

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**IN RE NAMENDA INDIRECT PURCHASER
ANTITRUST LITIGATION

No. 1:15-cv-6549 (CM) (RWL)

**DECISION AND ORDER DENYING DEFENDANTS' MOTION TO EXCLUDE THE
OPINIONS OF LAURA R. CRAFT.**

McMahon, C.J.:

Presently before the Court is Defendant's motion to exclude the opinions of Plaintiff expert Laura R. Craft, which Plaintiff offers in support of class certification.

For the reasons set forth below, that motion is denied.

I. BACKGROUND

This case's factual background and relevant regulatory scheme have been recounted at length in other opinions. *See New York v. Actavis, PLC* ("Namenda I"), No. 14-cv-7473, 2014 WL 7015198 (S.D.N.Y. Dec. 11, 2014), *aff'd sub nom. Schneiderman ex rel. New York v. Actavis, PLC* ("Namenda II"), 787 F.3d 638 (2d Cir. 2015); *Sergeants Benevolent Ass'n Health & Welfare Fund v. Actavis, PLC* ("Namenda III"), No. 15-cv-6549, 2016 WL 4992690 (S.D.N.Y. Sept. 13, 2016) (denying motion to dismiss in this litigation); *In re Namenda Direct Purchaser Antitrust Litigation* ("Namenda IV"), No. 15 Civ. 7488 (CM), 2017 WL 4358244, at *1 (S.D.N.Y. May 23, 2017) (granting in part and denying in part Plaintiffs' motion for collateral estoppel and partial summary judgment); *In re Namenda Direct Purchaser Antitrust Litigation* ("Namenda V"), 331 F. Supp.3d

152 (S.D.N.Y. 2017) (certifying class of direct purchasers of Namenda, and granting in part and denying in part Defendants’ motions to exclude expert opinions and for summary judgment).

Thus, only facts relevant to the current motions are summarized below. Unless otherwise mentioned, the facts detailed are not in dispute.

A. The Parties

Plaintiff Sergeants Benevolent Association Health & Welfare Fund (“SBA”) is a fund that administers the prescription drug benefit plan for active and retired New York City Police Department sergeants and their dependents. It represents a class of “end payors” of Namenda, which includes – subject to some exceptions – “All Third-Party Payors who indirectly purchased, and/or paid, and/or provided reimbursement for, some or all of the price for Namenda IR 5 or 10 mg tablets . . . and/or Namenda XR capsules[.]” (ECF 489). These end payors include entities like insurers and welfare plans like SBA.

Defendant Forest Laboratories is a limited-liability company incorporated in Delaware that manufactures and sells branded pharmaceutical products. Forest is a wholly owned subsidiary of Defendant Actavis PLC (now known as Allergan PLC). Defendants Merz GmbH & Co. KGaA.; Merz Pharma GmbH & Co. KGaA; and Merz Pharmaceuticals GmbH (collectively “Merz”) are headquartered in Germany and are also engaged in the development, production, and distribution of pharmaceutical products.

B. The Hatch-Waxman Act and Generic Competition

Under the Federal Food, Drug, and Cosmetic Act (“FDCA”), 21 U.S.C. § 301 *et seq.*, a pharmaceutical company must file a New Drug Application (“NDA”) with the FDA any time it wishes to market a new brand-name drug. The NDA must provide the agency with scientific data demonstrating that the new drug is safe and effective. *Namenda II*, 787 F.3d at 643; 21 U.S.C. §

355. The process is often very costly and time consuming, but once a patented drug is approved, it enjoys a period of exclusivity on the market (generally twenty years) – effectively, a government-sanctioned monopoly. During this exclusivity period, the drug’s developer can recoup its investment into the drug, as it faces no competition. However, once the exclusivity period ends and generic versions of the drug enter the market, it generally results in the brand-name drug losing more than 80% to 90% of its market share within six months – a process known in the industry as going off the “patent cliff.” *Namenda II*, 787 F.3d at 647.

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act (the “Hatch-Waxman Act”), Pub. L. No. 98–417, 98 Stat. 1585. Hatch-Waxman attempted to serve a dual purpose: to lower drug prices for consumers by encouraging generic competition with brand-name drugs; and to incentivize innovation from branded drug manufacturers by providing for patent extensions beyond the standard 20-year patent term. *Namenda II*, 787 F.3d at 644.

As to the first goal – encouraging generic competition – Hatch-Waxman permitted generic manufacturers to file an Abbreviated New Drug Application (“ANDA”), which allows a generic manufacturer to “piggy-back” on an already-approved branded drug’s NDA information to show that the generic is safe and effective. *Ibid*. The ANDA requires the generic manufacturer to certify that the generic has the same active ingredients as, and is “bioequivalent” to, the already-approved brand-name drug. *Ibid*; *see also* 21 U.S.C. § 355(j). A generic is “bioequivalent” to a brand-name drug if “the rate and extent of absorption of” the two drugs are not significantly different. 21 U.S.C. § 355(j)(8)(B)(i). In other words, two drugs are “bioequivalent” if they deliver the same amount of an active ingredient over the same amount of time. By allowing generic drug manufacturers to “piggy-back” their ANDAs on the scientific studies of already-approved drugs, Hatch-Waxman

reduced the development costs of lower-priced generics, speeding their introduction to the market. *Namenda II*, 787 F.3d at 644.

Apart from the federal regulatory landscape, many states also encourage generic competition through drug-substitution laws. These laws either permit or require pharmacists to replace a prescribed brand-name drug with a “therapeutically equivalent,” lower-priced generic if there is no express direction from the prescribing doctor that the prescription *must* be filled with the brand-name drug. *Id.* at 645. Whether a generic is “therapeutically equivalent” to the brand-name drug is state-dependent, but at least thirty states follow the FDA’s guidance and will only allow a generic substitution if the FDA designates the generic as “AB-rated” in a publication known as the “Orange Book.” *Ibid.* An AB-rated generic is one that is both “bioequivalent” to the brand-name drug and pharmaceutically equivalent in that it has the “same active ingredient, dosage form, strength, and route of administration[.]” *Ibid.*

However, the AB-rating requirement provides brand-name drug manufacturers with an opportunity to game the system by “product hopping” – developing a new version of the drug with a later patent expiration date, and then encouraging patients to switch to the new version before the original version goes off the “patent cliff.” Because an AB-rating requires the generic to deliver an identical amount of the drug in the same way and over the same amount of time, a brand-name manufacturer can develop a new version of the drug with a different rate of delivery that would preclude the generic to the original version from being rated as AB-equivalent to the new version. This is what SBA alleges occurred with the two versions of Namenda at issue in this lawsuit. *See infra*, Section I.D.

C. Generic Exclusivity and the Generic Settlements

Another way Hatch-Waxman furthers generic competition is by allowing the FDA to grant a 180-day exclusive marketing period to the first generic manufacturer to successfully file an ANDA. This period of exclusivity can be extremely profitable for whichever company successfully files first, because the FDA is prohibited from granting approval to any other generic manufacturer's ANDA for the same brand-name drug during that time. *See FTC v. Actavis, Inc.*, 570 U.S. 136, 144 (2013).

Yet, to successfully qualify for the exclusive marketing period, the generic manufacturer – in its ANDA – must “assure the FDA” that the generic “will not infringe” on any of the brand-name manufacturer's patents. *Id.* at 143 (citation omitted). The generic manufacturer can provide this assurance in several ways, but the only one relevant here is the “Paragraph IV” route – so named after 21 U.S.C. § 355(j)(2)(A)(vii)(IV). Under the Paragraph IV route, the generic manufacturer certifies that any relevant patent held by the brand-name manufacturer “is invalid or will not be infringed by the manufacture, use, or sale” of the generic. *Actavis*, 570 U.S. at 143 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)(IV)).

However, taking the Paragraph IV route automatically counts as patent infringement, and it often provokes a lawsuit from the brand-name manufacturer. If the brand-name manufacturer sues within 45 days of being notified that a generic manufacturer has filed a Paragraph IV Certification, the FDA “must withhold approving the generic, usually for a 30-month period, while the parties litigate patent validity (or infringement) in court.” *Ibid.* Like any lawsuit, the parties can decide to settle the case out of court, but in such a scenario, it is usually the plaintiff (the brand-name manufacturer and patent holder) that pays to settle the case against the defendant (the generic manufacturer and alleged infringer). Thus, these settlements are called “reverse payment” settlements or “reverse settlements.”

D. Factual History and Anticompetitive Allegations

In June 2000, Merz provided Forest with an exclusive license to U.S. Patent No. 5,061,703 (the “’703 Patent”), which gave Forest the right to market a memantine hydrochloride-based drug in the United States. Forest developed Namenda IR (immediate release); a twice-daily drug that is used to treat moderate to severe Alzheimer’s. Following FDA approval in late 2003, Forest began marketing Namenda IR and annual sales of the drug grew to approximately \$1.5 billion in 2012 and 2013. *Namenda II*, 787 F.3d at 647. Namenda IR’s exclusivity period based on the ’703 Patent was set to expire on October 11, 2015, after Forest obtained several extensions. *Namenda IV*, 2017 WL 4358244, at *6.

In June 2010, the FDA approved a second memantine-based drug developed by Forest: Namenda XR (extended release). Unlike Namenda IR, Namenda XR needed to only be taken once daily, but the two drugs have exactly the same active ingredient and exactly the same therapeutic effect. *Id.* at *19. Nonetheless, generics to Namenda IR – because it was not pharmaceutically equivalent to Namenda XR – would not be competitive with the new version. So Forest attempted to implement a “soft switch” between the two versions of Namenda, whereby it marketed the new version of the drug and reduced its price to encourage voluntary switching from consumers. Forest began marketing Namenda XR in 2013, *Namenda II*, 787 F.3d at 647, and it also stopped advertising Namenda IR. *Namenda III*, 2016 WL 4992690, at *5.

However, according to SBA, Forest decided that these efforts at a “soft switch” were unsuccessful because, by 2014, its internal projections estimated that only 30% of Namenda IR consumers would switch to Namenda XR before Namenda IR’s “patent cliff.” *Namenda III*, 2016 WL 4992690, at *5. So on February 14, 2014, Forest announced an intention to completely withdraw Namenda IR from the market by September 2014, while keeping Namenda XR on the

market. SBA alleges that this was an anticompetitive “hard switch,” through which Forest essentially tried to *force* consumers to switch to Namenda XR with no option to remain on the original version, before the first Namenda IR generic could hit the market.

SBA also alleges that Defendants entered into several anticompetitive “reverse payment” settlements with generic manufacturers between July 2009 and July 2010. The agreements provided that the generic manufacturers would not launch generic versions of Namenda IR onto the market until after July 11, 2015 – months before Namenda IR’s patent expired, but after the time in which Defendants, had they been successful, would have successfully implemented the “hard switch” for consumers. The Supreme Court has held that such “reverse payment” settlements are not immune to antitrust scrutiny. *Actavis*, 570 U.S. at 158.

E. History of Litigation

The present litigation comes after several lawsuits against the manufacturers of Namenda and its generic counterparts.

In 2014, after Forest announced that it was planning to discontinue Namenda IR, the State of New York sued Forest and Actavis in this Court to enjoin them from doing so, arguing that the “hard switch” was anticompetitive. *Namenda I*, 2014 WL 7015198, at * 1. The Honorable Judge Robert Sweet granted a preliminary injunction, and that ruling was affirmed on appeal. *Namenda II*, 787 F.3d at 663.

In August 2015, SBA filed the instant lawsuit, and in September 2015, direct purchasers of Namenda filed a similar lawsuit. (*See* Case No. 15-cv-7488 (CM)(RWL)). Both sets of Plaintiffs alleged that they were forced to pay supra-competitive prices for Namenda after Forest attempted to restrict access to Namenda IR. In addition to alleging the anticompetitive “hard switch” that was the basis of New York State’s lawsuit, Plaintiffs also alleged that Forest made several

anticompetitive “reverse payments” to stave off generic competition. Thus, several generic drug manufacturers were added as defendants to these lawsuits.

In September 2016, this Court denied the Defendants’ consolidated motions to dismiss. *Namenda III*, 2016 WL 4992690, at * 1.

The Court then stayed the indirect purchasers’ litigation (this case) until a resolution of the federal claims from the direct purchasers’ lawsuit. That lawsuit settled on the eve of trial. Following that, several of the generic defendants in this suit also settled. The only remaining defendants are those affiliated with the brand-name manufacturers and originators of Namenda – Forest and Actavis and their German counterpart, Merz.

Presently before the Court are two motions.

On July 7, 2020, SBA filed its motion for certification. Included in its attachments were the expert reports of Russell Lamb, Ph.D; William B. Vogt, Ph.D; and Laura Craft. (ECF 447).

On August 24, Defendants filed a motion to exclude the opinions and testimony of Laura Craft. Craft’s report goes to the identifiability and ascertainability of the proposed class, but the motion to exclude argues that she does not have the data she says she needs, and that her methodology is unreliable. (ECF 461, 477).

The motion to exclude is denied.

DISCUSSION

SBA seeks to certify the following class:

All Third-Party Payors who indirectly purchased, and/or paid, and/or provided reimbursement for, some or all of the purchase price for branded Namenda IR 5 or 10 mg tablets, their AB-rated generic equivalents, and/or Namenda XR capsules, other than for resale, in Alabama, Arizona, California, D.C., Florida, Hawaii, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island (for purchases after July 15, 2013), South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, for consumption by themselves, or their members, employees, insureds, participants,

or beneficiaries, from June 1, 2012 through December 31, 2017.

Excluded from the proposed Class are: (a) Defendants and Defendants' parents, subsidiaries and affiliates; (b) fully-insured health care plans (i.e., health plans that purchased insurance from another third-party payor covering 100% of the insureds' prescription drug benefits on behalf of the Plan's members and beneficiaries); (c) all federal or state governmental entities, excluding cities, towns or municipalities with self-funded prescription drug plans; and (d) Pharmacy Benefit Managers ("PBMs"). (ECF 489, pg. 2).

SBA's initial memorandum of law in support of certification proposed a class of "All persons or entities who indirectly purchased" or provided reimbursement for Namenda. (ECF 444). SBA then amended its proposed definition when it filed its reply. Although Ms. Craft's initial report dealt with the more expansive definition, there is no reason why her opinions would not also apply to the narrower definition.

A. Legal Framework

1. Class Certification and Rule 23

Rule 23 of the Federal Rules of Civil Procedure provides the legal framework for class certification. A class may be certified only if:

(1) the class is so numerous that joinder of all members is impracticable; (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.

Fed. R. Civ. P. 23(a). Commonly expressed, these are the requirements of numerosity, commonality, typicality, and adequacy of representation. *See, e.g., In re LIBOR-Based Fin. Instruments Antitrust Litigation*, 299 F. Supp.3d 430, 460 (S.D.N.Y. 2018).

In addition to the four factors outlined in 23(a), the Second Circuit has "recognized an implied requirement of ascertainability." *In re Petrobras Secs.*, 862 F.3d 250, 264 (2d Cir. 2017) (quoting *Brecher v. Republic of Argentina*, 806 F.3d 22, 24 (2d Cir. 2015)). This requirement "asks district courts to consider whether a proposed class is defined using objective criteria that establish

a membership with definite boundaries.” *Id.* at 269. It is a “modest threshold” that “will only preclude certification if a proposed class definition is indeterminate in some fundamental way.”

Ibid.

Satisfying all four Rule 23(a) prerequisites and the ascertainability requirement does not end the analysis. Plaintiffs must also establish at least one of the three requirements listed under Rule 23(b). *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 345 (2011). Here, SBA seeks certification under 23(b)(3), which permits a claim for class-wide damages if (1) “questions of law or fact common to class members predominate over any questions affecting only individual members” and “a class action is superior to other available methods for fairly and efficiently adjudicating the controversy.” Fed R. Civ. P. 23(b)(3). These two factors: “predominance” and “superiority” must both be satisfied. *See, e.g., Sykes v. Mel S. Harris and Assocs. LLC*, 780 F.3d 70, 82 (2d Cir. 2015).

“The party seeking class certification bears the burden of establishing by a preponderance of the evidence that each of Rule 23’s requirements has been met.” *Myers v. Hertz Corp.*, 624 F.3d 537, 547 (2d Cir. 2010). SBA has therefore submitted expert reports from Russell Lamb, Ph.D; William B. Vogt, Ph.D; and Laura R. Craft in support of its motion.

2. *Daubert* Standard

Generally, at a dispositive merits stage of a class-action suit (like summary judgment or trial), the admissibility of expert testimony is adjudicated under the familiar gatekeeping framework of Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms. Inc.*, 509 U.S. 579 (1993). *See Raskin v. Wyatt Co.*, 125 F.3d 55, 65 (2d Cir. 1997); *Namenda V*, 331 F. Supp.3d at 168. Rule 702 provides:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert’s

scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. “The Second Circuit has ‘distilled Rule 702’s requirements into three broad criteria: (1) qualifications, (2) reliability, and (3) relevance and assistance to the trier of fact.’” *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. 5, 27 (S.D.N.Y. 2020) (quoting *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d 430, 466 (S.D.N.Y. 2018)).

“Although Rule 702 sets forth specific criteria for the district court’s consideration, the *Daubert* inquiry is fluid and will necessarily vary from case to case.” *Amorgianos v. Nat’l R.R. Passenger Corp.*, 303 F.3d 256, 266 (2d Cir. 2002). But just because the inquiry is a “flexible one,” *Daubert*, 509 U.S. at 594, does not mean that a court is required “to admit opinion evidence that is connected to the existing data only by the *ipse dixit* of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered.” *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997). It is “critical that an expert’s analysis be reliable at every step.” *Amorgianos*, 303 F.3d at 267. The fundamental purpose of *Daubert* “is to ensure the reliability and relevancy of expert testimony,” *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999), “and district courts may not stray from those goals.” *In re Pfizer Inc. Secs. Litig.*, 819 F.3d 642, 658 (2d Cir. 2016). Ultimately, a district court has “broad discretion” in determining the admission or exclusion of expert opinions. *Boucher v. U.S. Suzuki Motor Corp.*, 73 F.3d 18, 21 (2d Cir. 1996).

3. Applicability of *Daubert* at the Class-Certification Stage

Neither the Supreme Court nor the Second Circuit has opined about whether district courts must evaluate whether a proffered expert’s opinions are admissible under *Daubert* for they to be

considered in support of class certification. See *In re U.S. Foodservice Inc. Pricing Litigation*, 729 F.3d 108, 129 (2d Cir. 2013). The Courts of Appeals are seemingly split on the issue.

The Seventh Circuit has held that a “district court must perform a full *Daubert* analysis before certifying the class if the situation warrants.” *Am. Honda Motor Co. v. Allen*, 600 F.3d 813, 816 (7th Cir. 2010). The Third Circuit has held similarly, explaining that, “Expert testimony that is insufficiently reliable to satisfy the *Daubert* standard cannot ‘prove’ that the Rule 23(a) prerequisites have been met ‘in fact,’ nor can it establish ‘through evidentiary proof’ that Rule 23(b) is satisfied.” *In re Blood Reagents Antitrust Litigation*, 783 F.3d 183, 187 (3d Cir. 2015).

But at least one Court of Appeals has held differently, holding that evidence that might otherwise be inadmissible at trial under *Daubert* can still be considered for certification. See *In re Zurn Pex Plumbing Prods. Liab. Litig.*, 644 F.3d 604, 611 (8th Cir. 2011). *Zurn* expressly rejected an invitation to apply the Seventh Circuit’s rationale in *American Honda*, and instead reaffirmed a prior ruling that had “explicitly rejected a request for a full *Daubert* inquiry at the class certification stage.” *Id.* at 612. (citing *Blades v. Monsanto Co.*, 400 F.3d 562, 569 (8th Cir. 2005)).

A decision from the Ninth Circuit has suggested that it finds the Eighth Circuit’s reasoning persuasive, holding “that a district court is not limited to considering only admissible evidence in evaluating whether Rule 23’s requirements are met.” *Sali v. Corona Regional Med. Ctr.*, 909 F.3d 996, 1005 (9th Cir. 2018). Although it did observe that “in evaluating challenged expert testimony in support of class certification, a district court should evaluate admissibility under the standard set forth in *Daubert*,” the question of “admissibility must not be dispositive.” *Id.* at 1006.

Given the various approaches, this Court is persuaded that a complete *Daubert* inquiry is necessary to analyzing a motion to exclude at the class-certification stage, and that only expert

reports that would otherwise be admissible at trial under *Daubert* can be considered in support of class certification. There are several reasons for this conclusion.

First, the Supreme Court has suggested – albeit in dicta – that *Daubert* may be necessary at this stage. In *Wal-Mart*, it commented that the district court in the case “concluded that *Daubert* did not apply to expert testimony at the certification stage of class-action proceedings. *We doubt that is so . . .*” *Wal-Mart*, 564 U.S. at 354 (internal citation omitted) (emphasis added). The Second Circuit has interpreted that statement as “suggesting that a *Daubert* analysis may be required at least in some circumstances.” *In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d at 129.

Second, the Supreme Court has held that a court’s certification analysis “must be ‘rigorous’ and may ‘entail some overlap with the merits of the plaintiff’s underlying claim.’” *Amgen Inc. v. CT. Retirement Plans and Trust Funds*, 568 U.S. 455, 465–66 (2013) (quoting *Wal-Mart*, 564 U.S. at 351)). Although courts must attempt to avoid touching on the merits of a suit when deciding certification, an overlap with the merits often “cannot be helped,” as class determination “generally involves considerations that are enmeshed in the factual and legal issues comprising” the case in chief. *Wal-Mart*, 564 U.S. at 351 (citation omitted). Thus, because determining certification may inevitably bleed into the merits of the case, *Daubert* is necessary to guard against possible discrepancies or inconsistencies that may arise as the litigation proceeds.

It would be incongruous to rule that an expert’s opinion can be relied upon in support of class certification, but – later in the litigation – determine that the same expert cannot be relied upon for purposes of summary judgment or trial. There is no reason to believe that a court takes on any less of a “gatekeeping” function for expert reliability at the class-certification stage.

Third, the Second Circuit has held that a court must “resolve[] factual disputes” at the class-certification stage and that any expert testimony offered in support must be more than simply “not

fatally flawed.” *In Re Initial Public Offerings Secs. Litig.*, 471 F.3d at 42 (emphasis added) (“*IPO*”). This threshold is necessarily met if *Daubert* is applied. In *IPO*, the Second Circuit rejected the holding in a prior case, *In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 135 (2d Cir. 2001), which had affirmed a district court’s conclusions about an expert’s class-certification evidence merely because the expert’s “methodology was not fatally flawed,” and was thereby – in the court’s view – “sufficiently reliable for class certification purposes.” *Visa Check*, 280 F.3d at 135. The express disavowal of *Visa Check* implies that the Second Circuit prefers a higher threshold, and a firmer methodological basis when evaluating experts at class certification.

This Court is not aware of any decision from this district explicitly suggesting that a *Daubert* inquiry was not necessary to decide a motion to exclude at the class-certification stage. In fact, the opposite is true; there are countless opinions applying *Daubert*. See, e.g., *In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. at 29; *In re Foreign Exch. Benchmark Rates Antitrust Litig.*, 407 F. Supp. 3d 422, 429 (S.D.N.Y. 2019); *In re LIBOR-Based Fin. Instruments Antitrust Litig.*, 299 F. Supp. 3d at 471.

In short, the Court agrees with the heavy weight of authority militating towards a *Daubert* inquiry at class certification.

B. Ms. Craft’s Expert Report is Admissible; Defendants’ Motion to Exclude is Denied

Defendants move to exclude the opinions of Laura R. Craft, whom SBA offers as an expert in determining whether the proposed class is ascertainable.

Ms. Craft’s opinions are principally outlined in her initial expert report, dated July 6, 2020, and which was filed in support of class certification. (ECF 447-3; 464-1). Other submissions related to Ms. Craft’s opinions in the record include: (2) a transcript of excerpts of her first deposition, taken on August 6, 2020 (ECF 464-2); (3) a rebuttal report, dated September 21, 2020

(ECF 492); (4) a transcript of excerpts of her second deposition, taken October 12, 2020 (ECF 523-1) and; (5) her amended rebuttal report, dated October 16, 2020 (ECF 523-3).

1. Craft's Qualifications and the Relevance of Her Opinions

Since 2004, Ms. Craft has been the president of OnPoint Analytics, Inc. (“OnPoint”), an economic and statistical consulting firm that specializes in database analytics. (Declaration of Laura R. Craft at ¶ 2, ECF 447-3; 464-1). OnPoint dedicates a significant portion of its business to the healthcare sector and to the pharmaceutical industry in particular. As president of OnPoint, Ms. Craft oversees the entirety of the firm’s work involving pharmaceutical products, including analyzing health insurance data, premium pricing data, claims processing data, and reimbursement data. (*Id.* at ¶ 4). She routinely works on pharmaceutical litigation, including cases involving antitrust allegations, and has worked on 60 such cases to date. (*Id.* at ¶ 2). Her duties pursuant to litigation include developing databases of transactions from multiple data sources, identifying potential class members, and removing individuals from the class who are uninjured or subject to class exclusions. She has served as an expert in six antitrust cases in the past four years, alone. (*Id.* at ¶ 4).

Ms. Craft has also co-authored several books on the pharmaceutical industry, including *Empirical Challenges in Pharma Litigation* – which was published in 2017. (*Id.* at ¶ 3). She has also taught two courses on data analytics in the pharmaceutical industry: *Data and Empirical Challenges in Pharmaceutical Litigation* and *Antitrust Claims Involving Pharmaceutical Products*, both of which have been approved for Continuing Legal Education credit in seven states. (*Id.* at ¶ 4). These credentials demonstrate that Ms. Craft has a wealth of experience in pharmaceutical data management and analysis.

There is also no dispute that Ms. Craft's opinions are relevant to the issue of class certification. The only actual point of contention is thus whether the opinions offered in her report are sufficiently reliable. *See In re Aluminum Warehousing Antitrust Litig.*, 336 F.R.D. at 27

2. Summary of Ms. Craft's Reports

Ms. Craft's submissions explain her conclusion that the proposed class is not only ascertainable, but that ascertaining its membership would be "a largely programmatic exercise that depends only on data routinely kept (and legally mandated) in the pharmaceutical industry, and which is characterized by extraordinarily high levels of standardization." (*Id.* at ¶ 1). Craft explains that transaction-specific data that tracks each purchase of Namenda exists and is available through several institutional sources. Once that data is aggregated, the relevant class exclusions can be applied, and the class members can be ascertained.

There are three institutional sources that collect electronic data for each specific prescription drug sale: (1) the pharmacy that dispenses the drug; (2) the Pharmacy Benefit Manager ("PBM") that processes the insurance claims connected to each purchase; and (3) the Third-Party Payor – very typically the insurer that reimburses all or part of the purchase price of the drug. (*Id.* at ¶ 25). SBA's proposed class now consists entirely of these Third-Party Payors ("TPPs") who reimbursed some amount of money for purchases of Namenda.

Whenever a prescription is filled, the pharmacy and TPP must be able to interact quickly to adjudicate the insurance claim so that the individual customer can be charged the correct price based on his/her insurance plan. However, given the large number of pharmacies and TPPs nationwide, having each TPP communicate directly with each individual pharmacy that fills the prescription (or vice versa) would be inefficient and cost prohibitive. TPPs hire PBMs to help fill this gap. PBMs act as intermediaries between TPPs and pharmacies, and are tasked with a variety

of roles, including negotiating drug prices with pharmacies, designing specific drug plans, enrolling new customers, and processing and adjudicating insurance claims.

Every time a prescription is filled, the PBM affiliated with the TPP performs a “claims adjudication,” an electronic process that occurs within a matter of seconds. First, it verifies the eligibility of the drug purchaser to determine that the individual is covered by a qualifying insurance plan. Second, it determines the drug’s coverage under the insurer’s formulary, and what co-payment or co-insurance should be applied. Third, it divides the purchase price of the drug between the individual consumer and the TPP. Fourth, it calculates (and commits the TPP to pay) the price of its share to the pharmacy. (*Id.* at ¶ 26).

Craft explains that the PBM performing the claim adjudication is legally required to collect, and so possesses, the data necessary to ascertain the proposed class, such as the TPP and the consumer payor for every purchase. (*Id.* at ¶ 18). Craft relies for her conclusion on declarations filed in other lawsuits by individuals who represent four of the largest PBMs in the country, all of whom aver that it is standard for their PBM to keep specific records on each drug purchase, and that the PBM would be able to identify the TPP for all transactions. (*Id.* at ¶ 43).

Craft further opines that nearly all the data necessary to ascertain the class could be obtained from a select few of the largest PBMs in the nation, which would make the process even simpler. The PBM industry is heavily concentrated: The seven largest PBMs processed 89% of the prescription drug transactions in the United States in 2015; 92% in 2016, and 96% in 2017. (*Id.* at ¶ 30). For Namenda, this share is likely to be “significantly higher” because of the “heavy involvement of Medicare Part D plans which are mainly offered by large commercial insurers with major PBM affiliations.” (*Ibid.*).

Federal regulations also require transaction-specific data to be highly standardized. This allows anyone interpreting the data received from different sources to do so relatively easily. Standardization also facilitates confirmation of the completeness of the data. (*Id.* at ¶ 19). For example, each drug is identifiable with a 10-digit FDA-assigned code known as the National Drug Code (“NDC”), and “the NDC is almost universally used by pharmacies, PBMs, and TPPs to communicate with each other about exactly what drug product has been dispensed and sold.” (*Ibid.*).

Craft opines that a simple methodology can be applied to this data to ascertain members of the class and those who are to be excluded from the proposed class. She explains how it works using data that was obtained by OnPoint from OptumRx, the third largest PBM in the nation, for several of the years between 2012 and 2020. (*Id.* at ¶ 44). This data contained information related to over eight million specific purchases of Namenda (IR and XR) during the relevant class period. (*Id.* at ¶ 58).

For each purchase, the OptumRx data contains several fields, which together can be used to “identify the payor of a given transaction”: Carrier ID, Carrier Description, Account Description, Employer Group ID, and Employer Group Description. (Craft Rebuttal at ¶ 37; ECF 523-3).

The “Carrier” (a term used by OptumRx, but which Craft says corresponds to similar terms used by other PBMs) is the “entity contracting with” the PBM for “claims processing services.” (*Id.* at ¶ 38). That entity’s identity is expressed in two ways in the data – the Carrier ID, which is an alpha-numeric code; and the Carrier Description, which is a text-based name. Both fields can be used to identify the entity that hired OptumRx to process claims. Typically, the Carrier is a TPP (i.e., a potential class member), but not always. For example, a self-insured plan may hire a Third-

Party Administrator (“TPA”) that contracts with the PBM to process claims on behalf of the plan. In such a scenario, the TPA would appear in the Carrier field instead of the entity that was funding the self-insured plan. (*Id.* at ¶ 39). For this reason, whoever is analyzing the data may need to look beyond the Carrier fields to the other fields to be able to definitively determine the end payor. For example, Craft states that the Account Description field “typically identifies the plan sponsor who is financially responsible for the prescription drug claims,” and the Employer Group fields identify “the population of individuals covered by the plan.” (*Id.* at ¶ 40). Craft opines that these additional fields can help determine whether a plan is fully-insured or self-insured, which is relevant to applying the class exclusions. (*Id.* at ¶ 41).

Craft also details how to ascertain who should be excluded from the proposed class. One exclusion is for fully-insured plans (Exclusion (b))¹ – plans that purchased insurance from another TPP that covered 100% of the insureds’ payments, such that the insuring TPP was the ultimate payor. Craft states that, in addition to the fields just described, these plans can also be identified through several identification numbers attached to every drug purchase. These numbers – the BIN (Bank Identification Number) and the PCN (Processor Control Number) in particular – “tell the electronic routing system where to direct the claim so that it can be adjudicated and a fixed payment liability created for the correct TPP.” (*Id.* at ¶ 72). The BIN and PCN are effectively linked to particular insurance plans maintained and processed by PBMs, and, “In the case of fully-insured plans, these fields together identify the insurance company that issued the plan and that will be paying for the prescription, rather than the employer that sponsored it.” (*Id.* at ¶ 75).

¹ In the original motion for class certification, the exclusion of fully-insured plans was Exclusion (c) (ECF 444), which is how Craft refers to the exclusion in her initial report. After Plaintiff amended its proposed class definition, this exclusion became Exclusion (b).

Although the BIN and PCN numbers were not included in the OptumRx data Craft was provided, Craft opines that this data exists. (Craft Rebuttal at ¶ 54).

For the class exclusion of federal and state drug plans (Exclusion (c))², Craft notes that “Government plans typically use the services of the major PBMs to adjudicate and pay their claims, just as other commercial plans do, and PBMs clearly know the identity of their payor clients.” (Craft Decl. at ¶ 77). Once that information is made known to the PBM, “these plans could be specifically flagged or withheld.” (*Ibid.*). Even if that process were somehow unfeasible, Craft explains that information about state/federal insurance plans is publicly available, and whoever is analyzing the raw PBM data can simply exclude those plans once a complete list of those plans is compiled. (*Id.* at ¶¶ 78–80).

In short, Craft’s method for ascertaining class members involves two steps: (1) obtain the necessary transaction-specific data from PBMs and other third-party data collectors on all purchases of Namenda during the relevant time period; and then (2) analyze that data using selected fields so as to identify third-party payors and then exclude those who are explicitly excluded from the proposed class. She ultimately concludes that the data with which she was provided show that (1) “the TPP and consumer Payors can be identified,” and (2) “the amount each paid is determinable through programmatic analysis of electronic data.” (*Id.* at ¶ 65). She also concludes that “class exclusions can readily be applied.” (*Id.* at ¶ 21).

3. Ms. Craft’s Opinions on Ascertainability are Sufficiently Reliable

Defendants make two main arguments about why Craft’s opinions should be excluded, both of which center on the reliability of her methodology: (1) Craft’s methodology is theoretical,

² In the original motion for class certification, the exclusion of federal and state drug plans was Exclusion (d), (ECF 444), which is how Craft refers to the exclusion in her initial report. After Plaintiff amended its proposed class definition, this exclusion became Exclusion (c).

in that neither she nor the Plaintiff has actually obtained the large amount of data necessary to employ it; (2) Craft’s methodology has never been applied to ascertain a class. Neither of these arguments is persuasive.

a. It Is Not Necessary to Possess All the Data Prior to Ascertaining the Reliability of the Proposed Methodology

The fact that SBA or Craft do not currently have *all* of the transaction-specific data necessary to ascertain the class does not mean that the information is unavailable or impossible to obtain; nor does it mean that Craft’s method for analyzing the data is unreliable. A significant portion of Craft’s initial report is dedicated to explaining how regulations and industry practice “all require a detailed electronic record” of each prescription drug purchase, and how that data is available from several institutional sources. (*Id.* at ¶¶ 18, 19, 27, 34). This opinion is based on Craft’s extensive experience working with pharmaceutical industry data, and is supported by her review of the sworn declarations of representatives of several of the nation’s largest PBMs, all of whom state that their PBM maintains transaction-specific records such that their TPP clients can be readily identified. (*Id.* at ¶ 43).

Defendants take issue with the fact that SBA made little effort during earlier portions of this litigation to obtain the data necessary to execute Craft’s methodology and identify the members of the proposed class. Defendants actually attempted to subpoena three of the nation’s largest PBMs to obtain transaction-specific data, but SBA moved for “an order quashing the subpoenas for documents and depositions the Defendants served on absent class members on the ground that discovery of absent class members is improper.” (ECF 171). SBA’s motion to quash was denied, but Defendants only succeeded in obtaining the transaction-specific data from one of the three PBMs upon whom they served subpoenas. The other two PBMs filed objections to the

subpoenas, which were attached to the *Daubert* motion. Defendants cite this as evidence that the data Craft relies upon is difficult to obtain or is otherwise unavailable. (*See* ECF 463, pg. 8).

This Court does not see how the failure to enforce subpoenas renders either the data unavailable or methodology unreliable. Defendants offer no evidence suggesting that Craft is wrong about the existence of the data; and were a class to be certified, it is highly unlikely that a judge of this court would refuse to enforce a subpoena for its production – provided, of course, that it was served on the correct entity (the two objecting entities argued that they were holding companies, not the PBMs that possessed the data. (*See* ECF 464-3, 464-4)). Craft’s methodology explains how to analyze pharmaceutical-industry data to obtain the information needed to identify class members; her explanations are reliably rooted in statements from PBMs themselves, who aver that they retain the information necessary to ascertain who their TPP clients. Moreover, Craft notes that the transaction-specific data could be obtained from a variety of sources aside from the PBMs, although it would be simplest to obtain the data from the PBMs directly.

b. The Fact That Craft Has Not Yet Ascertained Who Is In the Class Does Not Render Her Methodology for Doing So Unreliable

Defendants also take issue with the fact that Craft has yet to use her methodology to ascertain exactly who is in the class. That does not render her methodology unreliable. It just means that, prior to knowing whether a class would be certified, class counsel has not expended the time and effort (and money) needed to identify all of its members.

Moreover, Craft has described how her methodology would work in practice by extracting the information needed ascertain the end payor from a tranche of PBM data (obtained from OptumRx). (Craft Decl. at ¶¶ 44-58). Defendants contend that Craft’s analysis of this data subset is not dispositive of its reliability. They claim that when Craft was presented with an excerpt of

the raw OptumRx data at her deposition, she had difficulty identifying which of the “Carrier” fields corresponded to an actual Third-Party Payor and which ones corresponded to merely the administrative agent of a payor (i.e., the TPAs hired to process claims). (*See* ECF 464-2, pg. 19). Only actual Third-Party Payors would qualify as class members, while administrative agents would not. Defendants argue that this shows that the “Carrier” identification fields are insufficiently informative to make Craft’s methodology reliable.

Craft’s rebuttal explains how this characterization of her analysis is inaccurate. She reiterates that it is not just the “Carrier” fields that are relevant to determining the TPP, but *all* of the fields provided in the transaction-specific data. (Craft Rebuttal at ¶ 39). In addition to the fields in the OptumRx data she identified the first time around, Craft also explained how the electronic transaction numbers – namely, the BIN and PCN – could also be used to determine the ultimate end payor, especially for plans that may be fully insured. She also explained that, while the BIN/PCN entries were not included in the original batch of OptumRx data with which she was provided, that does not mean that these entries do not exist, or that they cannot also be used to determine potential class members. (*Id.* at ¶ 40).

Importantly, none of Defendants’ arguments discusses Craft’s conclusion that the PBMs themselves would be aware of which of their TPP clients (and associated insurance plans) covered/paid for Namenda. Thus, even if an individual analyzing the raw data had some difficulty analyzing the raw PBM data, the PBM itself would be able to provide the necessary information.

In short, just because the class members have not yet been identified does not mean they cannot be identified.

Both SBA and Defendants cite the same case in support of their respective positions: *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678 (E.D. Pa. 2020) (“*Niaspan*”), which makes it worthy

of mention, here. Ms. Craft was proffered as a plaintiffs' expert on the issue of class ascertainability in that indirect-purchaser case as well. The district court in *Niaspan* ruled that the identification of class members through Craft's "proposed methodology would be prohibitively expensive and thus infeasible," and denied plaintiffs' motion for certification (without prejudice to amend). *Id.* at 707. But contrary to Defendants' characterization, the court did not exclude Ms. Craft's opinions. Instead, it admitted them and considered them in support of certification, ruling that the methodology was "adequate under the liberal admissibility standard or Rule 702." *Id.* at 696. The court simply concluded that her unflawed methodology was prohibitively expensive.

Notably, Craft's opinions in *Niaspan* were much more threadbare than the reports she has offered in this litigation. She submitted only a "four-and-a-half-page Declaration of very limited scope," (Craft Rebuttal at ¶ 19), and did not test her methodology on any data set, as she did with the OptumRx data in this litigation. *Id.* at 696. The Court views *Niaspan* as more supportive of SBA's position than it is of Defendants'.

This Court is aware of several cases in which Craft's opinion was considered in support of class certification over the objection of defendants. *See In re Loestrin24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 400 (D.R.I. 2019) (denying motion to exclude Craft's declaration regarding ascertainability of a proposed class); *see also In re Restasis (Cyclosporine Ophthalmic Emulsion) Antitrust Litig.*, 335 F.R.D. 1, 24-25 (E.D.N.Y. 2020) (considering Craft's declaration as evidence in support of class certification absent a *Daubert* challenge); *In re Zetia (Ezetimibe) Antitrust Litig.*, Case No. 2:18-md-2836, 2020 WL 5778756 at *8-*10, (E.D. Va. Aug. 14, 2020) (same).

In short, Craft's opinions are not mere *ipse dixit*. She backs up her claims of the existence of the data by citing to industry regulations and through her review of sworn declarations of PBM representatives, and she has also detailed how to actually go through the necessary fields of a raw

PBM data set to determine the TPP. The fact that she does not yet have all the data necessary to definitively determine who the class members are does not render her proposed methodology for ascertaining the class unreliable.

CONCLUSION

Defendants' motion to exclude is denied. The Clerk of Court is respectfully directed to close Dkt. No. 461.

Dated: December 18, 2020

A handwritten signature in black ink, appearing to read "Pollen M. Hill", written over a horizontal line.

Chief Judge

BY ECF TO ALL COUNSEL