.*, location of the dispensing pharmacy, location of recipient consumer), and how much each EPP paid for the prescription drug (*i.e.*, the respective proportion of the total purchase price the consumer and TPP paid). (*See* Nov. 28, 2023 Tr. at T28:21–T32:10; Craft Rep. at ¶¶ 21, 28–30)).

Where PBMs handle data that surrounds claims involving ASOs and TPAs, Prime and Caremark stated the following. Ms. Fridberg certified that "for claims involving a TPA or ASO, Prime maintains data indicating the name of the TPA or ASO and the self-funded payor client of the ASO or TPA. Prime can associate these Carrier and Account IDs with Carrier and Account Names." (Fridberg Declaration at ¶ 16). Similarly, Mr. Devaney stated in his Declaration that "[t]he claims-related data can also be sorted with respect to transactions . . . involving Clients acting in an ASO or TPA capacity." (Devaney Declaration at ¶ 10). Mr. Devaney asserted that

"generally" the claims can be routed to exclude single-tier flat co-pay structure, state or federal agency, and ASO/TPA capacity to identify the ultimate end-payor. (Devaney Declaration at ¶ 9). Notably, both Prime and Caremark did not produce any data in this case identifying the ASO/TPA, or ultimate end-payor transactions. (Nov. 28, 2023 Tr. at T70:5–16; *see also* Craft Rep. at ¶ 37). There is no indication that the PBMs would be able to produce such data, and EPPs have not been able to corroborate the PBM executives' statements. As follows, Defendant has not been able to substantively respond to these statements.

In addition to PBM data, Ms. Craft points to other data sources that are useful in identifying inclusions in the class. For example, she points to documents produced by named TPP class plaintiff Bakers Local 433 Health and Welfare Trust (hereinafter, "Bakers Local 433"). The Bakers Local 433 data identifies the purchaser, the drug purchased, when it was purchased, where it was purchased, and for how much it was purchased. (*See* Nov. 28, 2023 Tr. at T36:22–T37:21; Craft Rep. at ¶¶ 65–67). Thus, in this instance, she relied on TPP data as opposed to PBM data.

In an example of another TPP data source, Ms. Craft refers to data from New Mexico United Food and Commercial Workers (hereinafter, "NMUFCW"), a named TPP Class plaintiff which employs a TPA to administer its prescription plan benefits.

The data from NMUFCW identifies the payor, the date of the transaction, the product purchased, and the location of the of the transaction. (Nov. 28, 2023 Tr. at T39:18–T40:25).

Ms. Craft bolsters her argument about the identification of class members through the use of the claims administration process. Specifically, Ms. Craft opines that class membership can be determined in an administratively feasible manner by using the routine claims administration process that includes claim forms containing affidavits. For this, Ms. Craft relies upon the Declaration of Mr. Eric Miller, Senior Vice President of Case Management with A.B. Data, Ltd.'s Class Action Administration Company to support the proposition that claims forms can verify information contained within the data provided to Plaintiffs. Mr. Miller stated:

> As part of the claims process, A.B. Data regularly obtains data from one or more of the multiple highly standardized and electronically stored sources of prescription transaction data including TPP records, pharmacy records, and records maintained by other third parties such as ASOs, TPAs and PBMs to identify class members and verify class membership, including that claimants purchased the drug(s) in question during the relevant time period, within class states (if necessary), and that they are not otherwise excluded from the class.

(ECF No. 1252-3 (hereinafter, "Miller Declaration") at ¶ 12). Notably, Mr. Miller did not explain what the highly standardized and electronically stored sources are.

In his Declaration, Mr. Miller stated that claims forms can verify information contained in the data and determine class membership. (Craft Rep. at ¶ 15; Miller Declaration at ¶¶ 2–3; 10–22). The process is described by Mr. Miller as follows.

A.B. Data has provided "notice to consumer[s] in cases involving pharmaceutical products" by various methods, including "direct mail notice by First Class U.S. mail to class members identified in PBM data and the data of other subpoenaed entities, such as TPPs, retail pharmacies and mail order pharmacies" and "[p]ublishing notice in targeted publications comprised of digital media and earned media. This includes placing digital banners, text and/or newsfeed ads on sites such as Google, Facebook and/or Instagram and targeting medical networks, including websites such as WebMD.com." (*See* Miller Declaration at ¶¶ 8a–8b). According to Mr. Miller, A.B. data creates a case-specific website for claimants to fill-out. (Miller Declaration at ¶ 11).

Claims information is obtained from multiple "highly standardized and electrically stored sources of prescription transaction data including TPP records, pharmacy records, and records maintained other third parties such as ASOs, TPAs and PBMs . . . ." (Miller Declaration at ¶ 12). In addition, the claims form has a separate "authorized agent section" for TPAs and ASOs to fill out and to set forth the class member section it represents. (Miller Declaration at ¶ 14). There is also a class member section "to capture information from the class members that will assist in determining eligibility" based upon the information provided in this form. (Miller Declaration at ¶ 15).

Examples of these claims forms were provided to the Court. (*See* ECF No. 1325-2). For example, EPPs submitted a model TPP claim form. On the top of the form, it reads: "Instructions for submitting your Third-Party Payor Claim Form," explaining that a TPP class member or an authorized agent can complete the form. (*Id.* at 78). The form notes relevant exclusions, stating that a TPP class member does not include: Defendants and their subsidiaries and affiliates; federal and state governmental entities; Medicare part d plans; and Medicaid plans. (*Id.* at 79). The form also outlines what information should be provided. EPPs had a prospective TPP class member itself—Bakers Local 433—complete this form. Bakers Local 433 indicated that it was a "Self-Insured Health & Welfare Fund" and indicated that "the total amount paid or reimbursed for prescriptions of branded Lipitor and/or AB-rated generic Lipitor, net of co-pays, deductibles and co-insurance between June 28, 2011 and December 31, 2012" was $43,251.87. (*Id.* at 82). Finally, in Section D, the form requires that claim documentation be attached for claims of $300,000 or more, also noting that data might also be required. (*Id.*). In Section E, there is a certification of truthfulness to be executed. EPPs also had an identical form completed by a TPP's registered agent. (*Id.* at 86). This document was completed by registered TPP agent Southwest Service Administrators, Inc. (hereinafter, "SSA") on behalf of United Food and Commercial Workers. The completed form indicated that SSA certified that "the total amount paid or reimbursed for

prescriptions of branded Lipitor and/or AB-rated generic Lipitor, net of co-pays, deductibles and co-insurance between June 28, 2011 and December 31, 2012" was $32,759.18. (*Id.* at 90).

Finally, there was a consumer claim form completed by named plaintiff, Nancy Billington. (*Id.* at 102). The document contains instructions for submitting the consumer claim form, breaking down the process step-by-step. There is an explanation of the class on page two of the form, stating that "you are a member of the Consumer Class if you purchased, paid, and/or provided reimbursement for some or all of the purchase price of **branded** Lipitor, without the use of a Pfizer co-pay card" in the Class states during the June 28, 2011 through November 29, 2011 timeframe. (*Id.* at 103 (emphasis in the original)). The form also clarifies that you are a member of the Consumer Class if "you purchased, paid, and/or provided reimbursement for some or all of the purchase price of **generic** Lipitor" in the Class states during the November 30, 2011 through December 31, 2012 timeframe. (*Id.* at 103 (emphasis in the original)). The certification lists all the exclusions, and Ms. Billington certified that she was not within any of the exclusions. One issue with this claims form is that it assumes that the consumer will understand the distinction between "branded" and "generic" Lipitor without defining these terms.

Overall, both the TPP and Consumer Class claims forms acknowledge that the claims administrator will review these submissions and will follow-up with the

claimant to either obtain necessary information to process the claim or to terminate the claim. This is an area where follow-up is necessary to determine the inclusions or exclusions within the class. The claims administrator implied the same within his Declaration—stating that there would be times in the claims process where individual calls to claimants would be needed "should additional information or documentation be required." (Miller Declaration at ¶ 20). Mr. Miller also stated that A.B. Data "is capable of performing additional checks." (*Id.* at ¶ 22). What these additional checks are, however, is not explained. After claims administrators compile the claims information submitted in the claims forms, the claims administrator transmits the data with appropriate codes to Ms. Craft's firm where it is "submitted . . . in a templatized form provided by the claims administrator that is read by a machine." (Nov. 28, 2023 Tr. at T70:17–25).

Along with the identification of class members comes its natural counterpart: class exclusions. This is one of the most disputed areas of Ms. Craft's report.

1. TPP Exclusions

In terms of the TPP exclusions, Ms. Craft provides the following ways to identify exclusions:

a. Defendants and their Subsidiaries or Affiliates

Ms. Craft explained that this proposed exclusion is "a common exclusion that should be easily applied." (Craft Rep. at ¶ 83). She states further that "Defendants

are well aware of each entity encompassed by this exclusion and can provide a list of entities to be excluded from the class. Once a list is generated, the claims administrator can easily exclude such entities as has been done in other class actions." (*Id.*).

b. Governmental Entities

Ms. Craft provides three ways to identify the governmental exclusions: (i) by having PBMs identify, flag or exclude transactions in which a federal or state government entity is the payor; (ii) by cross-checking a list of federal or state government payors against the names of the data and in the claim forms that are filed; and (iii) by requiring claimants to verify via an affidavit on claim form, under penalty of perjury, that they are not a federal or state government payor. (Craft Rep. at ¶¶ 84–90; Nov. 28, 2023 Tr. at T42:18–T47:8).

Ms. Craft goes into detail regarding the cross-checking of the sources, stating that in addition to the certification on the claims forms, data can be verified through other data sources. For example, Ms. Craft states that, aside from Medicare and Medicaid, there are five other major federal government programs: (i) Department of Defense/Tricare, (ii) the Department of Veterans Affairs, (iii) the Indian Health Service, (iv) the Children's Health Insurance Program, and (v) Ryan White ADAP. She states that "almost all of the federal government's prescription drug spending is accounted for by these major programs." (*Id.* at ¶ 85). Ms. Craft opines that the

major federal programs—with the exception of the Veterans Administration—use PBMs, and data from PBMs can identify the programs with field identifiers in the data such as HIS, CHIP, TRICARE, DoD, and ADAP. (*Id*).

Ms. Craft also states that third party sources such as Milliman, Inc., a benefits consultant and actuary; the National Conference of State Legislatures (hereinafter, "NCSL"); or State Offices of Personnel; can assist in identifying state government entities. (Craft Rep. ¶¶ 89–90; Nov. 28, 2023 Tr. at T42:18–T47:8). Specifically, she stated that NCSL, using information from Milliman, has identified states "where the government entities themselves provide the health benefit plan as distinguished from those where the state just pays premium to a commercial insurer to cover its employees[,]" consequently helping to cull the information that the claims administrator needs to review. (Craft Rep. at ¶ 89). Thus, where follow-up here is necessary, Ms. Craft states PBMs have an internal process for tracking and filtering out government payors, which can be used to cross-check the data and claim forms submitted by claimants. (*See* Craft Rep. ¶¶ 89–90; *see also* Fridberg Declaration at ¶ 14 ("Prime also maintains information that would allow it to identify, flag, or exclude transactions for which a state or federal governmental entity is the payor.")).

c. Medicare Part D and Medicaid Plans

In applying exclusions to the Medicare and Medicaid Plans, Ms. Craft states that PBM data can help identify these exclusions. Specifically, she states:

> PBM data consistently and explicitly identifies Medicare and Medicaid plans, sometimes in a "line of business" field and sometimes in plan description fields. There is no ambiguity in selecting and excluding claims associated with these plans. Medicare Claims are typically described as MEDD (Medicare Part D), PDP (freestanding Medicare Prescription Drug Plans that do not include health benefits), MAPD (Medicare Advantage Part D which combines health and prescription drug benefits), EGWP (Employer Group Waiver Plans, a te1m rese1ved for a customized fo1m of Medicare prescription dmg plans), or RDS (Retiree Dmg Subsidy, another variant on Medicare Part D plans). Medicare plan sponsors must enter into contracts with CMS which are listed on a CMS website. Similarly, Medicaid plans operated by the states are consistently identified by that te1m or a recognizable acronym (*e.g.*, MCAID) in PBM data, typically followed by the abbreviation of the state which the plan serves.

(*Id.* at ¶ 91). Ms. Craft states that using Prime data is particularly helpful in this pursuit since the "Client Type" field identifies the line of business associated with each claim. (*Id.* at ¶ 92). Accordingly, by filtering by the "Client Type" field, one can determine the number of claims that are for Medicaid ("MCAID" field) or Medicare ("MCARE" field) plans and would be excluded from both the TPP and the Consumer Classes. (*Id.*).

d. ASOs, TPAs, and fully insured health plans

In terms of identifying whether an ASO, TPA, or a fully-insured health plan was involved in the transaction (one of the implicit exclusions to the EPP class), the claims administrator must evaluate whether an ASO or TPA was involved in the transaction to determine an exclusion. The process of accomplishing this is explained through Declarations from employees who work for ASOs, TPAs, and

PBMs who confirm that their data can be adjusted to show whether an ASO or a TPA is involved in a transaction. Mr. David W. Perret, III, the Director of Pharmacy Operations at Blue Cross Blue Shield of Louisiana (hereinafter, "BCBSLA")—an insurer and ASO—stated that BCBSLA "can identify and produce data regarding prescription drug transactions by Line of Business. The data includes the name and other identifying information for all plans, including the plans for which BCBSLA is acting in an ASO capacity." (ECF No. 1252-14 (hereinafter, "Perret Declaration") at ¶ 11).

Ms. Shawn Lovering, an account manager at Southwest Service Administrators Inc. (hereinafter, "SSA"), a TPA for self-funded clients—including one named plaintiff—stated: "In my experience working with ten different PBMs, the TPA will provide information—including name and contact information—to the PBM regarding the underlying client on whose behalf it is providing TPA services, and the funding status of that client." (ECF No. 1252-15 (hereinafter, "Lovering Declaration") at ¶ 9). Ms. Lovering also identifies:

> In the claims data files provided by the PBM, the name of the underlying self-funded plan sponsor is typically reflected in the data field titled "CARRIER_NAME" if the client has directly contracted with PBM, or "ACCOUNT_NAME" OR "EMPLOYER_GROUP_NAME" if the TPA contract the PBM on behalf of its client.

(Lovering Declaration at ¶ 10). Other PBMs state the same. Ms. Tamara Cowley, the Associate Director of Business Intelligence at Humana, a PBM, states:

> Humana also maintains information that HPS has access to that would allow it to identify transactions where Humana, or the client it is contracting with, is acting in an ASO or Third Party Administrator ("TPA") capacity. Where the client is an ASO or TPA, Humana maintains data that would allow for the identification of the underlying self-insured payor.

(ECF No. 1252-4 (hereinafter, "Cowley Declaration") at ¶ 6). Ms. Craft states that the HPS data contains fields for each transaction needed to determine class membership, including exact product dispensed ("NDC" field), the date of the transaction ("SERVICE_DATE" field), pharmacy type ("RX_NTWK_TYPE_DESC" field), the pharmacy location ("PHAR_STATE" field), and the member's residence state ("MBR_STATE" field)—applicable for those claimants who filled prescriptions by mail order. (Craft Rep. at ¶ 45). The total payments to the pharmacy are broken out into the product cost ("PHAR_INGR_COST_AMT" field). (*Id.*). The dispensing fee paid to the pharmacy by the TPP is also represented ("PHAR_DISP_FEE_AMT" field) as well as any sales tax charged ("PHAR_SALES_TAX_AMT" field). (*Id.*). According to Ms. Craft, this "is a standard structure in the industry although the field names may vary slightly." (*Id.*).

2. Consumer Class Exclusions

In terms of the Consumer Class exclusions, Ms. Craft provides the following ways to identify exclusions:

a. Pfizer Co-Pay Card

To qualify as a member of the Consumer Class, a consumer must have made at least one of their Lipitor purchases during that time period without the use of a Pfizer Co-Pay card. In terms of identifying individuals who made purchases with a Pfizer Co-Pay Card, Ms. Craft declares that Pfizer created and maintained data related to the Pfizer Co-Pay Cards. Specifically, she states the following:

> When the Co-Pay Card was used, Pfizer would directly reimburse the pharmacy for a portion of the consumer's co-pay and the pharmacy would collect less from the consumer at point of sale, whether mail order or retail. This payment by Pfizer was processed as an "off-line" transaction between the pharmacy and Pfizer's program administrator and does not appear in the PBM or TPP data. However, the very nature of the program necessitated the collection and maintenance of electronic data linked to individual consumers each time it was used. The Co-Pay Cards were only accepted at participating pharmacies; where members sought reimbursement through the program at non-participating pharmacies, they were required to send their name, prescription, mailing address, as well as a copy of their Co-Pay Program Card to Pfizer to qualify for reimbursement. Activating a Co-Pay Card at a participating pharmacy required identification of the consumer and specifically linked their Lipitor purchases to them.

(Craft Rep. at ¶¶ 40–41).

Although EPPs are not in possession of discovery concerning Pfizer's Co-Pay Card program,[4] Ms. Craft relies upon a Pfizer presentation wherein the Lipitor $4 Co-Pay Card was identified together with data including the "Redemptions by Patient Out of Pocket Cost," showing the percentage of redemptions among "Tier 1

[4] At some point in time, Pfizer transferred its coupon program to Viatris, Inc. Viatris, Inc. may possess the records regarding the coupon program. However, EPPs have failed to subpoena them. (ECF No. 1259 at 32 n.12).

$0-$15," "Tier 2 >$15-$30," "Tier 3 >$30-$90," and "Cash>$90." (Craft Rep at ¶ 43). Ms. Craft concludes—without having reviewed the Pfizer Co-Pay Card program data—that this presentation demonstrates that Pfizer kept close track of the number of redemptions, including how much was spent, how often the redemptions occurred, and the specifics of the patients who made redemptions. (*Id.*)

b. Judges, Chambers' staff, Defendants' officers, directors, employees and their immediate families

Like the first TPP exclusion,[5] Ms. Craft explained that this proposed exclusion is simple to apply and that a list of individuals encompassing these groups can be provided and supplied to the claims administrator to cross-check the names in the lists and ensure that the consumers do not fall into one of these categories. (*Id.* at ¶ 95).

c. Individuals who purchased through a Medicare Part D or Medicaid Plan

Like the Medicare and Medicaid exclusion in the TPP class, Ms. Craft explained that the same process can be used to identify to filter through the consumer class exclusions within this category. (*Id.* at ¶ 96).

d. Individuals who only purchased branded Lipitor after November 30, 2011 and did not purchase generic atorvastatin calcium

Ms. Craft explains that this exclusion can be determined as follows:

[5] *See supra* at 19–20.

> a consumer did not purchase branded Lipitor during the Total Generic Exclusion period without the use of a co-pay card, it must have bought generic atorvastatin during the Generic Overcharge period to be a member of the Proposed Consumer Class. Either the data provided by the PBM, the TPP, or the consumer itself can be used to confirm that the consumer made at least one qualifying purchase of generic Lipitor after November 30, 2011. Purchases by a single enrollee are linked by their Member ID, thus allowing for the tracking of purchases across time.

(*Id.* at ¶ 97). Ms. Craft states that this is a "straightforward analysis" which is demonstrated by the data and documents produced by individual named consumers in the present litigation.

e. "Flat Co-Pay" consumers

With this exclusion, Ms. Craft states that it applies to "at most a very small set of consumers whose benefit plan requires a co-payment that does not vary based on the drug's status as a brand or generic." (*Id.* at ¶ 98). To support her assertion that the number of consumers falling into this category is small, Ms. Craft cites a 2011 Employer Health Benefits Annual Survey by the Kaiser Family Foundation and Health Research & Educational Trust, stating that "only 7% of covered workers in the U.S. had single-tier drug plans (excluding specialty tiers) that treat all drugs equivalently." (*Id.* at ¶ 99). Further, she stated that of those workers, "only 24% [were] subject to a copayment structure rather than a percentage co-insurance structure." (*Id.*). Ms. Craft further explained that:

> even for non-specialty drugs, at most 1.68% of covered workers could theoretically have the same flat copay for both brand and generic drugs

> (7% x 24%) = 1.68%), assuming that both were covered. However, single tier plans typically employ closed formularies that remove the brand entirely once a generic becomes available.

(*Id.*). From this, she concludes that "there are no, or almost no consumers whose claims would be subject to the same flat co-pay for the brand and generic." (*Id.*).

In determining how the flat co-pay exclusion can be confirmed, Ms. Craft states that the claims administrator can use "data and certifications to compare brand and generic copay amounts." (Craft Rep. at ¶ 98; Nov. 28, 2023 Tr. at T52:21–T53:17; *see also* Devaney Declaration at ¶ 9 ("The claims data can generally be sorted to exclude, for example, members of plans having single-tier flat co-pay structure (*i.e.,* where member pays same fixed co-pay amount . . . for any prescription received . . . .")).

3. Claims Administrator

Overall, the application of these exclusions across both classes is aided by input from claims administrator, A.B. Data. The claims administrator is tasked with culling the data and cutting the groups who are excluded from the proposed claims. According to Mr. Miller, A.B. Data provides the following solution to applying exclusions:

> 1) *Defendants, Judges, and Related Persons and Entities*: . . . . If provided with a list of entities that are specifically excluded from recovering in this matter, A.B. Data can cross-reference any claims it receives against that list. Claims forms in similar matters also typically require the claimant to certify that it is not one of the listed ineligible entities[;]

2) *Federal and State Government Entities*: . . . . During the claim submission process, any entity that submits a claim would be required to certify that it is not a federal or state entity . . . . [;]

3) *Fully insured Prescription Drug Plan*: . . . . In other similar matters, during the claim submission process, entities are required to certify that their claim was not fully insured through another entity during the class period . . . . [;]

4) *Consumers who never purchased the generic during the class period*: . . . The data can be used to verify that a consumer claimant purchased the generic during the class period. The claim form can also be used to obtain additional details and certifications. For example, the claim form could request that the consumer enter the total amount they paid for purchases of the brand drug, and separately, the total amount they paid for purchases of the generic drug. If the claimant inputs $0 in the generic field or leaves that field blank, a follow-up letter could be sent to the individual to confirm that they did not purchase the generic or to request additional documentation demonstrating that they purchased the generic product. In addition, the claimant would be required to certify that they purchased the generic product during the class period[;]

5) *Consumers with a flat co-pay structure*: . . . . The data and certifications can also be used to verify that a consumer claimant did not have a flat co-pay structure by comparing the copayment amounts for their brand and generic purchases. In addition, the claimant would be required to certify that they did not purchase under a plan that had a flat co-payment structure. If a PBM, TPA or ASO supplies the data, they can be asked to specify if any plans had a flat co-pay structure[;]

6) *Medicare Part D and Medicaid Plans*: . . . . [T]he claim form can include a requirement that the claimant certify that coverage was not supplied by one of these two plan types.

(Miller Declaration at ¶¶ 24–29).

ii. Defendant's Response

In response, Defendant argues that EPPs have not demonstrated a reliable and administratively feasible method to identify class members or to apply class exclusions. Further, Defendant argues that the proposed methodology has not been shown to be able to be implemented without excessive cost.

With regards to the method for identifying members, Defendant argues that the ascertainability methodologies rely almost exclusively on unsupported opinions and consist of the "same kind of conclusory assertions and promises of future compliance that the *Niaspan I* and other courts in the [Third Circuit have] consistently reject[ed] . . . ." (ECF No. 1259 at 19). Overall, Ranbaxy argues that these mere assurances that "'available data' can be used later, together with affidavits to confirm class membership is insufficient." (*Id.* at 21). Essentially, Defendant argues that the class member identification process is speculative as it "amounts to nothing but bare reliance on claims form certifications . . . in a post-liability claims administration process[,]" and relies on conclusions from an expert who did not review actual claims forms in the process. (*Id.* at 22). Defendant also takes issue with EPPs' method of applying exclusions, specifically with respect to governmental entities and ASOs, TPAs, and fully-insured health plans for TPPs and Pfizer Co-Pay Card Consumers and flat co-pay card consumers for the Consumer

Class. Against this backdrop, Defendant argues that the application of this alleged methodology is unfeasible given the cost.

Defendant repeatedly points out the fact that Ms. Craft does not appear to have a methodology. For example, at her March 2023 deposition, when asked about her methodology, Ms. Craft testified that her expert report "identif[ies] the kinds of information that can be used to address each of the criteria. I don't know whether that was described as a methodology in the report." (Craft Dep. T68:21–T70:20). She testified that "I think what I have described is a methodology for obtaining the information that would confirm that each of the criteria for class membership is met." (*Id.* at T71:4–18).

During oral argument on November 28, 2023, Defense Counsel questioned Ms. Craft regarding whether she had "laid out a step-by-step methodology by which the available data can be systematically analyzed to identify class members . . ." (Nov. 28, 2023 Tr. at T57:18–20). Ms. Craft responded that:

> the data is to be produced containing all of the essential fields to determine class membership. That data can then be, literally by a computer, analyzed to identify any claims that do not comply with the basic conditions of the class definition. And if there are any that do not comply, the claims administrator has, in my proposed methodology, the contact information to follow up with the entity that was submitting it, to see if further information is necessary or to resolve any issue.

(*Id.* at T57:21–T58:5).

Defendant's expert, Dr. Hughes, similarly hones in on this issue, criticizing EPPs' lack of methodology. At oral argument, Dr. Hughes opined:

> Ms. Craft says the data are available from a number of sources to verify class membership. This is not methodology, it's not a system, not a set of steps that one would go through to identify the class members. It's just simply saying, well, the data are all there that must be in there, and I guess now—or she's not going to go find it, but the potential class members themselves are going to go find it from these various data sources.

(Nov. 28, 2023 Tr. at T148:7–18). When Counsel asked a question about "any additional opinions with respect Ms. Craft's opinions with regard to the identification of potential TPP and consumer class members, Dr. Hughes responded that "for TPPs, there is not a reliable methodology for identifying the implicit exclusions. The ASOs, the TPAs, and the fully-insured health plans, there's not a reliable way of identifying them." (*Id.* at T148:19–25). He elaborated further, stating: "Again, I don't believe she has a methodology. She says the data are there that would allow them to be identified. But she has not had—she has not laid out a methodology with steps as to how she would do that to identify those entities." (*Id.* at T150:15–22).

Dr. Hughes confirmed that he could not identify whether a plan was fully insured from PBM data, but he was sometimes able to identify ASOs and TPAs from the PBM data. (*Id.* at T150:23–T151:2). He indicated that this was shown by an ASO column of the data. (*Id.* at T151:3–4). Dr. Hughes commented that this

column would not always tell him who the ultimate payor is, and that that information could be obtained through TPP data. Dr. Hughes stated: "otherwise, it's just individualized inquiry." (*Id.* at T151:5–11).

When questioned about what sort of inquiry would be required for the identification of the ultimate payor, Dr. Hughes stated: "So then you have got to go to another data source, match it up, and see who the ultimate—the ultimate payor is. But that's not generally going to be in the PBM data, at least not consistently." (*Id.* at T151:12–20). And, when Dr. Hughes was asked what data source might have such information, Dr. Hughes responded: "Well, the ASOs and TPAs themselves would have it. The TPPs themselves would have it. . . . [T]hat would be the two main sources of those data." (*Id.* at T151:21–24).

In addition to these alleged problems, Dr. Hughes' skepticism came down to two other points. First, Dr. Hughes expressed his doubts that this data could be presented cohesively. When questioned on Ms. Craft's proposed methodology as to whether different data could be harmonized, Dr. Hughes stated:

> Maybe, maybe not. There's ways that, using patient I.D.s, that the data sets can be harmonized. But even then, you can't always follow the consumers over time if they change plans or their plan changes PBMs. But again, in my experience, it's— and I've done a lot of data merging in my day, is that even if you have a patient number, it's not straightforward to just merge them together, it's actually a really big job. And you have to check your work. And you usually have to go in and make some adjustments by hand because of typos or omissions in the data.

(*Id.* at T150:2–8). Also, Dr. Hughes brought up issues with the data's age. Dr. Hughes noted:

> And keep in mind that we're going ten years back in the past and asking consumers to be able to accurately attest to those things on the left. To the consumer list, I would also add the patient number from their old—from whatever health plan they had ten years ago. Do they have that? Can they find that? What happens if it comes in and its blank, the patient number is blank? Then she can't merge it with anything. And so the affidavit would be quite useless.

(*Id.* at T154:18–T155:1).

iii. Application

EPPs' Motion for Class Certification fails to show that there is an administratively feasible mechanism for identifying whether class members fall within the class definition. Although Ms. Craft's report and testimony purport to establish that an administratively feasible mechanism exists for determining class membership, the Court does not agree.

To satisfy the ascertainability requirement, a plaintiff must present a methodology to identify class members and prove by a preponderance of the evidence that such methodology will not require extensive and individualized inquiry or mini-trials. *See Marcus*, 687 F.3d at 593. This ascertainability requirement is two-fold: "'(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.'" 974 F.3d at 469–70 (internal citations omitted). The Court discusses both requirements below.

A. *Objective Criteria*

At oral argument, Ms. Craft testified to the following when presented with the class definitions. With regard to the TPP class definition, Ms. Craft stated that it is "objective precisely because each of these criteria can be answered with a simple yes or no . . . . These are yes or no questions." (Nov. 28, 2023 Tr. at T34:14–16). She then evaluated the actual questions. Ms. Craft stated:

> They include: Did you pay for one of these drugs? Yes or no? Did you pay for it during the class period? Yes or no? Did you pay for it as a result of a transaction within one of the class states? Yes or no? Did you do so on behalf of a member employee insured participant or beneficiary for whom you are committed to provide benefits? Those are yeses and nos. These are objective, there's nothing vague or gray about that.

(*Id.* at T34:12–23). Similarly, with respect to the Consumer Class, Ms. Craft stated that it "has the same kind of yes or no questions as we talked about for the TPPs." (Nov. 28, 2023 Tr. at T48:21–T49:1).

The data and information presented is sufficient to satisfy the objective criteria prong of the ascertainability requirement. With respect to TPPs, the class definition is based on yes-or-no questions in a claims form, such as whether (1) an individual paid for (2) branded Lipitor or generic atorvastatin calcium (3) during one of two class periods (4) as a result of a prescription drug transaction that occurred within

one of the Class States and (5) if between June 28, 2011 and November 29, 2011, without using a Pfizer co-pay card. (*See* Nov. 28, 2023 Tr. at T48:21–T49:1; Craft Rep. at ¶ 4). Similarly, with respect to the Consumer Class, the criteria is based on yes-or-no questions in a claims form, such as whether (1) an individual paid for (2) branded Lipitor or generic atorvastatin calcium (3) during one of two class periods (4) as a result of a prescription drug transaction that occurred within one of the Class States and (5) if between June 28, 2011 and November 29, 2011, without using a Pfizer co-pay card. (*See* Nov. 28, 2023 Tr. at T48:21–T49:1; Craft Rep. at ¶ 4).

The evidence sufficiently supports the conclusion that the class definitions are adequately defined with reference to objective criteria, and Defendant does not argue otherwise. Rather, they focus their argument on the next ascertainability requirement: whether there is a reliable and administratively feasible mechanism for determining whether class members fall within the class definition.

B. *Reliable and Administratively Feasible Mechanism for Class Identification*

EPPs' ascertainability problem lies within their inability to provide a reliable and administratively feasible method to identify the class. To satisfy the ascertainability requirement, a plaintiff must present a methodology to identify class members and prove by a preponderance of the evidence that such methodology will not require extensive and individualized inquiry or mini-trials. *See Marcus*, 687

F.3d at 593. Importantly, identification in this context does not mean that "a plaintiff must be able to identify all class members at class certification—instead, a plaintiff need only show that 'class members *can* be identified.'" *Byrd*, 784 F.3d at 163 (quoting *Carrera*, 727 F.3d at 308 n.2). EPPs are unable to do so.

Ms. Craft's report delves into great detail regarding the availability of data, citing a variety of data sources. She includes data from the named plaintiffs and PBMs. Further, she explains that federal law, including HIPAA, mandates the creation, retention and standardization of pharmaceutical transaction data. That data includes information surrounding the precise drug sold, the dispensing date, the patient's identity, the insurer or its appointed administrator, the location of the transaction and the product's cost and how much that cost was allocated between the consumer and any TPP. She further states that the data is recorded and maintained by multiple entities, including the pharmacies that dispense the medication and the PBMs. As such, she notes that there are multiple data sources that reflect class member prescription drugs transactions. (Craft Reply Rep. at ¶ 3). However, the following question arises: how can EPPs show that the "methodology" put forth by Ms. Craft allows EPPs to manipulate the data and identify and exclude potential class members appropriately? In other words, how can EPPs show that class members can be identified?

At oral argument on November 28, 2023, Ms. Craft testified that the available data could be input into a computer program that, in turn, analyzes the data and identifies the claims that fall within the class definition. (Nov. 28, 2023 Tr. at T57:18–T58:5). In her report, Ms. Craft states that this process does not require individualized fact-finding. (Craft Reply Rep. at ¶¶ 13; 22–24; 34). Ms. Craft provided specific examples to explain that the data contains the information needed to identify class members. (*E.g.*, Craft Rep. at ¶¶ 60–80; Craft Reply Rep. at ¶¶ 19–20). Ms. Craft discussed how membership can be verified using lists provided to the Court and can "be enforced through certifications on claims forms" that are submitted as part of a claims administration process; ultimately, Ms. Craft concludes that class membership can be confirmed from multiple sources. (Craft Rep. at ¶ 19). Further, when asked specifically about her methodology at oral argument, Ms. Craft stated the following:

> the data is to be produced containing all of the essential fields to determine class membership. That data can then be, literally by a computer, analyzed to identify any claims that do not comply with the basic conditions of the class definition. And if there are any that do not comply, the claims administrator has, in my proposed methodology, the contact information to follow up with the entity that was submitting it, to see if further information is necessary or to resolve any issue.

(Nov. 28, 2023 Tr. at T57:18–T58:5).

Based upon the Court's review of the evidence, there is no methodology proposed that is specific to the case. Stating that data has been produced and can be

analyzed by a computer to determine where it complies with the conditions of the class definition is insufficient. The Court follows other courts who have decided similarly on this issue. For example, in *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 705 (E.D. Pa. 2020) (hereinafter, "*Niaspan I*"), the *Niaspan I* court examined class certification in a case involving a reverse payment settlement agreement concerning a lipid disorder medication, Niaspan. The *Niaspan I* court denied EPPs' motion for class certification on various grounds, including ascertainability. Ms. Craft, the ascertainability expert in that case, provided "a six-step methodology for identifying class members based on her experience manipulating pharmaceutical data, and that her methodology [was] particularly well-suited for the pharmaceutical industry, 'which are tracked, monitored, and recorded across a set of substantially uniform variables.'" *Niaspan I*, 464 F. Supp. 3d at 704–05. Even with this step-by-step method, the *Niaspan I* court denied class certification on the grounds that Ms. Craft's 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,'"—"[did] not offer a methodology specific to this case." *Id.* at 705 (internal marks and citations omitted). Indeed, the *Niaspan I* court noted that "plaintiffs must provide more than Craft's *ipse dixit* to prevail under a rigorous ascertainability analysis." *Niaspan I*, 464 F. Supp. 3d at 705.

Likewise, Ms. Craft's methodology here is not specific to the case; stating that data can be inputted into a computer which will cull the data does not offer a methodology specific to this case nor does it provide the Court with more than *ipse dixit* to determine its reliability. Further, EPPs' methodology proposed here is much weaker methodology than that presented in *Niaspan I*; although the methodology was described in various ways throughout Ms. Craft's Report, EPPs have pointed to a general process that is comprised of a computer program analyzing data and sifting through the same to determine inclusions and exclusions. While the Court does not doubt that such a method could create a feasible methodology in the appropriate case, the lack of specificity here with this process and the general discussion of a "computer program" undertaking this work is insufficiently specific to this case—particularly where the class is so vast. Such a methodology also does not present the Court or Defendant with an approach that can be critically evaluated. Indeed, like in *Niaspan I*, the lack of evidentiary support for this methodology fails to provide Defendant with the opportunity to meaningfully test or respond to the assumptions underlying EPPs' Motion for Class Certification.

Even if the methodology were specific to the case, there is no indication that that methodology could reliably identify class members. Ms. Craft's proposed methodology is vague; it fails to provide any concrete procedure or step-by-step methodology by which the Court could define the class, manipulate or analyze the

data, apply exclusions, and generate a list of class members that is not fact-intensive. Stating that data can be analyzed by computer software which determines whether someone is a class member is insufficient to satisfy the rigorous analysis of the class certification process since Ms. Craft's statements and conclusions amount to nothing more than representations that class membership could be determined from data that exists and is available. As the Court has noted throughout its analysis, neither Ms. Craft nor EPPs have presented the actual data underlying many of her assumptions; instead, she relies on the say so of PBM executives' Declarations. Take for example ASO and TPA data. Two Declarations on which EPPs heavily rely—Caremark and Prime—state that Caremark and Prime possess data that can identify ASOs and TPAs or the ultimate end-payor transactions. (Nov. 28, 2023 Tr. at T70:5–16; *see also* Craft Rep. at ¶ 37). There has been no evidence provided to the Court that the PBMs would be able to produce such data, and EPPs have not been able to corroborate the PBM executives' statements.[6] The only evidence provided to the Court is the Declarations presented by these two PBM executives. This does not hold up against the rigorous analysis required of the class certification process—especially since Defendant has not been afforded the opportunity to substantively respond to these statements.

[6] *See* discussion at *supra* 12–13.

Putting aside these concerns with the methodology, the reliability of the methodology is also in question. Even assuming that the data exists, there is no indication that it could be manipulated in a feasible manner to make the identification of class members possible. As Dr. Hughes pointed out, EPPs have failed to provide the Court with evidence that the data provided from multiple different entities could be harmonized. As Dr. Hughes stated, the data harmonization process is "not straightforward" and you cannot "just merge [data] together[;] it's actually a really big job. And you have to check your work. And you usually have to go in and make some adjustments by hand because of typos or omissions in the data." (Nov. 28, 2023 Tr. at T150:1–8). EPPs have provided no information as to how this process would be undertaken, how long it would take, or how much it would cost—only opining that this process has been done or could be done. Such statements are insufficient to show the reliability of the data in question. The Court is also concerned regarding data harmonization given the age of the records in question. Here too EPPs have insufficiently addressed the problems implicated by the data's age and how such data could be reliable. *See Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1833, 2015 WL 3623005, at *10 (E.D. Pa. June 10, 2015) (stating how, while one consumer's prescription history dating back to 2006 had been presented to the *Vista Healthplan* court, the record contained "no evidence that other pharmacies kept reliable records of this same type of patient data over that time

period" and how "it is insufficient to simply make assurances that records are readily available without providing evidence that 'retailer records in this case can be used to identify class members.'" (quoting *Carrera*, 727 F.3d at 308)). Overall, even though at class certification, Plaintiffs "need only show that 'class members *can* be identified[,]'" Plaintiffs have not made such a showing with the evidence presented. *Byrd*, 784 F.3d at 163 (internal citations omitted) (emphasis in the original).

Additionally, EPPs' methodology does not provide an administratively feasible manner of ascertaining exclusions. That is, there is no manner presented where EPPs will identify exclusions in a manner that is not fact-intensive, requiring individualized fact-finding. This task is rendered difficult—particularly where EPPs propose to certify two classes with more than nine explicit exclusions. Using the rigorous analysis required under the class certification process, the Court finds this process to be fact-intensive, requiring individualized fact-finding. The exclusions relevant to the two different classes is discussed below.

a) TPP Class Exclusions

EPPs principally argue that the proposed methodology fails to provide an administratively feasible manner of identifying federal and state government entities and ASOs, TPAs, and fully-insured health plans. These issues are discussed below.

With respect to Ms. Craft's methodology for excluding state and federal government entities, Ms. Craft provides three ways by which these entities can be

excluded. First, Ms. Craft states that PBMs can identify, flag, or exclude transactions involving a federal or state government payor. (Craft Rep. at ¶ 86). Second, she states that a list of federal and state government payors can be cross-checked against the names in the data and in the claim forms that are submitted. (*Id.* at ¶ 89). Third, she claims that claimants can be required to verify via a certification on the claim form that they are not a state or government payor. (*Id.* at ¶¶ 85–90). Defendant argues that this reliance on affidavits to confirm that a payor is not a state or government entity "amounts to nothing more than the alleged class member's 'say so' that they fall within the class and are not excluded[,]" further noting that the evidence presented is insufficient to show that these entities could be excluded. (ECF No. 1259 at 29).

The Court first notes the similarities between EPPs' methodology here and that put forth in *In re Niaspan Antitrust Litig.*, 555 F. Supp. 3d 155, 165 (E.D. Pa. 2021), *aff'd*, 67 F.4th 118 (3d Cir. 2023) (hereinafter, "*Niaspan II*"). The *Niaspan II* court evaluated the same exclusion applicable to EPPs. EPPs in that case posited that these exclusions could be identified by:

> (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.

Id. at 164. The *Niaspan II* court further noted that Ms. Craft "claim[ed] that PBMs' websites 'confirm . . . that they have the capability to tailor their programs to the needs of federal and state government entities and [PBMs] aggressively market this capability.'" *Id.* The *Niaspan II* court noted that Ms. Craft also stated that "PBMs 'must . . . maintain . . . data that identifies government payors' because '[f]ederal law prohibits enrollees in federal health programs from participating in pharmacy incentive programs.'" *Id.* Overall, the *Niaspan II* court found that this evidence sufficiently showed that EPPs presented an administratively feasible mechanism for excluding federal and state government plans from the proposed class. *See Niaspan II*, 555 F. Supp. 3d at 164–65. The *Niaspan II* methodology is similar to that put forward by EPPs here. Indeed, EPPs have proposed to use PBM data and data from third parties Milliman, the NCSL or State Offices of Personnel to identify and exclude government entities. (Craft Rep. at ¶¶ 89–90; *see also* Nov. 28, 2023 Tr. at T42:18–T47:8). Also similar to *Niaspan II*, EPPs have put forth a manner of culling down the data, stating the manner in which state government data can be narrowed. Specifically, Ms. Craft notes that these third-party sources allow for the data to be culled and grouped into different categories by state, thus narrowing the relevant states by which a claims administrator would analyze the data. Ms. Craft also notes in this case that "[m]ajor PBMs . . . aggressively market their specialized skills in

handling federal and state government plans to assure regulatory compliances[]" on their websites. (Craft Rep. at ¶ 87). Further, Ms. Craft notes that "[f]ederal law prohibits enrollees in federal health programs from participating in pharmacy incentive programs[,]" thereby meaning that pharmacies and PBMs "must identify which prescriptions are reimbursed under federal and state programs." (Craft Rep. at ¶ 88). These similarities noted, *Niaspan II* is distinguishable given the notable difference with EPPs' methodology here.

The main problem rests again with EPPs' reliance on PBM data to confirm the exclusions. Per their own documents, the PBMs on which EPPs rely for providing the information about the federal and government entities—CVS Caremark, Express Scripts, MedImpact and Optum RX—account for (at most) around 40 percent of the market share of annual prescription volume in the relevant time period. (Craft Rep. at Table 2; *see also* ECF No. 1259 at 29). How EPPs can show that the federal and state entities unaccounted for in the PBM data they do have—either in the other roughly sixty percent of PBM data or by supplementing that data with the Milliman data, NCSL, State Offices of Personnel data, or historical state data lists—seems highly speculative and to the Court, amounts to relying on "say so" representations by EPPs. These "say so" representations may require individualized inquiry. Further, even assuming that federal law does mandate the retention of federal health program enrollee information by pharmacies and PBMs,

there is no evidence provided to the Court that the other data sources that are not pharmacies or PBMs on which Ms. Craft relies could fill this gap. These issues—not present in *Niaspan II*—render Ms. Craft's methodology for excluding these federal and state governmental entities unreliable. And, without more evidence, such a methodology does not pass the rigorous analysis required of the Court in the class certification process.

EPPs' proposed methodology to exclude fully-insured health plans, ASOs, and TPAs also falls short. First, the Court notes its serious reservations with respect to EPPs' ability to identify ASOs. Take Ms. Craft's reliance on Humana data to identify ASOs. In support of the assertion that ASOs can be identified using Humana data, Ms. Craft states that Humana uses two fields to identify the customer's funding status: an ASO indicator variable ("ASO_IND" field) and a line of business description ("LOB_DESC" field). (Craft Rep. at ¶ 47). Ms. Craft further states: "The ASO_IND variable is populated with yes ("Y") if the identified Customer is self-funding [i.e., the end payor] and is an ASO client of Humana, or no ("N") if the plan is fully insured and the identified insurer is therefore the TPP." (*Id.*). However, as Ranbaxy's Counsel pointed out, when the "ASO_IND" field was set to "Y," the results in the "Customer Name" field identified Humana, which acts as both an ASO and end payor. (Nov. 28, 2023 Tr. at T71:1–T73:12). Thus, the data ultimately provided by Humana when manipulated could not accurately identify the ultimate

end payor as Ms. Craft had opined. In addition and as the Court has previously stated, two Declarations on which EPPs heavily rely—those of Ms. Fridberg and Mr. Devaney—state that Caremark and Prime possess data that can identify ASOs and TPAs or the ultimate end-payor transactions. (Nov. 28, 2023 Tr. at T70:5–16; *see also* Craft Rep. at ¶ 37). Yet this data has not been produced in this matter, and there has been no evidence provided to the Court that the PBMs would be able to produce such data. This amounts to nothing more than relying upon say so representations from Declarations that something could be accomplished.

Even when looking at how Ms. Craft states that this exclusion could be applied, Ms. Craft states that EPPs rely on the PBM executives' representations which state that the data they possess can confirm exclusions. Without having seen this underlying data, Ms. Craft refers to Ms. Fridberg's Declaration, which states that "Prime maintains data indicating the name of the TPA or ASO and the self-funded payor client of the ASO or TPA. Prime can associate these Carrier and Account IDs with Carrier and Account Names." (Fridberg Declaration at ¶ 16; Craft Rep. at ¶ 37; Nov. 28, 2023 Tr. T62:16– T62:9). Neither Ms. Craft nor Ms. Fridberg describe how Carrier and Account IDs will be associated with Carrier and Account Names from the Prime data. (*Id.*). When evaluating this situation under the rigorous analysis required by the class certification process, the Court is unconvinced by EPPs' approach to excluding fully-insured health plans, ASOs, and TPAs given that

there has been little to no data produced on this point to support such an assertion. The Court believes this approach to exclusions amounts to nothing more than relying on EPPs' "say so" representations.

Moreover, as Dr. Hughes points out, the data to be retrieved is ten years old. The data's age implicates several issues such as the fact that the data may be incomplete or corrupted due to its age and changes in technology. Ms. Craft does not provide an opinion on this issue, and EPPs offer no evidence as to how this aged data can be used to identify and exclude fully-insured health plans, TPAs, and ASOs. "[A]ssurances that a party 'intends or plans to meet the requirements' are insufficient to satisfy Rule 23." *Carrera*, 727 F.3d at 311 (internal citations omitted). Without more, the Court cannot determine whether fully-insured health plans, TPAs, and ASOs can be identified and excluded from the class in an administratively feasible manner.

This brings the Court to another concern: even assuming that ASOs, TPAs, and fully-insured health plans could be identified through data produced by PBMs or from claim forms, the Court is unconvinced that these additional steps can be done in (1) an administratively feasible manner that (2) would not necessitate mini-trials or individualized fact-finding. This is because of the actual status of the insurance company with reference to its consumer. Often, an insurance company may be an ASO for some customers and a TPP for others. The Court's understanding is that a

claim form[7] will provide a question about the insurance company's status. This answer will be verified through the PBM data. As demonstrated from the above discussion, however, PBM data may be insufficient. Accordingly, the verification of status requires a review of the underlying documents between the insurance company and the client—a process that requires extensive and individualized fact-finding and follow-ups.

After having carefully reviewed the record and the evidence set forth by EPPs under the rigorous analysis required in the class certification process, the Court concludes that EPPs have not carried their burden by a preponderance of the evidence in setting forth a reliable and administratively feasible mechanism for identifying and excluding federal and state government entities; fully-insured health plans; TPAs; and ASOs. *See In re Wellbutrin XL Antitrust Litigation*, 308 F.R.D. 134, 150 (E.D. Pa. 2015).

b) Consumer Class Exclusions

As for the Consumer Class, Ranbaxy takes issue with EPPs' method for ascertaining members in the Total Generic Exclusion Period (June 28, 2011 through November 29, 2011) who used Pfizer Co-Pay Cards and for excluding "flat co-pay"

[7] *See supra* at 15–19.

consumers who purchased Lipitor via a fixed dollar copayment that did not vary based on the drug's status as a brand or generic. These issues are discussed below.

The Total Generic Exclusion Period within the Consumer Class definition excludes individuals who used Pfizer co-pay cards to pay for purchases of Lipitor. EPPs admit the Pfizer co-pay cards have not been reviewed, but EPPs purport to exclude this category of consumers based on Ms. Craft's conclusion that Pfizer kept records of the Pfizer Co-Pay Card Program; this assertion is based upon a Pfizer PowerPoint presentation on the co-pay cards which discussed the redemptions by patients and showed percentages of redemption among different tiers of costs. (ECF No. 1252 at 31).

EPPs present the Court with no methodology regarding the Pfizer Co-Pay Card exclusion. Although this co-pay card selection may be easily adduced, the Court does not accept EPPs' representations—which Ms. Craft has not seen or reviewed—that such data is available in such a manner that it can be used in an administratively feasible way to determine class membership of consumers falling within the Total Generic Exclusion Period. Without having reviewed—let alone seen—the Pfizer co-pay data, EPPs' contentions and Ms. Craft's conclusion are not corroborated. Moreover, Dr. Hughes explains that co-pay cards are issued in different amounts and, depending on the amount of the benefit, a co-pay card individual may or may not have an antitrust injury. Dr. Hughes claims the amount

of the injury, if any, may be determined by individually reviewing co-pay card documents. (Nov. 28, 2023 at T147:1–14). This would result in further individualized inquiry. The Court is unable to evaluate these statements based upon the information before it.

The Court also has concerns regarding the EPPs' exclusion for flat co-pay consumers within the Consumer Class definition. EPPs define this group of excluded consumers as those "who purchased Lipitor only via a fixed dollar copayment that does not vary on the basis of the drug's status as brand or generic." (ECF No. 1252 at 12). EPPs provide three ways to identify this exclusion. First, EPPs propose to compare the brand and generic co-pay amounts from the data to determine if they are identical. (Craft Rep. at ¶ 98). Second, EPPs state that consumers can verify, through claim form affidavits, that consumers did not make a purchase using a flat co-pay plan. (*Id.*). Third, EPPs state that PBMs can flag plans that utilize a flat co-pay structure. (*E.g.*, Craft Rep. at ¶ 100; Devaney Declaration at ¶ 9). EPPs note in a footnote that flat co-pay plans cannot be excluded because the TPP portion of the payment qualifies for the TPP class. (ECF No. 1252 at 34 n.18).

Ms. Craft relies upon a 2011 survey by the Kaiser Family Foundation and Health Research & Educational Trust to conclude that there would be no, or few consumers whose claims would be subject to the same flat co-pay for the brand and

generic drugs. (*See* Craft Rep. at ¶ 99). While PBM declarants state that that claims data can generally be sorted to exclude members of plans having single-tier flat co-pay structure, EPPs in their brief concede that PBMs would only be able to flag the plans that apply a flat co-pay structure because TPPs qualifying for class membership would be included in those flagged plans. (ECF No. 1252 at 34 n.18). Another concern facing the Court is EPPs' failure to address how, in light of Pfizer's brand continuity program, a brand Lipitor purchaser could have paid the same co-pay as a generic—even if the brand did not have a flat co-pay structure. (*See* ECF No. 1326-3 at 12). As such, the only method to reliably identify flat co-pay consumers would be through an individualized analysis of the consumer's health plan documents and the say so of the claims forms submitted; EPPs have failed to address how flat co-pay plans would then be removed from the resulting list without excluding qualifying TPPs.

The Court finds the *In re Wellbutrin XL Antitrust Litigation*, 308 F.R.D. 134 (E.D. Pa. 2015) decision instructive here. There, the court granted a motion to decertify an indirect purchaser class for several reasons, including that the class failed to show how records from various disparate entities could be synthesized to ascertain the consumers that paid a flat co-payment for the purchase of the brand drug and generic drug. *Id.* at 150. Instead, the *In re Wellbutrin* court found that the class's evidence on ascertainability "barely [went] further than repeated assurances

that showing ascertainability in a pharmaceutical case is not difficult and there are extensive purchase records in the pharmaceutical industry that could be used . . . ." *Id.* In a similar way, EPPs through their expert have provided the Court with mere assurances that—based on extensive records available—a reliable and administratively feasible mechanism exists to sift through the TPPs who applied a flat co-pay structure. The Court has no way of knowing how this could be done, and with the information before it, it appears that to exclude flat co-pay consumers would require an individualized fact-finding inquiry and a review of the TPP data. This process would be burdensome, fact-intensive, and like a mini-trial. EPPs' highly individualized information and "*ad hoc* approach . . . does not adequately establish a feasible methodology to address the many class exclusions." *Niaspan I*, 464 F. Supp. 3d at 705.

After having reviewed the record and the evidence set forth by EPPs with the rigorous analysis required of the Court, the Court concludes that EPPs have not carried their burden by a preponderance of the evidence in setting forth a reliable and administratively feasible mechanism for identifying and excluding members of the Consumer Class. *See In re Wellbutrin XL Antitrust Litigation*, 308 F.R.D. 134, 150 (E.D. Pa. 2015).

c) Costs

As a final note, the Court notes that neither EPPs nor their expert have discussed or offered an opinion as to the costs involved with implementing their proposed methodology. At oral argument on November 28, 2023, Ms. Craft admitted that she "wasn't asked to offer an opinion" about the cost of her proposed ascertainability methodology, though she added that the process would be "very inexpensive." (Nov. 28, 2023 Tr. at T76:1–13). The cost factor is relevant to the determination of whether the proposed methodology can be implemented in an administratively feasible manner, and the Court does not believe that the record supports that the ascertainability methodology can be.

In particular, the Court harbors concerns regarding the cost of the claims administration process; related to the fact-intensive and time-involved nature of reviewing available data is the cost of this process. At its broadest, the claims administration process is comprised of a claimant submitting identification and proof of loss to the class administrator. Then, the claims administrator will review and verify the loss and the claims form. If the claims administrator questions the loss on the claims form, then he or she will contact the claimant. Once the claims administrator accepts the claim, the completed claim will be transmitted to Ms. Craft's firm for processing. Yet even in this process, the claims administrator may follow-up with the claimant several times. There is no estimate as to how many follow-ups may be necessary or how much this initial claims process would cost.

Moreover, EPPs have not explained whether the costs associated with the claims administrator rise as the number of individual contacts with claimants rises. If there are many contacts with many individual claimants, the cost here could be substantial.

While the EPPs need not lay out these costs with certainty, they must provide the Court with more information than it will be "very inexpensive." This does not meet the burden of proof. The Court harbors significant doubt that this methodology would be cost effective—especially when looking at other antitrust cases presented with similar methodologies. *See Niaspan I*, 464 F. Supp. 3d 678 at 707 (noting how, while even "if identification of class members [were] technically possible, EPPs' proposed methodology [might] be prohibitively expensive and thus infeasible" when looking at similar pay-for-delay cases).

III.

Given that the Court has previously ruled that EPPs cannot prove an essential element of their action, causation, this Motion is accordingly denied. (*See* ECF No. 1415).

However, even if the Court had not granted summary judgment on causation, class certification would still be denied. This is because EPPs have failed to show by a preponderance of the evidence that there is a reliable and administratively

feasible mechanism for determining whether class members fall within the class definition as required under Rule 23(b)(3).[8]

Peter G. Sheridan

PETER G. SHERIDAN, U.S.D.J.

[8] Without analyzing Dr. Hal Singer's report, his use of average cost per pill on an overall basis as a measure of determining damages where there are rebates to specific TPPs requires further discussion.