

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF VIRGINIA  
Norfolk Division

CAREFIRST OF MARYLAND, *et al.*,

Plaintiffs,

v.

Case No. 2:23-cv-629

JOHNSON & JOHNSON, *et al.*,

Defendants.

**OPINION & ORDER**

Plaintiffs CareFirst of Maryland, Inc., Group Hospitalization and Medical Services, Inc., and CareFirst Bluechoice, Inc. (collectively “CareFirst”) move to (1) certify a class and appoint class representatives and class counsel and (2) approve class notice, notice plan, claims form, and appointment of notice administrator. ECF No. 343. Defendants Johnson & Johnson and Janssen Biotech, Inc. (collectively “J&J”) dispute that the class is ascertainable and that common issues predominate. J&J also moves to exclude the expert opinions and testimony of Laura Craft (ECF No. 503), Dr. Rena Conti (ECF No. 516), and Dr. Michael Malecki (ECF No. 498), which CareFirst relies on in support of class certification.

For the reasons stated herein, the motions to exclude are **DENIED**, and the motion for class certification is **GRANTED IN PART** and **DENIED IN PART**.

**I. BACKGROUND**

The Court has previously described the factual background of this case, so it will not do so here. ECF No. 119 at 2–7; ECF No. 592 at 1–2. CareFirst now moves to

certify two classes under Fed. R. Civ. P. 23(a), 23(b)(3), and 23(g): a “Damages Class” and an “Unjust Enrichment Class,” defined as:

All Third-Party Payers who indirectly purchased or paid for, as part of a prescription drug benefit, some or all of the purchase price for Stelara in the [Damages Class or Unjust Enrichment]<sup>1</sup> States or Territories for personal use by their members, enrollees or beneficiaries, from January 1, 2024 until December 31, 2025 (the “Class Period”).

The following entities are excluded from the Damages Class:

- a) J&J and its subsidiaries and affiliates;
- b) federal and state governmental entities; and
- c) Third-Party Payers whose only purchases were made pursuant to any Medicaid plan, whether Fee-for-Service or Managed Medicaid.

ECF No. 343 1–2; ECF No. 641 ¶¶ 323–33. CareFirst relies on the expert opinions of Laura Craft to support its ascertainability argument and the expert opinion of Dr.

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<sup>1</sup> The damages class states and territories are: Alabama, Alaska, Arizona, Arkansas, California, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Illinois, Indiana, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.

The unjust enrichment class states and territories are: Alabama, Alaska, Arizona, Arkansas, California, Colorado, Connecticut, District of Columbia, Florida, Georgia, Hawaii, Illinois, Iowa, Kansas, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Puerto Rico, Rhode Island, South Carolina, South Dakota, Tennessee, Utah, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.

Rena Conti and Dr. Michael Malecki to support its predominance argument. J&J moves to exclude the opinions of all three experts. ECF Nos. 498, 503, 516.

CareFirst also moves to appoint the following: (1) CareFirst as representative of the class, ECF No. 362 at 17–18; (2) Hannah W. Brennan, Abbye R. K. Ognibene, and Peter D. St. Phillip as Co-Lead Class Counsel and William H. Monroe, Jr. as Local Liaison Counsel, *id.* at 35; and (3) Eric J. Miller, Vice President of Case Management for A.B. Data, as Notice and Claims Administrator, *id.* at 36. Finally, CareFirst asks for approval of its proposed summary notice, long-form notice, claim form, and notice plan. *Id.*

## II. LEGAL STANDARDS

### A. Motions to Exclude Expert Opinions Under Fed. R. Evid. 702

Fed. R. Evid. 702 allows a “witness who is qualified as an expert by knowledge, skill, experience, training, or education” to “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’s opinion reflects a reliable application of the principles and methods to the facts of the case.

Fed. R. Evid. 702.

The proponent of the testimony “must establish its admissibility by a preponderance of proof.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir.

2001). In assessing the admissibility of expert testimony, the district court must assess whether the testimony is both relevant and reliable. *Daubert v. Merrell Dow Pharmas., Inc.*, 509 U.S. 579, 589 (1993).

Testimony is relevant if it has “a valid scientific connection to the pertinent inquiry as a precondition to admissibility.” *Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017) (quoting *Daubert*, 509 U.S. at 592).

The test of reliability is “a flexible one” and considers whether the testimony “is supported by adequate validation to render it trustworthy.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260–61 (4th Cir. 1999) (quoting *Daubert*, 509 U.S. at 590, 594–95). The court focuses on the “principles and methodology employed by the expert, not the conclusions reached.” *Id.* Several factors may guide a judge’s determination of reliability, including whether the theory (1) can be or has been tested; (2) has been peer reviewed or published; (3) has a high known or potential error rate; and (4) enjoys general acceptance within the relevant scientific community. *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001).

## **B. Class Certification**

Fed. R. Civ. P. 23(a) provides four prerequisites to certify a class:

- (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.

(numerosity, commonality, typicality, and adequacy, respectively) Fed. R. Civ. P. 23(a). In addition, the Fourth Circuit has instructed district courts that Fed. R. Civ. P. 23 contains an implicit requirement that the members of a proposed class be ascertainable—that is, “readily identifiable.” *EQT Prod. Co. v. Adair*, 764 F.3d 347, 358 (4th Cir. 2014). The party moving for class certification bears the burden of establishing each of these requirements. *Lienhart v. Dryvit Sys., Inc.*, 255 F.3d 138, 146 (4th Cir. 2001).

Once the Fed. R. Civ. P. 23(a) showings have been made, the moving party then “bears the burden of demonstrating that the proposed class fits into one of the specific forms of class adjudication provided by [Fed. R. Civ. P.] 23(b).” *Krakauer v. Dish Network, LLC*, 925 F.3d 643, 655 (4th Cir. 2019). A class may be maintained under Fed. R. Civ. P. 23(b)(3) if “questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods.” Fed. R. Civ. P. 23(b)(3) (predominance and superiority). The moving party must demonstrate all Fed. R. Civ. P. 23 requirements by a preponderance of the evidence. *Comcast Corp v. Behrend*, 569 U.S. 27, 33 (2013).

Class actions pursuant to Fed. R. Civ. P. 23(b)(3) also require notice to class members, who are afforded an opportunity to opt out of the class at the certification stage. Fed. R. Civ. P. 23(c)(2).

### **III. ANALYSIS**

CareFirst's proposed classes meet the Fed. R. Civ. P. 23 requirements by a preponderance of the evidence except as to its state law consumer protection and unjust enrichment claims (Counts III and IV). Therefore, the Court will certify the classes as to Counts I and II. The Court also approves the appointment of class representatives, class counsel, notice administrator, and the notice plan. The Court will not address the claim form at this time.

#### **A. Numerosity**

The proposed classes are numerous. "There is no mechanical test for determining" numerosity. *Kelley v. Norfolk & W. Ry. Co.*, 584 F.2d 34, 35 (1978). But where the number of potential class members is in the thousands, as is the case here, numerosity is clearly met because joinder would be impracticable. ECF No. 362 at 15; see *Brady v. Thurston Motor Lines*, 726 F.2d 136, 145 (4th Cir. 1984) (a class of 74 persons is likely "well within the range appropriate for class certification"); *Gunnells v. Healthplan Servs.*, 348 F.3d 417, 425 (4th Cir. 2003) (a class of 1,400 members "easily satisfied [Fed. R. Civ. P.] 23(a)(1)'s numerosity requirement"). CareFirst estimates there are thousands of third-party payers (TPPs) who meet the class definitions. ECF No. 362 at 15.

## **B. Commonality**

“Plaintiffs must establish that the common contention is one capable of classwide resolution such that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.” *Stafford v. Bojangles’ Restaurant, Inc.*, 123 F.4th 671, 679 (4th Cir. 2024) (citation omitted). However, where a class is sought to be certified under Fed. R. Civ. P. 23(b)(3), the commonality inquiry is “subsumed under, or superseded by, the more stringent [Fed. R. Civ. P.] 23(b)(3) requirement” of predominance. *EQT Prod.*, 764 F.3d at 365. Therefore, the Court will evaluate commonality as part of the predominance inquiry.

## **C. Typicality & Adequacy of Representation**

CareFirst establishes typicality and adequacy of representation as class representative. Typicality requires that class representatives “be part of the class and possess the same interest and suffer the same injury as the class members.” *Gen. Tel. Co. of Southwest v. Falcon*, 457 U.S. 147, 156 (1982); *see also Deiter v. Microsoft Corp.*, 436 F.3d 461, 466 (4th Cir. 2006) (“The representative party’s interest in prosecuting his own case must simultaneously tend to advance the interests of the absent class members.”). Typicality “tends to merge” with the adequacy of representation requirement, *Deiter*, 436 F.3d at 466, which looks for conflicts of interest between named parties and the class members, *AmChem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997). Where a conflict of interest is “fundamental”—that is where members do not all “share common objectives and the same factual and

legal positions,” adequacy is defeated. *Sharp Farms v. Speaks*, 917 F.3d 276, 296 (4th Cir. 2019) (quotation marks and citation omitted).

CareFirst seeks appointment as class representative and has shown both typicality and adequacy of representation. CareFirst is a TPP: It purchases Stelara at third-party pharmacies where its health plan members have prescriptions filled. ECF No. 184 ¶¶ 17–22. Therefore, its interests are aligned with those of absent class members because they each seek to prove that J&J acted unlawfully “in the same way” by delaying competition. ECF No. 362 at 18. CareFirst suffered the same injury as all other class members: “overcharges on purchases of Stelara.” *Id.* In other words, CareFirst’s claim does not differ from those of the absent class members, and there is no apparent conflict of interest.

#### **D. Ascertainability**

CareFirst establishes that its proposed classes are ascertainable. Under Fed. R. Civ. P. 23’s implicit ascertainability requirement, in the Fourth Circuit a class cannot be certified unless class members are “readily identifiable . . . in reference to objective criteria.” *EQT Prod. Co.*, 764 F.3d at 358. The goal is not to “identify every class member at the time of certification” but to “ensure that there will be some administratively feasible way for the court to determine whether a particular individual is a member at some point.” *Krakauer*, 925 F.3d at 648 (quotation marks and citations omitted); *see also EQT Prod. Co.*, 764 F.3d at 358. A class should not be certified if “extensive and individual fact-finding” or “mini-trials” would be required to identify class members. *EQT Prod. Co.*, 764 F.3d at 358.

The parties agree that the class definitions present sufficiently objective criteria: “(1) whether a TPP purchased Stelara, (2) whether a TPP made at least one of those purchases within the applicable states, and (3) whether a TPP purchased Stelara during the [c]lass [p]eriod.” ECF No. 362. However, the parties hotly contest whether the class members and class exclusions are readily identifiable in an administratively feasible way.<sup>2</sup> To support its ascertainability analysis, CareFirst relies heavily on the expert opinions of Laura Craft, which J&J moves to exclude. *See* ECF No. 503. Therefore, the Court will assess the admissibility of Craft’s opinions first.

*i. Laura Craft*

Craft’s expert opinions are admissible. She examines several categories of “electronic data common to the [pharmaceutical] industry”—transaction data from TPPs themselves, claims data from pharmacy benefit managers (PBMs) that process claims on behalf of TPPs,<sup>3</sup> and claims data compiled by Rawlings Analytics, LLC<sup>4</sup>—and concludes that “class members can reliably be identified” using a combination of this data. ECF No. 512 ¶ 14.

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<sup>2</sup> The Court held a hearing on November 4, 2025, primarily to address the question of ascertainability. *See generally* ECF No. 701.

<sup>3</sup> “Almost all claims adjudication is handled by a PBM[,] which acts as an intermediary for TPPs.” ECF No. 512 ¶ 19.

<sup>4</sup> Rawlings, a data analytics firm, will be discussed in more detail below. *Infra* Part III.D.ii.b.

Craft's opinions are: (1) the proposed Classes are objectively defined, ECF No. 512 ¶ 15; (2) “[p]harmaceutical industry operations and regulatory structure result in accurate, detailed, and standardized electronic records for each [c]lass transaction,” *id.* ¶¶ 16–17; (3) “[d]ata produced in this case confirm that [c]lass [m]embers will be able to produce authoritative claims records establishing their eligibility,” *id.* ¶¶ 18–19; (4) “[e]xcluded TPPs can be identified,” *id.* ¶ 20; (5) “[a] typical claims administration process would identify [c]lass [m]embers and assure only eligible entities participate in any [c]lass recovery,” *id.* ¶ 21; and (6) “[r]eliable data exist[] to establish the amount of any manufacturer rebates paid in connection with [c]lass [m]ember purchases,” *id.* ¶ 22.

J&J challenges both the reliability and the relevance of Craft's opinions.<sup>5</sup> However, J&J's relevance argument is merely its reliability argument repackaged: J&J argues that Craft's opinions would be unhelpful to the factfinder because she does not propose an administratively feasible methodology of identifying class members. ECF No. 504 at 31–32. This argument misconstrues the independent relevance inquiry. Craft's opinions are clearly relevant under *Daubert* because they each have a “valid scientific connection to the pertinent inquiry” of ascertainability. *Nease*, 848 F.3d at 229; *Daubert*, 509 U.S. at 592. In other words, each opinion is

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<sup>5</sup> J&J does not challenge Craft's qualifications, which are undoubtedly extensive. She is highly experienced in pharmaceutical data analysis and has a long history of providing expert testimony regarding pharmaceutical data management in complex litigation. ECF No. 512 ¶¶ 2–5; *id.* at 73–75.

aimed at assisting CareFirst to establish—and the Court to evaluate—ascertainability.

Craft’s opinions are also reliable.<sup>6</sup> She backs up her claims regarding the existence of standardized, accurate records by citing industry regulations and reviewing sworn declarations, and she proposes a methodology for identifying class members using raw data from PBMs, TPPs, and Rawlings.

J&J contends that Craft “did nothing to evaluate reliability, accuracy, or potential error rate of her proposed methodology for identifying class members”—*i.e.*, that she did not adequately validate her opinions. ECF No. 504 at 10 (punctuation omitted). CareFirst responds that Craft *did* assess the sample claims data for “completeness and standardization” but did not test the “accuracy” because “these records have to exist in electronic, accurate form for legal and operational reasons.” ECF No. 582 at 26.

Craft’s review of the sample TPP transactional, Rawlings, and PBM claims data and sworn declarations regarding the availability and accuracy of such data, along with her experience working with pharmaceutical data, are enough to

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<sup>6</sup> The parties extensively discuss other cases in which courts have evaluated Craft’s opinions in support of ascertainability. *See, e.g., In re Generic Pharms. Pricing Antitrust Litig.*, No. 2:16-md-27242, 2025 WL 754567 (E.D. Pa. Mar. 7, 2025); *Gov’t Emps. Health Ass’n v. Actelion Pharms. Ltd.*, No. 1:18-cv-3560, 2024 WL 4122123 (D. Md. Sept. 6, 2024); *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352 (D.R.I. 2019); *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-md-2836, 2020 WL 5778756 (E.D. Va. Aug. 14, 2020), *report and recommendation adopted*, No. 2:18-md-2836, 2021 WL 3704727 (E.D. Va. Aug. 20, 2021); *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389, 2024 WL 2865074 (D.N.J. June 6, 2024); *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678 (E.D. Pa. 2020). But the Court must make an independent determination here.

adequately validate her conclusions. In assessing the accuracy, standardization, and completeness of the data she proposes for identifying class members, Craft begins by detailing the “[l]ayers of compliance and reporting requirements” of the U.S. pharmaceutical industry, which result in “highly standardized and readily available” records. ECF No. 512 ¶ 17; *see also id.* ¶ 32 (“[T]he pharmaceutical industry is highly regulated for health and safety reasons.”). That information, coupled with her extensive professional experience, lead Craft to conclude that the data are accurate. For example, Craft’s conclusion that TPP claims data are “accurate, detailed, and standardized” is based both on legal reporting requirements and her “more than 20 years of experience in th[e] field” during which time she has not seen any evidence that TPP electronic record keeping “system[s] ever fail[] to correctly[] and automatically” create an accurate electronic record. ECF No. 512 ¶ 16.

Craft then examines the sample data itself for completeness—*i.e.*, whether the data include the fields necessary to identify class members—and concludes that class members can be readily identified for each category of data and that non-qualifying entities can be removed. ECF No. 512 ¶¶ 45–73. Her conclusions are supplemented by the declarations of several “persons and entities centrally involved in creating and using prescription purchase data” who attest to the existence and retrievability of various categories of data, such as historical PBM data that differentiate between TPP and intermediary clients. *Id.* ¶¶ 9, 55, 57. Craft therefore adequately addresses whether the data she proposes utilizing are both accurate and reliable.

J&J also argues that Craft does not offer a methodology for combining the various datasets and identifying class members. ECF No. 504 at 5–6, 9–11, 14–15. But Craft does propose a five-step methodology, laid out in her reply report: (1) TPPs review the class definitions; (2) TPPs determine whether they are excluded from the classes because they are either federal or state government entities, J&J or one of its subsidiaries or affiliates, or Medicaid plans; (3) potential class members access their claims data; (4) potential class members filter their data for Stelara purchases in 2024 or 2025, in class states, for which they paid all or part of the drug cost; and (5) the entity submitting the claim attests to the former steps during the claims administration process. ECF No. 512-1 ¶ 9.

It is true that Craft does not propose a methodology for consolidating, merging, or standardizing the categories of data she discusses. ECF No. 504 at 11. But while CareFirst must make that showing to justify certifying its proposed classes, Craft need not do the same for her opinions to be admissible. *See In re Amitiza Antitrust Litig.*, No. 1:21-cv-11057, 2025 WL 2690871, at \*6 (D. Mass. Sept. 19, 2025) (expert “need only provide good grounds” for their opinions and is “not required to put forth a methodology for ascertainability, which is [the plaintiff’s] burden to prove”) (quotation marks and citation omitted)); *In re Niaspan Antitrust Litig.*, 494 F. Supp. 3d 678, 695 n.3 (E.D. Pa. 2020) (“The analysis under *Daubert* involves a preliminary assessment of admissibility and has no effect on the Court’s substantive analysis of whether the admissible evidence satisfies the more rigorous [Fed. R. Civ. P.] 23 ascertainability requirement.”).

Craft instead relies on her experience and a declaration from A.B. Data Vice President Eric J. Miller, to conclude that class members can be identified in part because “[c]ourts have repeatedly approved claims administration processes employing this same information to identify class members, apply exclusions, and allocate recoveries.” ECF No. 512 ¶ 74; ECF No. 512-1 ¶ 11. J&J’s objections to Craft’s reliance on her experience and Miller’s declaration goes “to the weight of her testimony and not its admissibility.” *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d at 696 (finding that Craft’s proposed methodology for identifying class members from TPP, PBM, and pharmacy data was reliable and admissible despite no specific testimony on how the data would be merged and standardized).<sup>7</sup> Therefore, the motion to exclude her opinions (ECF No. 503) will be denied.

*ii. Ascertainability Analysis—Readily Identifiable*

CareFirst, relying on Craft’s opinions, demonstrates that 90–95% of class members are readily identifiable. The proposed classes are composed of TPPs “that committed to provide consumers with prescription drug benefits and have, as a result, paid all or part of the purchase price” of branded and biosimilar Stelara. ECF No. 360-6 ¶ 7. TPPs include “commercial insurers, employers that self-fund their employees’ health insurance, and Taft-Hartley union funds.” ECF No. 362 at 10–11.

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<sup>7</sup> Furthermore, J&J’s insistence that Craft’s proposal is *ipse dixit* testimony does not hold up. ECF No. 597 at 14–17. She thoroughly tests her data to determine whether TPPs are readily identifiable; and while it is true that her proposed methodology does not account for data compilation and standardization, here again J&J conflates Craft’s burden with CareFirst’s. And ultimately it is CareFirst who must demonstrate that an administratively feasible methodology exists.

CareFirst proposes using three categories of data—TPP records, Rawlings, and PBM records—to identify class members.

Given legal requirements and industry standards, all records include the TPP purchase date as well as a national drug code, which uniquely identifies the specific product and would be used here to filter for Stelara purchases. ECF No. 360-6 ¶¶ 24–25. As to the location of the purchase, Craft explains that because Stelara is only available through specialty pharmacies, doses are shipped to patients. *Id.* ¶¶ 26–27. Therefore, she proposes that the patient’s state of residence—*i.e.*, the “[m]ember [s]tate”—“should be treated as the state in which the transaction took place.” *Id.* ¶ 28. J&J does not contest this. In Craft’s data review, member state information was available in 98% of the Stelara purchases reported by TPPs and 99% of the Stelara purchases reported by PBMs. *Id.* She proposes using the prescriber state or the provider’s national provider identifier (NPI) as a proxy where the member state information is not available. *Id.* Once the relevant data are obtained, the process of identifying the (1) purchase date, (2) product, and (3) state is relatively straightforward, as data from the TPPs themselves and from PBMs confirm.

CareFirst also shows that the universe of class members can be readily identified, because the six largest PBMs capture 90–95% of all outpatient prescription drug transactions, and additional class member data can be obtained from Rawlings and/or by subpoenaing additional PBM data. ECF No. 360-6 ¶ 19; ECF No. 701 at

41:13–24.<sup>8</sup> For these reasons, the Court is satisfied that CareFirst can readily identify class members and exclusions using PBM, Rawlings, and TPP data.

*a. PBM Records*

PBMs handle the “vast majority” of the claims adjudication process, which is a prerequisite to filling a prescription for an insured patient. ECF No. 360-6 ¶ 39. The process uses a common data structure created by the National Council for Prescription Drug Programs (NCPDP) that is mandated to be used to process claims for all insured outpatient prescription drug purchases. *Id.* ¶¶ 16–17. Therefore, PBM data include mandatory fields that make class member identification possible. *Id.* ¶ 40 tbl.2. Declarations from PBMs Prime Therapeutics, Humana, and Caremark confirm that they are required to use the NCPDP standard formats when adjudicating claims.<sup>9</sup> *Id.* ¶ 41.

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<sup>8</sup> Much of CareFirst’s ascertainability argument in its briefing rests on the fact that TPP data themselves contain information about their own drug purchase records and so data collected during the claims process can identify class purchases. However, the focus of the ascertainability analysis asks whether class members can be identified prior to the claims process, and so the Court must be—and is—assured that other sources of data can cover the universe of class purchases such that class members can be readily identified. TPP data will be a helpful backstop and gap-filler to the extent needed but should not be the primary dataset relied on to identify class members at the outset.

<sup>9</sup> J&J challenges CareFirst’s reliance on the Humana and Prime Therapeutics declarations to buttress its ascertainability argument, because CareFirst “failed to obtain these declarations during fact discovery, prejudicing J&J’s ability to test [CareFirst’s] claims.” ECF No. 394 at 20 n.7. However, because “[d]ata [from Humana and Prime Therapeutics] was produced prior to the close of fact discovery,” the Court will not exclude these declarations. *See Abu-Eid v. Discover Prods., Inc.*, 589 F. Supp. 3d 555, 561 (E.D. Va. 2022) (denying motion to strike declaration because “the facts on which [the expert] relied in preparing for his declaration were disclosed to the plaintiff during discovery”); *Baltimore Aircoil Co., Inc. v. SPX Cooling Techs. Inc.*, No.

Six PBMs were responsible for processing 95% of U.S. outpatient prescriptions in 2024. ECF No. 360-6 ¶ 19. Craft reviewed data produced by five of those six PBMs as well as one smaller PBM and determined that the data “specify the exact product, quantity dispensed, transaction date, payment by the TPP[,] . . . payment by [b]eneficiary[,] . . . [and] [t]ransaction location.” *Id.* ¶ 53. While the headers for each set of data vary slightly, “their correct interpretation is intuitively obvious.” *Id.*

There are a couple of caveats to this relatively straightforward data analysis. First, when PBMs act on behalf of TPPs, they often negotiate rebates with drug manufacturers. ECF No. 360-6 ¶ 22. These rebates are recorded and connected to “individual drug purchases by identified [p]lans linked to a particular TPP,” and “the vast majority” of rebates are passed on to TPPs. *Id.* For example, Caremark and OptumRx each declare that their rebate pass-through rate is 98%. *Id.* ¶ 84. Craft reviewed aggregated rebate data for Stelara purchases from four PBMs to confirm that the rebate pass-through rate was 100% or close to it.<sup>10</sup> *Id.* ¶ 86.

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1:13-cv-2053, 2016 WL 4426681 (D. Md. Aug. 22, 2016), *aff'd*, 721 F. App'x 983 (Fed. Cir. 2018) (denying motion to strike declarations because party had notice of the underlying opinions) (unpublished).

<sup>10</sup> As explained in the predominance section, differentiating rebate harm—*i.e.*, determining whether some TPPs suffered rebate harm or not—is a damages issue and not an injury issue, because all TPPs that suffered overcharge and rebate harm can be aggregated for injury purposes. An individualized inquiry would be necessary when it comes to damages, but that would not defeat class certification because that is what the claims process would address.

Second, some TPPs contract with an administrative services only (ASO)<sup>11</sup> provider or a third-party administrator (TPA),<sup>12</sup> who then contracts with the PBM for claims adjudication on the TPP's behalf. ECF No. 360-6 ¶ 56. Craft states that in those situations, the PBM data includes both the ASO/TPA name and the underlying TPP's name, as confirmed by declarations from Humana and Prime Therapeutics. *Id.* ¶ 57; ECF No. 349-35 ¶ 6; ECF No. 349-36 ¶ 3.

J&J contends that the PBM data cannot be used to distinguish between TPPs and intermediaries and points out specific deficiencies in each set of data from OptumRx, MedImpact, Caremark, Prime Therapeutics, and Humana. ECF No. 394-2 ¶¶ 39–40; ECF No. 394-3 at 4. But CareFirst explains that the necessary data to determine whether an entity is a TPP or an ASO is always kept in a PBM's records for “regulatory reasons” and to “ensure that payments are made properly,” even if a PBM does not “systematically track” that information in its claims data. ECF No. 701 at 40:17–3; 44:8–25. Therefore, the data are always obtainable.

The Court is satisfied that the necessary data exist and can be subpoenaed.

*b. Rawlings*

CareFirst additionally proposes that counsel can identify class members using Rawlings, which has “access to claims data on over 250 million Americans” including

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<sup>11</sup> ASOs “provide administrative services to employers and labor organizations that prefer to self-fund benefits for their employees or members rather than purchasing a policy of insurance for them.” ECF No. 512 ¶ 10.

<sup>12</sup> Non-insurers providing ASO services are referred to as TPAs. ECF No. 512 ¶ 18 n.27.

“claims data for purchases of Stelara and its biosimilar analogs.” ECF No. 349-15 ¶¶ 7, 16. Mark Fischer, president of Rawlings from 2018 to 2024, estimated that Rawlings covers over 80% of total U.S. Stelara purchases.<sup>13</sup> ECF No. 419-1 ¶ 21 (quoting ECF No. 414-4 at 182:18–23); *see also* ECF No. 701 at 10:17–20.

Rawlings is the “largest and most established healthcare claims recovery company” and has “significant expertise working with health care data,” including related to “asserting claims in litigation.” ECF No. 349-15 ¶¶ 3, 5. Rawlings has been retained for claims data compilation in multiple TPP cases. *Id.* ¶¶ 7, 18, 19; *see also id.* ¶ 25 (listing 49 litigations where Rawlings “submitted claims for recovery in TPP class settlement distributions and/or represented insurance clients and their self-funded customers and managed allocation among all the participating TPPs”).

While J&J argues that Rawlings “appears to have modified or manipulated its clients’ data” and that CareFirst does not provide information about how data are standardized, ECF No. 394 at 17 (emphasis removed), it is apparent from Fischer’s testimony that Rawlings’s data processing does not change any data but rather catalogs it into uniform columns. ECF No. 414-4 at 5:9–13 (Fischer testifying “we don’t change or manipulate the client data[] other than to map [them] to a common format that we can mine”). Rawlings can identify: (1) the PBM involved in the transaction (if any), (2) the name of the insurer, (3) the type of plan (*e.g.*, commercial,

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<sup>13</sup> J&J argues that the Rawlings’s data are incomplete and it is unclear what percentage of TPP class members they cover. ECF No. 394 at 18. However, CareFirst does not propose that it rely *only* on Rawlings data but that Rawlings provides an additional dataset it can use to identify class members.

Medicare Part D), (4) the plan name, (5) whether that plan is self-funded or fully insured, (6) name and/or identifier of the self-funded plan sponsor or employer group, (7) member state, (8) pharmacy state and whether it is a mail-order pharmacy, (9) whether the TPP is a federal or state government entity, and (10) whether the client was operating in an ASO capacity and, if so, on which TPP's behalf. ECF No. 349-15 ¶¶ 27–28. Rawlings can produce these data “[w]ith authorization from its clients.”<sup>14</sup> ECF No. 362 at 23.

J&J argues that the data are incomplete. As an example, Dr. Laura E. Happe assessed that the “Funding Type” field for 37% of BCBS NC’s claims for Stelara during the proposed class period was blank. ECF No. 394 at 17. So she asserts that “there is no way to identify whether the underlying plan was fully insured” or self-funded. *Id.* at 18. CareFirst responds that the funding field “need not be populated to determine the ultimate purchaser” because the “group number” field was populated 100% of the time and serves as a reliable surrogate. ECF No. 418 at 17. Thus, the Court finds no reason to doubt Fischer’s testimony that Rawlings can identify whether a plan is self-funded or fully insured. To the extent Rawlings does not present complete data, the Court is adequately assured that PBM data (described above) would cover any gaps. *Supra* Part III.ii.a.

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<sup>14</sup> J&J questions how CareFirst will know which of Rawlings’s clients would need to provide authorization. ECF No. 394 at 17. Even though CareFirst does not provide an answer, it is obvious that once Rawlings identifies the relevant dataset, it will have a list of TPPs from which it needs to obtain authorization.

Therefore, Rawlings appears to provide an accurate compilation of data that could be used to identify at least some of the class members.

c. *TPP Records*

Many TPPs maintain their own drug purchase records that can be obtained and “easily filtered.” ECF No. 362 at 20. For any drug purchase, the patient and the TPP split the purchase price, which “necessitates an electronic record[-]keeping system” so that a TPP can be correctly billed for its share of the cost. 360-6 ¶ 16. Craft avers that in her “more than 20 years of experience in the field,” she has never seen the electronic system “fail[] to correctly[] and automatically[] link a drug purchase to its correct TPP.” *Id.* Furthermore, the NCPDP ensures a mandatory common data structure. *Id.* ¶ 17.

Some TPPs, such as employee groups or unions, use an agent to facilitate pharmaceutical transactions. ECF No. 362 at 20–21. The agents are either PBMs or insurers functioning as ASOs, and TPPs can obtain records of their purchases from those agents. *Id.* at 21.

Craft analyzed data produced by CareFirst and “standardized” by Rawlings and determined that “the exact product purchased, the quantity dispensed, the date of the transaction, and the amount paid by the TPP for the drug” was available for each transaction. ECF 360-6 ¶¶ 47–48. She determined that the data specified where CareFirst was acting as an ASO, so those purchases (*i.e.*, purchases by self-funded plans) could be filtered. *Id.* ¶ 49; *see also* ECF No. 418 at 15. Craft also analyzed data

compiled by Rawlings for TPPs Humana, BCBS NC, and MMOH, which all similarly included the relevant data fields. ECF No. 360-6 ¶¶ 50–51.

J&J contends that CareFirst fails to show that TPPs “even *have* the information necessary to self-identify whether they are class members,” as Craft does not identify who the TPPs are or explain whether TPPs such as “small businesses who self-insure”<sup>15</sup> would have such data. ECF No. 394 at 16. CareFirst represents that self-funded entities generally contract with TPPs like CareFirst as ASOs, so TPPs (or PBMs) will have all the necessary data on self-funded entities. ECF No. 701 at 8:14–15; 46:1–9.

Overall, CareFirst shows that TPP data can be used to readily identify class members.

*d. Class Exclusions*

CareFirst excludes three categories of entities from its class definitions: (1) J&J and its subsidiaries and affiliates, (2) federal and state governmental entities, and (3) TPPs whose only purchases were made pursuant to a Medicaid plan. ECF No. 343 at 2–3. J&J does not contest the feasibility of identifying its own subsidiaries and affiliates but argues that there is no way of reliably excluding the second two categories from the class. ECF No. 394 at 21–22. CareFirst demonstrates that all exclusions are readily identifiable.

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<sup>15</sup> Some TPPs self-fund insurance for their employees instead of purchasing health insurance through an insurance company.

1. *Federal and State Governmental Entities*

CareFirst, relying primarily on Craft's reports, states that government entities are "limited in number," "knowable from public sources," and "tracked by PBMs and insurers," who often use "specific business units to track [governmental entities] due to regulatory requirements." ECF No. 362 at 24–25; ECF No. 418 at 19. In response, J&J argues that CareFirst does not show *how* it will identify and exclude government entities or whether PBM, TPP, or Rawlings data include the information necessary to identify claims such entities paid. ECF No. 418 at 18–19.

CareFirst adequately shows that government entities can be identified. Craft provides three ways to achieve this: (1) requiring TPPs to verify via an affidavit on the claims form that they are not a government entity, (2) having PBMs and insurers identify or exclude transactions where the government entity is the payer, and (3) pulling a list of government payers from online resources.

Miller declares that in his experience, "potential [TPP] claimants always understand whether they are a [f]ederal or [s]tate [g]overnment [e]ntity and are able to attest thereto." ECF No. 349-16 ¶ 49. And Fischer testifies that in multiple TPP class actions, Rawlings was able to produce data that excluded governmental entities. ECF No. 349-15 ¶¶ 29–30. Fischer also testified that PBMs and insurers know which of their clients meet these criteria. ECF No. 414-4 at 12:21–15:11 ("it's actually easy, because [insurers have] a list of all their government customers," each with a unique "group number" and have a separate "government business division").

***Federal Entities***— Craft explains that there are a number of ways to identify federal entities. There are five “major programs” that are “usually readily identifiable in PBM claims data.” ECF No. 360-6 ¶ 62. Craft reviewed data from two PBMs to confirm that the data identify particular federal program types. ECF No. 419-1 ¶ 71. J&J contends that Craft’s proposed “manual string searches for government-like terms and abbreviations” to “weed out government payers one-by-one” is just an individualized inquiry and not administratively feasible. ECF No. 394 at 22. But Craft’s string searches appear to be the plan names and abbreviations, which is not an individualized inquiry and can be completed in a single step in a data filtering process. *See Id.*; ECF No. 360-6 ¶ 62.

Craft also contends that “PBMs know which of their clients are government entities” and that PBMs, drug manufacturers, and TPPs are subject to regulations that require them to “identify and distinguish government plans” as “a standard business practice.” ECF No. 360-6 ¶¶ 63–67. Finally, Craft explains that all pharmacies have a unique NPI number, which is required to be reported in PBM data and has been reported for 99.99% of potential class transactions for the PBM data produced in this case. ECF No. 419-1 ¶¶ 72–73.

At a minimum, it appears that (1) TPP claimants can identify whether they are governmental entities, (2) CareFirst can reliably use NPI numbers to identify federal governmental entities from PBM data, and (3) Rawlings is also able to exclude governmental entities.

***State Entities*** — Craft provides examples of data sources that identify self-funded health plans for state employees. ECF No. 419-1 ¶ 68. Based on research compiled by the National Conference of State Legislature, 19 states have some self-funding options, and two states are fully insured. *Id.* ¶ 68 fig.9. Craft contends that information about these health plans is “a matter of public disclosure” and can be obtained online or by contacting the state Office of Personnel Management. *Id.* ¶ 69.

Craft also explains that PBMs can identify state government plans from available data, as confirmed by declarations from Prime and her review of Humana and Caremark data, and that managers of state plans know they are government entities and would be required to attest to the inapplicability of the state government entity exclusion in a claims submission. ECF No. 419-1 ¶¶ 76, 79. Therefore, Craft shows that state entities are readily identifiable.

## 2. *Medicaid Plans*

Craft explains that Medicaid plans are “readily identifiable in PBM and other data using Line of Business and other fields as well as plan names.” ECF No. 360-6 ¶ 70. She asserts that states are required by law to “track and publicly report each of their Medicaid plans to [the Centers for Medicare & Medicaid Services (CMS)].” *Id.* Presumably Medicaid plan names are therefore identifiable from a review of the CMS website. Furthermore, Craft contends—relying on declarations from Humana and Caremark—that PBMs are able to identify Medicaid claims. *Id.* ¶ 72.

Craft has reviewed data from Caremark, OptumRx, Prime, MedImpact, Humana, and CarelonRx and confirmed that a “Line of Business” or equivalent field

exists. ECF No. 360-6 ¶ 57. She then proposes supplementing the “Line of Business” field with string searches on the “Carries, Account, Group, or any other naming fields” to ensure all Medicaid purchases are excluded. *Id.* ¶ 59. Though specific string searches may need to be created for various datasets, the Medicaid purchases are adequately identifiable. *See* ECF No. 701 at 56:2–57:4.

*iii. Ascertainability Analysis—Administrative Feasibility*

In addition to demonstrating that the data are readily identifiable, CareFirst also shows that its method for compiling the data and applying exclusions is administratively feasible.

J&J argues that “pointing to various datasets and claiming that someone, theoretically, *could* use them to identify class members is not a sound methodology.” ECF No. 394 at 24 (emphasis in original). In other words, J&J contends that Craft has “offered no roadmap for how those datasets will be merged and analyzed to identify class members in an administratively feasible way” and that her reliance on Miller’s declaration does not provide the necessary detail. *Id.*

CareFirst’s briefing does not outline a clearly defined methodology for compiling the various datasets, but CareFirst has subsequently adequately clarified its plan: A.B. Data will subpoena, compile, and analyze the relevant data from PBMs and Rawlings, supplementing with TPP data during the claims administration process. ECF No. 701 at 7:12–8:1, 10:24–11:6, 12:5–12, 53:16–54:2 (describing “separat[ing]” claims administration process from ascertainability methodology); *see also* ECF No. 349-16 ¶¶ 32–55 (describing the compilation and analyzing process).

Once the data are obtained, A.B. Data will use its proprietary program to review and assess the sufficiency and completeness of the data, run a duplicate matching search, and then conduct an investigation to evaluate whether a TPP is eligible based on transaction data. ECF No. 349-16 ¶¶ 40–44.

In its *Daubert* motion, J&J argues that CareFirst’s proposal requires TPPs to self-identify as members of the class, shifting the burden of identifying class members onto the absent members themselves, creating an opt-in class. ECF No. 504 at 15–16. CareFirst responds that they are not suggesting class members “self-identify” but rather that TPPs “prove their class membership through claims data.” ECF No. 582 at 24. Because CareFirst has represented that it will identify TPPs through PBM and Rawlings data, as explained above, the Court is assured that CareFirst has not created an opt-in class. *See* ECF No. 597 at 10 (J&J acknowledging that “Craft does not suggest that there are no records or other data that can be used to identify class members and that the Court must resort to TPP self-identification—in fact, she testified that the[re are] ‘multiple sources of data’ available in the industry”).

J&J also argues that CareFirst’s “self-identification proposal” also implicates due process concerns because J&J will not be able to test the reliability of the evidence submitted to prove class membership until after class certification. But due process does not require perfect class member identification at the class certification stage; rather, the inquiry is “whether the defendant will receive a fair opportunity to present its defenses when putative class members actually come forward.” *Williams v. Big Picture Loans, LLC*, 339 F.R.D. 46 (E.D. Va. 2021), *aff’d sub nom. Williams v.*

*Martorello*, 59 F.4th 68 (4th Cir. 2023). J&J would still be able to challenge class membership after trial or settlement when the claims process begins.

For these reasons, CareFirst demonstrates that it can readily identify class members in an administratively feasible way.

#### **E. Predominance**

CareFirst demonstrates predominance as to its federal and state-law antitrust claims (Counts I and II) but fails to do so as to its state-law consumer protection and unjust enrichment claims (Counts III and IV). Therefore, the Court will deny class certification as to Counts III and IV.

Predominance asks whether “questions of law or fact common to class members predominate over any questions affecting only individual members” and tests whether the proposed class is “sufficiently cohesive to warrant adjudication by representation.” Fed. R. Civ. P. 23(b)(3); *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625 (1997); *see also Gariety v. Grant Thornton, LLP*, 368 F.3d 356, 362 (4th Cir. 2004). “An individual question is one where members of a proposed class will need to present evidence that varies from member to member, while a common question is one where the same evidence will suffice for each member to make a *prima facie* showing or the issue is susceptible to generalized, class-wide proof.” *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (citation and quotation marks omitted). Where “central issues” predominate, the action may meet Fed. R. Civ. P. 23(b)(3)’s standard “even though other important matters will have to be tried separately, such as damages or some affirmative defenses peculiar to some individual class members.”

*Tyson Foods*, 577 U.S. at 453. “Predominance is a test readily met in certain cases alleging . . . violations of the antitrust laws.” *Amchem Prods.*, 521 U.S. at 625.

A plaintiff in an antitrust action must prove three elements: (1) violation of the antitrust laws, (2) antitrust injury, and (3) damages. *Windham v. Am. Brands, Inc.*, 565 F.2d 59, 65 (4th Cir. 1977). CareFirst contends that it will rely on common evidence to prove all the elements of its action: “(i) J&J had market power over the U.S. market for Ustekinumab; (ii) J&J fraudulently procured and baselessly asserted the ’307 patent; (iii) J&J wrongfully acquired the Momenta patents; (iv) those actions delayed the entry of more affordable biosimilar medications; (v) all, or virtually all, class members suffered antitrust impact and overcharges; and (vi) aggregate damages and unjust enrichment are payable to the classes.” ECF No. 362 at 9. CareFirst also asserts that its state-law antitrust, consumer protection, and unjust enrichment claims are premised on these same sets of facts and therefore predominance is satisfied as to the state-law actions. *Id.* at 27–28.

CareFirst relies on the expert report of Rena Conti to show that virtually all class members suffered the same injury as a result of J&J’s alleged anticompetitive conduct and that damages or unjust enrichment calculations are uniform. *See generally* ECF No. 523-1. CareFirst also relies on Michael Malecki to establish that virtually all payers would have achieved cost savings from a September/October 2023 launch of biosimilar versions of Stelara. *See generally* ECF No. 499-3. J&J challenges the admission of both experts’ opinions. *See* ECF No. 498; ECF No. 516. Therefore, the Court will first address—and deny—J&J’s motions to exclude.

*i. Rena Conti*

CareFirst uses Conti's report to demonstrate that common evidence will show that all class members were injured by J&J's anticompetitive conduct—*i.e.*, antitrust impact. ECF No. 362 at 30. Conti concludes that: (1) virtually all damages class members suffered overcharges and injury; (2) J&J received inequitable profits and virtually all unjust enrichment class members were injured; (3) damages can be calculated to a reasonable degree of economic certainty on a class-wide basis and the methodologies are flexible and may be applied to any modified but-for launch scenarios; and (4) inequitable profits J&J collected can be calculated to a reasonable degree of economic certainty on a class-wide basis and the methodologies are flexible and may be applied to any modified but-for biosimilar Ustekinumab launch scenarios. ECF No. 523-1 ¶¶ 7–11. Conti's opinions are admissible.

J&J does not challenge Conti's extensive qualifications. ECF No. 587 at 8–9; ECF No. 523-1 ¶¶ 15–21. Nor does J&J challenge the relevance of Conti's opinions—which is clear, since the Court must evaluate whether antitrust impact can be determined by common evidence in order to determine predominance. ECF No. 587 at 8. J&J *does* challenge the reliability of Conti's opinions on two grounds: (1) Conti ignores the real world in constructing her model, and (2) her aggregate damages methodology is unreliable because it is built on incomplete and deficient data.

*a. Real-World Evidence*

Conti concludes that all or virtually all class members were injured due to J&J's Stelara price increases in January 2024 and January 2025, which would not

have occurred absent the challenged conduct. ECF No. 587 at 26. Conti relies on common evidence to show class members paid artificially inflated prices. ECF 523-1 ¶¶ 90–152 (relying on data regarding biologics recently experiencing biosimilar entry, J&J forecasts, J&J documents, J&J expert testimony, rebate contracts, and forecasts from biosimilar manufacturers). She discusses the evidence of injury in two categories: Stelara-Stelara injury, where TPPs that actually paid for Stelara would have paid for Stelara in the but-for scenario; and Stelara-biosimilar injury, where TPPs that actually paid for Stelara would have paid for the biosimilar in the but-for scenario. *Id.* ¶ 153.

J&J argues that Conti ignores “the real world” in offering her opinions by not analyzing how many TPPs suffered injury in a but-for world by continuing to purchase brand-name Stelara versus purchasing biosimilars, not relying on how rebates varied by TPP in the real world, and assuming J&J would have stopped increasing Stelara’s list price in a but-for world where biosimilars entered the market in October 2023. But Conti sufficiently factored each of these considerations into her methodology. Therefore, it appears J&J’s actual issue is with the “conclusions reached” and not with Conti’s “principles and methodology.” *Westberry*, 178 F.3d at 260–61.

First, J&J contends that Conti’s methodology is unreliable because she does not analyze how many TPPs suffered each type of injury. ECF No. 523 at 7. But that argument conflates injury and damages. Conti proffers sufficiently reliable analysis for whether class-wide injury is determinable based on common evidence; she does

not need to conduct a granular analysis as to what type of injury each class member experienced. *See In re Amitiza Antitrust Litig.*, 2025 WL 2690871, at \*4 (admitting Conti's testimony where defendants conflated the injury and damages analyses).

Next, J&J similarly argues that Conti does not determine how many class members would have experienced unchanged rebates versus increased rebates. ECF No. 523 at 8–9, 16–17. J&J mischaracterizes Conti's conclusions regarding Stelara-Stelara injury as having two independent potential bases: higher net prices due to higher rebates or higher gross prices. *Id.* But Conti's conclusions are not either-or. Instead, she says that “[a]ll [c]lass [m]embers paid a gross retail price for Stelara higher than the one they would have paid in the but-for scenario.” ECF No. 523-1 ¶ 157. And because of that, all class members are injured “as long as they would have received the same or higher rebate percent for Stelara in the but-for world as they received in the actual world.” *Id.* J&J does not argue that any class members' rebates would have decreased. ECF No. 587 at 27; ECF No. 523-1 ¶ 158 (“There are no TPPs or virtually no TPPs for which Stelara rebate percentages would have been lower . . . .”).<sup>16</sup> Determining whether some TPPs suffered rebate harm or not is a damages issue, not an injury issue, because *all* TPPs allegedly suffered the harm of overcharge, and rebate harm can be aggregated for injury purposes. Therefore,

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<sup>16</sup> J&J's argument that Conti changed her opinion in her reply report selectively identifies language from her opening report to create an apparent conflict. But the reports are consistent: In both, Conti asserts that all class members were injured by higher gross retail prices and higher—or the same—rebates. ECF No. 523-1 ¶ 152; ECF No. 523-2 ¶ 36.

Conti's injury methodology is reliable without an inquiry into how each class member's rebates were changed.

Finally, J&J avers that Conti does not factor into her analysis the fact that J&J *did* increase its wholesale acquisition cost (WAC) prices upon biosimilar entry in January 2025, and that therefore her conclusion that J&J would not have increased Stelara's WAC upon biosimilar entry ignores the real world. ECF No. 523 at 17–18. In fact, Conti factors J&J's January 2025 price increase into her analysis. ECF No. 523-2 ¶¶ 20–21 (concluding that the increase would not have occurred absent the alleged delay in biosimilar competition from October 2023 to January 2025). While J&J may disagree with her conclusions, they are rooted in sound analysis of what J&J would have done absent a delay in biosimilar competition, based on J&J's forecasts and other biosimilar entries.

J&J also challenges Conti's conclusions based on other biosimilar entries, arguing that three of the eight drugs Conti looked at showed that WAC increased on biosimilar entry. ECF No. 523 at 10, 18. But Conti adequately explains that these price increases either occurred prior to biosimilar launches or were significantly delayed or decreased in response to biosimilar entry. ECF No. 587 at 25–26; ECF No. 523-2 ¶¶ 74, 94. Therefore, Conti did not ignore the real world but rather adequately factored J&J's forecasts and conduct and other biosimilar entries into her analysis.<sup>17</sup>

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<sup>17</sup> J&J also argues that Conti's treatment of J&J's WAC increase in January 2025 as being "tainted" is contrary to how she treats J&J's actual rebating practices and her reliance on what happened to biosimilar WAC prices in the real world. ECF No. 523 at 19. But this argument misconstrues Conti's analysis. Conti analyzes Stelara-biosimilar injury using the biosimilar WAC prices of other biosimilar launches, which

*b. Aggregate Damages*

J&J asserts that Conti's aggregate damages methodology is unreliable because it is premised on incomplete and deficient data, that averaging improperly masks price variation between individual TPPs, and that her but-for world approaches—the “Humira yardstick” and the “J&J forecast”—generate false positives.

At the outset, “Conti’s ‘yardstick’ methodology and her use of averages are widely accepted methods of proving antitrust injury and damages on a classwide basis.” *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294, 305 (D. Mass. 2021) (collecting cases); *see also In re Actos Antitrust Litig.*, 2024 WL 4251891, at \*24 (S.D.N.Y. Aug. 9, 2024) (relying on Conti’s average aggregate damages and yardstick methodology to certify a class). And this case is no different. Conti adequately explains why branded and biosimilar Humira prices provide a reliable analog for Stelara. ECF No. 523-1 ¶¶ 185–188. J&J’s only gripe with Conti’s methodology is that it generates false positives. ECF No. 523 at 14, 25–26. However, Conti adequately explains that the false-positive analysis is incorrectly premised on the assumption that J&J did not increase its WAC price in January 2025—an assumption Conti does not make. ECF No. 587 at 33; ECF No. 523-2 ¶¶ 108–109.

J&J also contends that the data Conti relies on—from a third-party data provider called IQVIA—is unreliable because (1) 60% of claims in her IQVIA dataset

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have nothing to do with Stelara and would not be affected by J&J’s January 2025 increase. ECF No. 587 at 24. Additionally, Conti’s analysis of J&J’s rebating practices after the *Amgen* settlement is only in response to critiques of her model by J&J’s expert witness. *Id.* Conti only bases her rebating analysis on pre-settlement forecasts and rebating behavior. *Id.*

fail to identify the payer and (2) 36% of the transactions do not reflect the proper price. ECF No. 523 at 11–12. CareFirst asserts that IQVIA data is the “gold standard” for prescription drug sales data in the US and that it has been used in many class actions. ECF No. 587 at 17, 27.

J&J maintains that IQVIA data does not include the data necessary to systematically exclude non-class transactions because 60% of the data cannot be linked to any individual TPP and are aggregated into undefined categories. ECF No. 523 at 11, 20. Therefore, the data she uses in her analysis could have come from government payers or a PBM or ASO transaction. *Id.* at 21. But Conti has demonstrated that the IQVIA data can be used to readily identify class purchases on a classwide basis—that is, by reliably excluding non-class member transactions. ECF No. 523-1 ¶ 198; ECF No. 523-2 ¶¶ 126–132 (describing how she identifies individual payer and plan names to exclude non-class member claims). For example, Conti explains that data labeled PBM or TPA represent transactions for which the TPP is not known but that the underlying claim is appropriately included in the damages calculation. ECF No. 523-2 ¶ 129; *see In re Actos*, 2024 WL 4251891, at \*25 (holding that IQVIA data which include transactions where PBMs were the payers were properly included in assessing TPP damages).

Additionally, Conti’s estimation of the percentage of transactions that are for government payers based on the data that is available is a reliable methodology. ECF No. 523 at 21–22; ECF No. 587 at 31; *see In re Ranbaxy*, 338 F.R.D. at 304 (“Even if the proposed DPP classes include a de minimis number of uninjured members, that

fact alone is not fatal to class certification.”). Conti is correct that data need not be “perfect” but must instead be the “best available measure.” ECF No. 523-2 ¶ 124; *see In re Amitiza*, 2025 WL 2690871, at \*20 (“Courts have not required absolute precision as to damages.”).

Thus, J&J’s argument that Conti improperly imputed gross price estimation to 36% of claims also does not render her opinions unreliable. IQVIA’s database of over 600,000 transactions reports only average wholesale price (AWP) for about 36% of the claims whereas Conti relies on gross retail price for her calculations. ECF No. 587 at 30; ECF No. 523 at 11. Because relying on AWP would increase the aggregate overcharge damage calculations, Conti imputed the average gross retail price from the 64% of claims that did include that figure to the remaining 36% of claims. ECF No. 523-2 ¶ 137. Conti tested the reliability of the methodology by statistical testing. ECF No. 587 at 30 (citing ECF No. 523-3 at 181:8–182:9). That is sufficient to demonstrate that this methodology is reliable.

Finally, J&J’s argument that Conti’s data are inconsistent with PBM and TPP data produced in this case is irrelevant. ECF No. 523 at 12, 23–24. Whether IQVIA data is consistent with other sources of data is not the proper inquiry—rather, the inquiry is whether Conti has shown that her methodology for assessing classwide damages is reliable. She has done so by relying on generally accepted methods of

modeling damages and testing her results. The motion to exclude her opinions (ECF No. 516) will be denied.

*ii. Michael Malecki*

CareFirst relies on Malecki's opinions to provide additional "common evidence of impact to TPPs." ECF No. 362 at 31. CareFirst asked Malecki to opine on "whether or not any given payer (e.g., health plan) would have achieved cost savings from a September/October 2023 launch of biosimilar versions of Stelara, either by selecting a biosimilar with a lower net price or by selecting Stelara . . . with a net price that had been reduced due to biosimilar competition." ECF No. 499-3 ¶ 1. Malecki, relying primarily on his professional expertise, concludes that "[a]ll or virtually all payers in 2022 knew biosimilar versions of Stelara were imminent," would have "availed themselves of the cost savings that a 2023 launch of biosimilars versions of Stelara would have brought," were in fact able to "take business actions to avail themselves" of those cost savings and would have in fact realized cost savings. *Id.* ¶ 13. Malecki coins this framework the knowledge-willingness-ability framework. *Id.* ¶ 14.

CareFirst contends that Malecki's opinions are "specialized knowledge" under Fed. R. Evid. 702. ECF No. 580 at 13. Where an expert bases his conclusions upon "experience and training" rather than "a methodology or technique," the opinion must still satisfy Fed. R. Evid. 702, but the Court is not bound to use the particular factors outlined in *Daubert* in making that assessment. *Talkington v. Atria Reclamelucifers Fabrieken BV*, 152 F.3d 254, 265 (4th Cir. 1998); *see also Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 150 (1999) ("[W]e can neither rule out, nor rule in, for all

cases and for all time the applicability of the factors mentioned in *Daubert*.”). So Malecki must put forward sufficient opinions based on adequate experience and qualifications. *Talkington*, 152 F.3d at 265. The Court must assess whether Malecki explains “how [his] experience leads to the conclusion reached, why [his] experience is a sufficient basis for the opinion, and how [his] experience is reliably applied to the facts.” *United States v. Wilson*, 484 F.3d 267, 274 (4th Cir. 2007). Malecki does that, so his opinions are admissible.

*a. Qualifications & Specialized Knowledge*

Malecki combines his experience in the biopharmaceutical industry with documentary evidence to support his analysis. Malecki holds a Ph.D. in biological chemistry and molecular pharmacology and has 17 years of experience in the biopharmaceutical market access and payer decision-making space. ECF No. 499-3 ¶¶ 2, 7. His expertise lies in evaluating “how medicines are assessed for formulary<sup>18</sup> inclusion and other coverage determinations.” *Id.* ¶ 2. He is president and chief executive officer of Apex Market Access Inc., a consultancy firm providing research, analysis, and strategic services to biopharmaceutical and medical device manufacturers, and he has held previous roles in biopharmaceutical spaces where his responsibilities included market access research. *Id.* ¶¶ 3–6.

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<sup>18</sup> “A formulary is the list of drugs covered by the patient’s insurance, and it is typically divided into various ‘tiers.’ Drugs on preferred tiers generally have lower co-pays, and drugs on less-preferred tiers generally have higher co-pays.” ECF No. 394 at 9. Formularies are generally designed by the health insurer or a PBM hired by the health insurer. *Id.*

J&J argues that Malecki does not have the relevant experience necessary to establish him as an expert in formulary management of biologic medicines primarily because he has never managed a formulary, never worked for a health insurer, TPP, or PBM, never been a member of a committee within a TPP or PBM that ultimately decided which drugs are included on formularies, and never negotiated placement of a biosimilar drug on a formulary. ECF No. 499 at 7. It is true that Malecki does not claim that he has experience with formularies. ECF No. 499-3 ¶¶ 4-7. However, he does discuss being responsible for “pricing and pricing research,” “direct payer negotiations,” “developing all aspects of Amgen’s U.S. and Global plans to achieve profitable access for the medicines [he] covered” and being “responsible for . . . biosimilars research, analysis, and product commercialization,” which all could potentially—and likely did—entail formulary negotiations or management. *Id.* ¶ 4-6. More importantly, these experiences show Malecki’s history of assessing the market dynamics and pricing of biosimilars, which would necessarily include knowledge of how formularies are created and how they respond to biosimilar market entry.

Similarly, J&J argues that Malecki’s opinions reflect his “view of common sense, not application of any specialized knowledge,” because he relies primarily on internet sources and the “common sense that a payer would like to save money.” ECF No. 499 at 17 (citing ECF No. 499-2 at 13:20-24). But whether a payer would likely know about the availability of biosimilars and whether they would choose to include a biosimilar on their formulary is not necessarily common sense to a layperson.

Malecki's report shows that while it is common sense that a business would want to save costs, here, virtually all payers in 2022 would have tried to—and actually did—save costs specifically by including biosimilar versions of Stelara on their formularies. Malecki relies on his knowledge of, for example, "biosimilar first" formulary design approaches, which demonstrate "payers' continued efforts and ongoing responsibility to know when biosimilars will enter the market." ECF No. 499-3 ¶ 22. That is not a "common sense" inference; it is based on Malecki's expertise.

*b. Relevance & Reliability*

J&J also contends that Malecki's opinions are not helpful because he "assumes a prerequisite to TPP injury"—that the launch of a biosimilar version of Stelara in 2023 would have led to a reduced net price. ECF No. 499 at 11–13. CareFirst does not dispute that Malecki makes this assumption. Instead, CareFirst offers Malecki's opinions to support classwide injury in conjunction with Conti's economic opinions regarding the impact of delayed biosimilar entry and other evidence. ECF No. 580 at 17–18. As CareFirst correctly states, "Malecki specifically need[] [not] be the *sole* source of that proof." *Id.* at 17.

CareFirst offers Malecki's opinions to "untangle any complexity and assist the [factfinder] in evaluating crucial aspects of market access and formulary design in the biologic/biosimilar marketplace." ECF No. 580 at 6. Malecki attempts to do just that by opining on whether it was realistic for virtually all payers to be aware of the launch of Stelara biosimilars and then to act on that knowledge.

Malecki sufficiently explains how and why he reached his conclusions—based in part on his expertise and in part on documentary evidence. He rests his determination on what was publicly known about Stelara biosimilar potential launches in 2022, ECF No. 499-3 ¶ 16, historical evidence of broad payer awareness and proactive responses to biosimilars, *id.* ¶¶ 17–21, and “biosimilar first” policy popularity, *id.* ¶ 22. He bases his willingness assessment on payers’ public statements about cost savings generally and from the biosimilar market, *id.* ¶¶ 24, 28, “private label” biosimilar launches, *id.* ¶ 25–26, and CMS’s focus on Stelara as a cost-saving effort, *id.* ¶ 27. And he shows ability by describing the process through which formularies are created. *Id.* ¶¶ 34, 39–43.

The Court finds that Malecki’s opinion is relevant to the question of whether a classwide assessment of antitrust impact predominates and that it is reliable because it is rooted in experience and documentary evidence.

*c. State of Mind Opinions*

Finally, J&J argues that Malecki’s opinions about “what tens of thousands of corporate entities knew and what they intended to do with that knowledge” is inadmissible state-of-mind evidence. ECF No. 499 at 18. However, expert opinions on what a “hypothetical average [r]easonable [f]irm” would do are common and accepted. *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-md-2836, 2022 WL 4362166, at \*6 (E.D. Va. Aug. 15, 2022); *see also In re HIV Antitrust Litig.*, 656 F.Supp.3d 963, 1006 (N.D. Cal. Feb. 17, 2023) (experts may “opine on what a rational, objective actor would have considered in light of [economic] information” and collecting cases saying the

same). Additionally, the exclusion of opinions as to state of mind is generally cabined to the criminal context. *See Fed. R. Evid. 704.*

In short, the Court concludes that Malecki's knowledge and experience satisfy the requirements of Fed. R. Evid. 702, and thus his opinions are admissible. J&J's motion to exclude those opinions (ECF No. 498) will also be denied.

***iii. Predominance Analysis—Violation of the Antitrust Laws***

CareFirst says it will use common evidence to prove that J&J unlawfully prolonged its monopoly and delayed biosimilar competition for Ustekinumab and that absent such anticompetitive conduct, biosimilar products would have entered the market in October 2023. ECF No. 362 at 28. Such common proof will include J&J's documents and communications, economic evidence, 12 expert reports on merits issues, and evidence produced by nonparty biosimilar manufacturers and other nonparties. *Id.* at 28–29. Therefore, “[i]f each class member pursued its claims individually, the class member would have to prove the same antitrust violations using the same documents, witnesses, and other evidence.” *In re Wellbutrin XL Antitrust Litig.*, No. 2:08-cv-2431, 2011 WL 3563385, at \*1 (E.D. Pa. Aug. 11, 2011). J&J does not contest that common questions of antitrust conduct predominate.

***iv. Predominance Analysis—Antitrust Injury***

CareFirst shows that common issues of antitrust injury predominate. CareFirst relies on (1) Conti's expert opinions to establish that virtually all class members suffered overcharges and injury as a result of J&J's alleged conduct, (2) Malecki's expert opinions to demonstrate that absent J&J's alleged conduct, health

plans would have purchased biosimilar Ustekinumab, and (3) J&J's admissions to support both assertions. While the standard for assessing predominance is higher than that of admissibility, Conti and Malecki's opinions reliably establish that issues of classwide injury predominate for the same reasons as explained above.<sup>19</sup>

J&J construes CareFirst's theory of injury as two separate sources of injury: (1) paying a higher gross price *or* (2) receiving lower rebates. ECF No. 394 at 27. But as CareFirst explains, Conti concludes that virtually all TPPs suffered injury from a prolonged period of higher gross retail prices and that the absence of higher rebates was "an *additional* kick in the shin." ECF No. 418 at 21. As the Court explained above, differentiating rebate harm is a damages issue that does not defeat class certification because the claims process would adequately address the individualized inquiry.

J&J also contests CareFirst's characterization of J&J's statements as "admissions" during its litigation with Amgen about the potential impact of the Wezlana launch. ECF No. 394 at 28. But whether such quotes are properly characterized as admissions is not the inquiry at this stage. CareFirst has adequately explained that it will rely on these statements as common proof of classwide injury. ECF No. 362 at 31–32.

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<sup>19</sup> J&J reasserts many of the same arguments it made in its *Daubert* motions. The Court will not address these arguments anew. Additionally, J&J improperly challenges two aspects of Conti's damages model in its argument that classwide issues of injury do not predominate. Those arguments will be addressed in the damages section.

Finally, J&J claims that Conti relied on averaging IQVIA data in assessing classwide injury. ECF No. 394 at 32. This is not true. In assessing classwide *injury*, Conti relies on data regarding biologics recently experiencing biosimilar entry, J&J forecasts, J&J documents, J&J expert testimony, rebate contracts, and forecasts from biosimilar manufacturers. ECF No. 523-1 ¶¶ 93–152. She relies on IQVIA data for her damages analysis only.

*v. Predominance Analysis—Overcharge Damages*

CareFirst also demonstrates that overcharge damages can be assessed on a classwide basis. As explained above, Conti models overcharge damages and unjust enrichment using: (1) a “yardstick” approach in which she uses an analogous drug, Humira, to model a but-for generic entry of biosimilar Ustekinumab, ECF No. 523-1 ¶¶ 185–93, and (2) a forecast approach using market share estimates from J&J’s December 2022 forecasts and estimates of biosimilar price from biosimilar Ustekinumab manufacturers’ forecasts, *id.* ¶¶ 194–96. She then describes in detail each step of her damages estimate calculation. *Id.* ¶¶ 201–219.

J&J argues that Conti’s Humira-based yardstick “ignores record evidence that AbbVie’s experience with Humira is a poor comparator for Stelara.” ECF No. 394 at 34. Setting aside the fact that J&J again improperly conflates Conti’s injury and damages analyses, Conti shows that her methodology is sufficiently reliable to support common questions of antitrust injury.

The “yardstick” methodology is a “commonly used model in antitrust cases” because given the “inherent difficulty of identifying a but-for world, antitrust

damages need not be measured with certainty.” *Gov’t Emps. Health Ass’n v. Actelion Pharm. Ltd.*, No. 1:18-cv-3560, 2024 WL 4122123, at \*16 (D. Md. Sept. 6, 2024) (collecting cases) (quotation marks and citation omitted); *see also In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 232 (E.D. Pa. 2012). Instead, an antitrust plaintiff “need only show that a reliable method is available to prove damages on a class-wide basis.” *Gov’t Emps. Health Ass’n*, 2024 WL 4122123, at \*16 (quotation marks and citation omitted). Conti does that with her yardstick model.<sup>20</sup>

Conti also demonstrates that her forecast approach is a reliable method of estimating classwide damages. ECF No. 523-1 ¶¶ 194–195. J&J questions why Conti does not use late 2023 forecasts from J&J. ECF No. 394 at 34. But Conti explains that she could not rely on forecasts after May 2023, when the settlement agreement with Amgen was in place, because “any expectations from after that point were tainted by the influence of the settlement.” ECF No. 523-2 ¶ 93. This is sufficient justification for Conti’s reliance on the December 2022 forecast.

*vi. Predominance Analysis—Unjust Enrichment Damages*

While neither party explicitly addresses Conti’s unjust enrichment model, Conti also adequately shows that classwide unjust enrichment can be calculated using a two-step method: First, by relying on IQVIA and J&J data to calculate actual profits (gross sales minus the cost of manufacturing, marketing, rebates, and other offsets). ECF No. 523-1 ¶ 221. Second, by calculating the profits J&J would have made

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<sup>20</sup> Additionally, while it is not dispositive of reliability, the Court notes that J&J executives themselves have stated that Humira is “probably the best thing to model” what Stelara sales would look like post-biosimilar entry. ECF No. 418 at 25.

on sales to class members (the difference between J&J's actual profits and their estimated profits absent delay in biosimilar Ustekinumab entry). *Id.* Conti's yardstick and forecast methodologies for estimating profits absent delay mimic her methodologies for estimating overcharge damages. *Id.* ¶¶ 221–28.

*vii. Predominance Analysis—Rebate Contract Variability*

As a potentially independent barrier to predominance, J&J asserts that class members cannot be identified without individualized inquiry because it has individually negotiated rebate contracts with many TPPs that sometimes include arbitration clauses, class action waivers, or both. ECF No. 394 at 35. Additionally, some TPPs may be third-party beneficiaries of PBM rebate contracts that include such clauses. *Id.*

That some putative class members may be subject to mandatory arbitration or class action waivers is not a bar to class certification. *Sheet Metal Workers Loc. No. 20 Welfare & Benefit Fund v. CVS Pharmacy, Inc.*, 540 F. Supp. 3d 182, 212–13 (D.R.I. 2021); *Herrera v. LCS Fin. Serv. Corp.*, 274 F.R.D. 666, 681 (N.D. Cal. 2011) (“The fact that some members of a putative class may have signed arbitration agreements or released claims against a defendant does not bar class certification.”). Courts have held that arbitration agreement issues do not have to be resolved at class certification but can instead be resolved through the creation of subclasses or elimination of some

class members at a later stage, if J&J moves to enforce. *Slamon v. Carrizo (Marcellus) LLC*, 2020 WL 2525961, at \*22 (M.D. Pa. May 18, 2020) (collecting cases).

J&J has not provided any information on the extent of potential arbitration or class action agreement issues such as the number of clauses or any varying language between clauses such that individual issues would predominate.<sup>21</sup> *Slamon*, 2020 WL 2525961, at \*22; *see also Monroe v. Stake Ctr. Locating, LLC*, 2025 WL 938103, at \*8 n.7 (E.D. Va. Mar. 27, 2025) (at class certification, it is “unclear” how many class members signed arbitration agreements or the extent to which the defendant will seek to uphold the agreements and so the existence of such agreements does not defeat class certification). While J&J provides one contract that applies to relevant purchases, that is not enough information to determine the extent of the alleged issue, and indeed that contract does not contain an arbitration clause. ECF No. 418 at 30; *see* ECF No. 394-8.

The possibility of rebate contracts presenting individual issues does not defeat predominance because larger common issues predominate and because the rebate

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<sup>21</sup> CareFirst also contends that J&J waived its arbitration and/or class waiver argument by failing to raise it prior to class certification. ECF No. 418 at 30. Because the arbitration clauses and/or class action waivers are not a barrier to class certification, the Court need not decide if J&J waived this argument. But in any event, CareFirst is wrong. While, generally, a party waives arbitration by seeking a merits decision before attempting to arbitrate, a party can move to enforce arbitration rights against class members at class certification. *In re Titanium Dioxide Antitrust Litig.*, 962 F. Supp. 2d 840, 853 (D. Md. 2013). The cases CareFirst cites for support are in the context of motions to compel arbitration, not motions for class certification. *See, e.g., Degidio v. Crazy Horse Saloon & Rest. Inc.*, 880 F.3d 135, 141 (4th Cir. 2018); *Fraser v. Merrill Lynch Pierce, Fenner & Smith Inc.*, 817 F.2d 250, 252 (4th Cir. 1987). J&J is not looking to compel arbitration here.

inquiry can be assessed at a later stage—*i.e.*, through the claims process after settlement or trial.

***viii. Predominance Analysis—State Law Variation***

CareFirst asserts that its state antitrust, consumer protection, and unjust enrichment claims are premised on the same set of facts and that the various state laws either mirror federal law or that any variance is sufficiently immaterial such that predominance is met. ECF No. 362 at 27–28. However, CareFirst does not carry its burden to demonstrate that state-law consumer protection and unjust enrichment law issues predominate, so the classes must not be certified as to Counts III and IV.

As the Court has previously determined, the states included in CareFirst’s class definitions interpret their antitrust laws in harmony with federal law. *See* ECF No. 119 at 42–43. Therefore, the Court is satisfied that state antitrust law issues predominate.

CareFirst contends that each relevant state consumer protection statute is modeled on Section 5 of the FTC Act, 15 U.S.C. § 45(a)(1).<sup>22</sup> This is an

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<sup>22</sup> Ala. Code §§ 8-19-10(e), *et seq.*; Alaska Stat. §§ 45.50.471, *et seq.*; Ariz. Rev. Stat. §§ 44-1521, *et seq.*; Ark. Code Ann. §§ 4-88-101, *et seq.*; Cal. Bus. & Prof. Code §§ 17200, *et seq.*; Cal. Civ. Code §§ 1750, *et seq.*; D.C. Code §§ 28-3901, *et seq.*; Fla. Stat. §§ 501.201, *et seq.*; Ga. Stat. §§ 10-1-390, *et seq.*; 815 Ill. Comp. Stat. Ann. §§ 505/1, *et seq.*; Ind. Code Ann. §§ 24-5-0.5-3, *et seq.*; 5 Me. Rev. Stat. §§ 207, *et seq.*; Mass. Gen. Laws ch. 93A, §§ 1, *et seq.*; Mich. Comp. Laws Ann. §§ 445.901, *et seq.*; Minn. Stat. §§ 325F.68, *et seq.*; Mo. Rev. Stat. §§ 407.010, *et seq.*; Mont. Code, §§ 30-14-101, *et seq.*; Neb. Rev. Stat. §§ 59-1601, *et seq.*; Nev. Rev. Stat. §§ 598.0903, *et seq.*; N.H. Rev. Stat. §§ 358-A:1, *et seq.*; N.M. Stat. Ann. §§ 57-12-1, *et seq.*; N. Y. Gen. Bus. Law §§ 349, *et seq.*; N.C. Gen. Stat. §§ 75-1.1, *et seq.*; Or. Rev. Stat. §§ 646.605, *et seq.*; R.I. Gen. Laws §§ 6-13.1-1, *et seq.*; S.C. Code §§ 39-5-10, *et seq.*; S.D. Codified Laws §§ 37-24-1, *et seq.*; Tenn. Code Ann. §§ 47-18-101, *et seq.*; Tex. Bus. & Com. Code §§ 17.41, *et seq.*; Utah Code Ann. §§ 13-11-1, *et seq.*; Vt. Stat. Ann. tit. 9, §§ 2453, *et*

oversimplification of the reality. While several states' consumer protection statutes have incorporated Section 5 by reference<sup>23</sup> and other states' courts have looked to Section 5 for guidance,<sup>24</sup> some states do not appear to do either.<sup>25</sup>

Courts "commonly certify end-pay[e]r classes seeking to recover for delayed generic competition under the laws of multiple states." *Zetia*, 2020 WL 5778756, at \*26. However, CareFirst does not "submit[] a compilation of the relevant state antitrust and consumer protection statutes as well as interpretative case law," which would show the statutes' alleged similarities and account for any differences. *Id.* at \*26–27. Instead, it submits a chart containing only seven (of 33) states' consumer protection statutes and an argument for why each of those statutes is interpreted in harmony with federal law. ECF No. 349-5 at 29–32; ECF No. 701 at 60:17–61:4, 61:17–21 (representing that the chart "outlines the similarities and distinctions

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*seq.*; Va. Code Ann. §§ 59.1-196, *et seq.*; West Va. Code §§ 46A-6-101, *et seq.*; Wyo. Stat. §§ 40-12-100, *et seq.*

<sup>23</sup> Alabama, Alaska, Arizona, Florida, Georgia, Illinois, Maine, Massachusetts, Montana, New Hampshire, New Mexico, Nebraska, New York, North Carolina, Oregon, Rhode Island, South Carolina, Tennessee, Texas, Utah, Vermont, West Virginia.

<sup>24</sup> See *Nationwide Biweekly Admin., Inc. v. Superior Ct.*, 462 P.3d 461, 471 (Cal. 2020) (Section 5 is "persuasive but not controlling or determinative") (quotation marks and citation omitted); *State v. Minnesota Sch. of Bus., Inc.*, 935 N.W.2d 124, 136 (Minn. 2019) (FTCA is "instructive" where the suit was brought by the Minnesota Attorney General); *Schuchmann v. Air Servs. Heating & Air Conditioning, Inc.*, 199 S.W.3d 228, 234 (Mo. Ct. App. 2006) (looking to FTC Act's definitions for guidance); *Gross-Haentjens v. Leckenby*, 38 Or. App. 313, 316 (1979) (at least a prior version of Oregon's consumer protection statute was modeled on the FTC Act).

<sup>25</sup> Arkansas, D.C., Indiana, Michigan, Nevada, South Dakota, Virginia, Wyoming.

between the various consumer protection statutes and the harmony or lack thereof with federal law"). This is not enough to establish predominance. *Compare Gariety v. Grant Thornton, LLP*, 368 F.3d 356, 371 (4th Cir. 2004) ("The plaintiffs have the burden of showing that common questions of law predominate, and they cannot meet this burden when the various laws have not been identified and compared.") *with In re Ranbaxy*, 338 F.R.D. at 306 ("variety of state laws . . . does not overwhelm predominance" because the plaintiffs "provided charts compiling the state laws" and have "identified the substantial similarities").

CareFirst also does not catalog the various states' unjust enrichment laws, contending they are "premised on the same conduct and rely upon the same evidence" and that the variations among the state law causes of action are "immaterial." ECF No. 362 at 28. While this may be true, CareFirst must provide *some* analysis and effort to establish predominance beyond its say so.

Therefore, CareFirst only demonstrates predominance<sup>26</sup> as to the federal and state antitrust laws (Counts I and II).

#### **F. Notice**

Classes certified under Fed. R. Civ. P. 23(b)(3) require "the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort." Fed. R. Civ. P. 23(c)(2)(B). Notice must "clearly and concisely state in plain, easily understood language: (i) the nature of the

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<sup>26</sup> CareFirst also demonstrates commonality as to the federal and state antitrust laws. *Supra* Part III.B.

action; (ii) the definition of the class certified; (iii) the class claims, issues, or defenses; (iv) that a class member may enter an appearance through an attorney if the member so desires; (v) that the court will exclude from the class any member who requests exclusion; (vi) the time and manner for requesting exclusion; and (vii) the binding effect of a class judgment on members under [Fed. R. Civ. P.] 23(c)(3)." *Id.* Notice ensures absent class members have the opportunity to opt out, protecting their due process rights. *Bell v. Brocket*, 922 F.3d 502, 511 n.3 (4th Cir. 2019).

The Court approves the appointment of A.B. Data Ltd. as the notice and claims administrator in this case and approves A.B. Data's proposed notice plan and notice forms. ECF No. 362 at 36. However, the Court will defer approval of the claims form given the early stage of the case and given CareFirst's representation that the claims form approval is not critical at this juncture. ECF No. 701 at 73:8–11.

*i. Appointment of Notice and Claims Administrator*

The Court approves A.B. Data's appointment as notice and claims administrator. A.B. Data has developed and implemented notification and claims administration programs in "thousands of class actions" over a span of more than two decades, including in generic drug antitrust class actions concerning end payers. ECF No. 349-16 ¶¶ 3–5; *see also* ECF No. 349-17 at 11–13. Additionally, many courts, including in this district, have recognized A.B. Data's experience administrating such complex class actions. *See, e.g., In re NeuStar, Inc. Sec. Litig.*, No. 1:14-cv-885, 2015 WL 5674798, at \*13 (E.D. Va. Sept. 23, 2015); *In Re Zetia*, 2022 WL 3337794, at \*4;

*In re NII Holdings, Inc.*, No. 1:14-cv-227, 2016 WL 7045624, at \*2 (E.D. Va. May 16, 2016).

*ii. Notice Plan and Forms*

A.B. Data's notice plan is sufficient under Fed. R. Civ. P. 23 and consists of (1) direct mail to potential TPP class members using A.B. Data's proprietary database, (2) a digital advertising campaign, (3) a news release disseminated over PR Newswire, and (4) a toll-free telephone number and class notice website to address potential inquiries. ECF No. 349-16 ¶ 8.

In seeking approval of a notice plan, parties “should be able to indicate how great a percentage of the overall class will be reached by individual notice” as well as for the notice plan in its entirety. Federal Judicial Center, *Judges Class Action Notice and Claims Process Checklist and Plain Language Guide*, at 3 (2010), <https://www.fjc.gov/sites/default/files/2012/NotCheck.pdf> (last visited December 5, 2025) (“The lynchpin in an objective determination of the adequacy of a proposed notice effort is whether all the notice efforts together will reach a high percentage of the class. It is reasonable to reach between 70–95% [of class members].”).

Here, Miller, A.B. Data's senior vice president of case management, estimates that the notice plan will “have a ‘reach’ that exceeds 95% of the relevant Stelara purchases at issue” and “an extremely high percentage of potential class members,” meaning “close to the universe of potential class members.” ECF No. 702-1 ¶ 6. He does not estimate what percentage of members will be reached by individual notice. While the percentage of relevant *purchases* reached is a different inquiry than the

percentage of relevant *class members* reached, the Court is satisfied, given Miller’s representations, that the notice plan will reach at least 70% of class members.

To identify individual potential class members, A.B. Data proposes to use its “proprietary database of approximately 42,000 entities,” including TPPs and entities that represent TPPs, which it compiled using data from U.S. Department of Labor Form 5500 filings, the Pharmacy Benefits Management Institute, and prior pharmaceutical litigations that it has administered. ECF No. 349-16 ¶¶ 9–10. The database includes the names and addresses for each entity and sometimes the email address. *Id.* Once it identifies the class members, A.B. Data will send a summary notice via postcard by first-class mail, ensuring all addresses are standardized and updated; A.B. Data will also send notice by email, where email addresses are available. *Id.* ¶¶ 14–15, 17. Miller also explains that in his experience, “providing notice to the entities on the proprietary list results in notice also being disseminated to thousands of additional TPPs not listed in the database because notice is often forwarded by PBMs, TPS, and other organizations.” *Id.* ¶ 13.

Courts have approved of the use of A.B. Data’s database for individual notice and it “appears to be an industry appropriate method for facilitating notice to end pay[e]rs in similarly defined classes.” *In re Zetia*, 2022 WL 3337794, at \*5 (collecting cases); ECF No. 349-16 ¶ 11. Additionally, many pharmaceutical antitrust class actions have approved notice plans that primarily notify TPPs by mail. *See In re Restasis*, 527 F. Supp. 3d at 273–74 (collecting cases). Because the summary notice appears to contain all information required under Fed. R. Civ. P. 23(c)(2)(B) in

concise, easy-to-understand language, A.B. Data's individual notice plan does not present any issues of reliability or accuracy and appears to be the best practicable method of serving individual notice. ECF No. 349-18 at 3–4.<sup>27</sup>

A.B. Data will also distribute a news release via PR Newswire's US1 and on X, and will run a banner ad for 30 days on "selected industry-related websites that A.B. Data regularly utilizes to successfully notify" class members, which will include an embedded link to the settlement website. ECF No. 349-16 ¶¶ 18–21. The Court has reviewed the proposed banner language and is adequately assured that it will properly alert potential class members that the notice is applicable to them such that they will click on the embedded website link for more information. ECF No. 700-1; *see, e.g.*, *In Re Zetia*, 2022 WL 3337794, at \*6 (approving banner advertisement with substantially similar language).

Finally, A.B. Data will "update and maintain the case-specific website and toll-free number with an automated interactive voice response [] system." ECF No. 349-16 ¶ 22. The website will include the long-form notice, Complaint, settlement agreement (if the parties settle), claim form, answers to frequently asked questions, opt-out instructions, and claim submission instructions. *Id.* ¶ 23.

The Court is satisfied that the proposed notice methods and content are adequate. *See In re NeuStar*, 2015 WL 5674798, at \*12 (approving similar notice plan).

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<sup>27</sup> The long-form notice also includes this information in clear, easily understood language. ECF No. 349-19. While not necessarily concise, it is a prudent supplement to the summary notice.

## II. CONCLUSION

The plaintiffs' motion for class certification, appointment of class representatives and class counsel, approval of class notice, notice plan, and claims form, and appointment of a notice administrator (ECF No. 343) is **GRANTED IN PART** and **DENIED IN PART**.

The proposed class is **CERTIFIED** as to Counts I and II. Class representatives, class counsel, and the class administrator are **APPOINTED** as requested. The proposed class notice and notice plan are **APPROVED**.

Class certification is **DENIED** as to Counts III and IV.

The Court **RESERVES RULING** on approval of the claim form.

The defendants' motions to exclude the expert opinions and testimony of Michael Malecki, Laura Craft, and Rena Conti (ECF Nos. 498, 503, 516) are **DENIED**.

**IT IS SO ORDERED.**



/s/

Jamar K. Walker  
United States District Judge

Norfolk, Virginia  
December 5, 2025