UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE AMITIZA ANTITRUST LITIGATION	)	Civil Action No. 21-11057-MJJ

MEMORANDUM OF DECISION

September 19, 2025

JOUN, D.J.

Plaintiffs FWK Holdings, LLC, Meijer, Inc., Meijer Distribution, Inc., and KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc., bring this antitrust class action against Defendants Takeda Pharmaceutical Company Ltd. and Takeda Pharmaceuticals USA, Inc. ("Takeda") for violations of Section 1 of the Sherman Act, 15 U.S.C. § 1. [Doc. No. 28]. Before me are two motions for class certification and related motions to exclude. First is the Direct Purchaser Plaintiffs' (hereafter, "Plaintiffs" or "DPPS") Motion to Certify Class. [Doc. No. 248]. DPPs ask the Court to: (1) appoint Meijer, Inc., Meijer Distribution, Inc. (collectively "Meijer") and KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("KPH") as Class Representatives; (2) appoint Hagens Berman Sobol Shapiro ("HBBS") as Class Counsel; and (3) certify a class comprised of the following:

> All persons and entities in the United States and its territories that directly purchased brand Amitiza and/or generic Amitiza in any form from Takeda or any generic Amitiza manufacturer other than Par, or their subsidiaries or affiliates, from the beginning of the period of delayed generic entry until January 2023.

[Doc. No. 248].

In their Reply, DPPs introduced an amended class definition, requesting that the court certify a class comprised of:

> All persons and entities in the United States and its territories that directly purchased brand Amitiza and/or generic Amitiza in any form from Takeda, DRL, Sun, Teva, Amneal, or Zydus, or their subsidiaries or affiliates, from the beginning of the period of delayed generic entry until January 2023.

[Doc. No. 319 at 9].

For the reasons set forth below, DPPs' Motion for Class Certification is GRANTED in part and DENIED in part. Defendants' Motion to Strike Plaintiffs' Amended Class Definition, [Doc. No. 365], is GRANTED. I adopt Plaintiffs' initial class definition proposed in their Motion, [Doc. No. 248]. As explained further below, I exclude from the class Meijer and the thirteen AG-only purchasers who purchased directly from DRL and Sun. Accordingly:

(1) KPH Healthcare Services, Inc., a/k/a Kinney Drugs, Inc. ("KPH") is appointed as Class Representative for the DPPs;

(2) Hagens Berman Sobol Shapiro ("HBBS") is appointed as Lead Class Counsel for the DPPs;

(3) The DPP class shall be comprised of: All persons and entities in the United States and its territories that directly purchased brand Amitiza and/or generic Amitiza in any form from Takeda or any generic Amitiza manufacturer other than Par, or their subsidiaries or affiliates, from the beginning of the period of delayed generic entry until January 2023; and

(4) Excluded from the class are the defendants and their officers, directors, management, employees, parents, subsidiaries, and affiliates, all governmental entities, and R&S Northeast.

As explained further below, Plaintiffs' Motion to Require Takeda to Withdraw Letters to Absent Class Members is GRANTED in part, to the extent that Takeda must withdraw those letters, but DENIED in part, to the extent that Plaintiffs request prohibiting Takeda from further communicating with those class members. Additionally, Defendants' Motion to Exclude the

opinions of Dr. Rena Conti, [Doc. No. 363], and Motion to Strike the declaration of Thomas M. Sobol, [Doc. No. 290], are DENIED.

Next is the End-Payor Plaintiffs' ("EPPs") Motion for Class Certification. [Doc. No. 395; 23-cv-12918 Doc. No. 117]. For the reasons explained below, the EPP's Motion is GRANTED and Defendants' Motion to Exclude Certain Opinions of Dr. Martin E. Kovach, [Doc. No. 545; 23-cv-12918 Doc. No. 152], is DENIED. Accordingly:

(1) Premera Blue Cross ("Premera") is appointed as Class Representative for the EPPs;

(2) Lowey Dannenberg, P.C. is appointed as Lead Class Counsel for the EPPs;

(3) The EPPs Damages Class shall be comprised of: All entities that indirectly purchased or paid for some or all of the purchase price of Amitiza and/or AB-rated generic versions of Amitiza in Arizona, California, Connecticut (7/10/2017 or later), District of Columbia, Florida, Hawaii, Iowa, Kansas, Maine, Maryland (10/1/2017 or later), Michigan, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, and Wisconsin, from any of the Defendants or any other generic manufacturer, or their subsidiaries or affiliates, from October 1, 2016, through and until the anticompetitive effects of Defendants' conduct cease (the "Class Period");

(4) The EPPs Unjust Enrichment Class shall be comprised of: All entities that indirectly purchased or paid for some or all of the purchase price of Amitiza and/or AB-rated generic versions of Amitiza in Alabama, Arizona, California (11/30/2021 or later), Colorado (6/7/2023 or later), Connecticut (7/10/2017 or later), District of Columbia, Hawaii, Iowa, Kansas, Maine, Maryland (10/1/2017 or later), Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, from any of the Defendants or any other generic manufacturer, or their subsidiaries or affiliates, from October 1, 2016, through and until the anticompetitive effects of Defendants' conduct cease (the "Class Period"); and

(5) The following persons and/or entities are excluded from both Classes: (a) natural person consumers; (b) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (c) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (d) all persons or entities who purchased Amitiza or its AB-rated generic for purposes of resale from any of the Defendants or any generic manufacturer; (e) fully insured health plans (i.e., health plans that purchased insurance covering 100% of their obligation to members); and (f) pharmacy benefit managers.

I. BACKGROUND[1]

Defendant Takeda Pharmaceutical Company Limited ("Takeda Japan") is a Japanese corporation that owns and controls Takeda Pharmaceuticals U.S.A., Inc., ("Takeda U.S.A.," together with Takeda Japan, "Takeda"). [Doc. No. 28 at ¶ 9]. Par Pharmaceutical, Inc. ("Par") is a New York corporation. [*Id.* at ¶ 11]. Sucampo Pharmaceuticals, Inc. ("Sucampo") was a Delaware corporation that co-developed and commercialized Amitiza with its partner Takeda and was a party to the agreements alleged to be anticompetitive here. [*Id.* at ¶ 12]. Plaintiffs Meijer, FWK and KPH were direct purchasers of Takeda's brand Amitiza, who allege that, due to Takeda and Sucampo's anticompetitive agreement with Par, Plaintiffs purchased brand and authorized generic Amitiza at supra-competitive prices and suffered antitrust injury as a result of the anticompetitive conduct and seek recovery for those overcharges. [*Id.* at ¶¶ 6-8].

Plaintiffs allege that in September 2014, Takeda and Sucampo reached an anticompetitive agreement (the "Agreement") under which Par would delay launching a generic version of Amitiza until January 1, 2021, at which point it could either sell its own generic product or a Sucampo-supplied product and the parties would agree to split the generic revenue 50/50. [*Id.* at ¶ 209; Doc. No. 61 at 5]. Takeda and Sucampo in turn agreed to "keep[] other generics out of the market for as long as they possibly could," and to structure the royalty for sales of the Par generic in such a way that, according to plaintiffs, would effectively "ensure[] that there would only be a single generic" available in the market via a declining royalty structure—upon the entry of one other generic after Par's launch, the 50/50 profit split would decline to a 15% royalty that Par would pay to Takeda and Sucampo, and upon the entry of additional generics, the royalty would decline to zero. [Doc. No. 28 at ¶¶ 209, 212, 214; Doc. No. 61 at 6].

[1] For a more detailed relevant background, *see* [Doc. No. 61].

Although Sucampo and Takeda retained the right to launch a competing AG product, Plaintiffs allege that the Agreement's declining royalty structure upon the entry of other generics made it so that Sucampo had no incentive to sell an AG through Takeda. [Doc. No. 61 at 6]. On January 4, 2021, Par began sales of a generic Amitiza, electing to sell a Sucampo-supplied AG product as opposed to launching its own generic. [Doc. No. 28 at ¶ 255]. Plaintiffs allege that in the absence of the anticompetitive agreement, there would have been at least two generics in the market as early as July 17, 2015, namely, Par's Abbreviated New Drug Application ("ANDA") product and Takeda's authorized generic, with other generics likely to follow. [*Id.* at ¶ 4].

II. PROCEDURAL HISTORY

On June 25, 2021, Plaintiffs FWK and Meijer filed an initial complaint against Defendants Takeda and Par. [Doc. No. 1]. On September 20, 2021, Plaintiffs filed an amended complaint. [Doc. No. 28]. On June 14, 2024, DPPs filed their Motion for Class Certification. [Doc. No. 248]. In their motion, DPPs asked that I certify a class comprising the following:

> All persons and entities in the United States and its territories that directly purchased brand Amitiza and/or generic Amitiza in any form from Takeda or any generic Amitiza manufacturer other than Par, or their subsidiaries or affiliates, from the beginning of the period of delayed generic entry until January 2023.

On August 23, 2024, Defendants filed their Opposition and motion to strike the Sobol Declaration. [Doc. Nos. 290, 292]. On August 28, 2024, Plaintiffs filed their Motion to require Takeda to withdraw letters to absent class members, [Doc. No. 295]. On September 23, 2024, Plaintiffs filed their Reply in further support of class certification. [Doc. No. 319]. In their Reply, DPPs introduced an amended class definition, requesting that the court certify a class comprised of:

> All persons and entities in the United States and its territories that directly purchased brand Amitiza and/or generic Amitiza in any form from Takeda, DRL,

> Sun, Teva, Amneal, or Zydus, or their subsidiaries or affiliates, from the beginning of the period of delayed generic entry until January 2023.

[Doc. No. 319 at 9]. On October 25, 2024, Defendants moved to strike this amended class definition and moved to strike and moved to exclude the opinions of Dr. Rena Conti. [Doc. Nos. 363, 365]. That same day, Defendants filed a sur-reply. [Doc. No. 361]. On November 1, 2024, DPPs filed a sur-sur-reply. [Doc. No. 380].

On November 12, 2024, the EPPs moved for class certification. [Doc. No. 395]. On January 29, 2025, Defendants filed their opposition. [Doc. No. 505]. On March 12, 2025, EPPs filed their reply. [Doc. No. 527]. On April 10, 2025, Defendants filed a sur-reply. [Doc. No. 548]. That same day, Defendants filed their motion to exclude the opinions of Dr. Martin Kovach. [Doc. No. 545].

III. MOTIONS TO EXCLUDE

A. Dr. Rena Conti

Defendants move to exclude the opinions of DPPs' expert Dr. Conti. [Doc. No. 363] Pursuant to Federal Rules of Civil Procedure 26(a)(2)(B) and 37(c)(1), Defendants request that "Dr. Conti's opinions on (i) whether every member of the putative class suffered an antitrust injury, (ii) whether the "brand-only" purchasers suffered any antitrust injury, and (iii) whether the 'generic only' purchasers suffered any antitrust injury be excluded from the Court's consideration of the DPP's motion for class certification." [Doc. No. 364-1 at 1-2]. Defendants argue that Dr. Conti refused to answer certain questions regarding the meaning, application, and basis of her opinions during her deposition and therefore unfairly denies Defendants the means to challenge these opinions.

I find that Dr. Conti has provided ample bases for her opinions through her expert reports and related materials. Defendants' apparent frustration with Dr. Conti's answers during her

deposition do not amount to a refusal to provide information, but rather a disagreement between the parties regarding their respective positions. Accordingly, the parties' experts may battle out such disagreements during trial, but Defendants' motion does not raise any concerns warranting exclusion. As explained in more detail below, generic-only purchasers lack standing to remain in the class. As such, my analysis of whether Dr. Conti's opinions should be excluded will be limited to the relevant challenges to her opinions on class-wide and brand-only injury.

Rule 26 of the Federal Rules of Civil Procedure governs a party's duty to disclose and sets forth the general provisions related to discovery. Specifically, Rule 26(a)(2)(B) outlines the requirements for expert witnesses who must submit a written report. The report must contain:

> (i) a complete statement of all opinions the witness will express and the basis and reasons for them; (ii) the facts or data considered by the witness in forming them; (iii) any exhibits that will be used to summarize or support them; (iv) the witness's qualifications, including a list of all publications authorized in the previous 10 years; (v) a list of all other cases in which, during the previous 4 years, the witness testified as an expert or at trial or by deposition; and (vi) a statement of the compensation to be paid for the study and testimony in the case.

Fed. R. Civ. P. 26(a)(2)(B).

Where a party fails to comply with Rule 26, Rule 37 provides an applicable enforcement mechanism. Under Rule 37(c)(1), a party that fails to disclose information or identify a witness as required by Rule 26(a) or (e) may not use that information or witness "to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." Fed. R. Civ. P. 37(c)(1). In addition to exclusion, the rule permits the court to impose other appropriate sanctions, including payment of reasonable expenses, informing the jury of the failure, or any other sanction listed in Rule 37(b)(2)(A)(i)-(vi).

Ultimately, the trial court retains "broad discretion" in determining whether a party has adequately complied with disclosure obligations related to expert testimony. *Holtje v. Waterman*,

11 Mass.L.Rptr. 89 (1999) (citing 8 Wright & Miller, Federal Practice and Procedure §2050 (1970)). The purpose of the rule is to ensure that expert testimony is both reliable and fairly disclosed to opposing parties in a timely and complete manner, thereby avoiding unfair surprise and promoting judicial efficiency.

1. Dr. Conti's Opinions Regarding Class-Wide Injury

Dr. Conti clearly defines the injured class as being composed of those purchasers who paid a supra-competitive price. According to Dr. Conti, injury occurs at the point of sale, when a purchaser pays an inflated price due to suppressed generic competition. Dr. Conti has provided sufficient data and evidence to support these opinions. [Doc. No. 382-1 at 10].

Defendants mischaracterize Dr. Conti's analysis by conflating the concepts of injury and damages. As Plaintiffs explain, injury arises from the act of paying a supra-competitive price, whereas damages refer to the quantum of harm suffered as a result. [*Id.* at 12]. Defendants argue that Dr. Conti applies inconsistent methodologies, but they fail to acknowledge the distinct legal and economic meanings of injury and damages. Dr. Conti's approach therefore remains consistent and economically sound within both frameworks. Further, Dr. Conti notes that Defendant's expert, Dr. Saravia, offers largely legal rather than economic objections to her conclusions. [*Id.* at 10]. These critiques do not undermine Dr. Conti's economic findings, nor do they provide a valid basis to exclude her testimony. The purpose of the disclosure requirements under the Federal Rules of Civil Procedure is to "put the opposing party on notice." [*Id.* at 8]. Dr. Conti's disclosures meet and exceed this standard. *See Resendes v. Boston Edison*, 38 Mass.App.Ct. 344, 351 (1955). As such, her testimony is appropriate and compliant with the rules governing expert testimony.

2. Dr. Conti's Opinions Regarding Brand-Only Purchasers

Dr. Conti has provided ample support for the inclusion of brand-only purchasers of Amitiza within the injured class. Defendants claim that once a generic enters the market, the impact on brand-only purchasers is insignificant because brand-loyal purchasers would have continued purchasing the brand-name drug exclusively in the real world. However, Dr. Conti's report explains and detail why brand-only purchasers experience injury when generic competition is delayed. Furthermore, I am unconvinced that Dr. Conti refused to answer questions regarding this phenomenon. Rather, the deposition testimony shows that Dr. Conti had difficulty answering questions that were based on what Dr. Conti believed were incorrect premises or hypotheticals, and Dr. Conti has otherwise fully disclosed the bases of her opinions. *Asacol* is inapposite. That was an end-payor class action where Dr. Conti could not point to any "documents or admissions" that would support a finding that individual consumers suffered injury, and certification of a class containing uninjured class members would preclude defendants from "raising genuine challenges at trial to the assertion of liability by individual members of a class that was known to have members who could not be presumed to be injured." *In re Asacol Antitrust Litig.*, 907 F.3d 42, 54, 57 (1st Cir. 2018). As Plaintiffs explain, "[t]he situation here is quite different because direct purchaser wholesalers' purchases are of such a quantity that individual patients' actions are irrelevant to their overall purchasing habits, and wholesalers, unlike individual patients, are not brand loyal." [Doc. No. 382-1 at 15].

For these reasons, Defendants' Motion to Exclude the Opinions of Dr. Rena Conti, [Doc. No. 363], is DENIED.

B. Dr. Martin Kovach

Defendants move to exclude the opinions of EPPs' expert, Martin E. Kovach. [Doc. No. 545]. Specifically, Defendants move to exclude Dr. Kovach's opinions that (1) the proposed classes are ascertainable using administratively feasible methodologies and, (2) all or virtually all proposed class members were injured. [*Id.*]. In his report, Dr. Kovach opined that "members of class were economically injured and that classwide damages were calculable using common evidence" and that "the claims data he reviewed was sufficient to determine, for each drug claim, the information relevant for determining class membership." [Doc. No. 558 at 10]. Defendants argue that Dr. Kovach knows little about the methodology that Plaintiffs propose to ascertain the class, and that his opinions are not supported by valid evidence or based on the facts of the case. [Doc. No. 546 at 5]. Defendants also contend that Dr. Kovach lacks the expertise to offer opinions with respect to antitrust injury, and that his "opinion that 'all or virtually all' class members are injured is conclusory, at best, and lacks any empirical basis." [*Id.*]. Plaintiffs respond that Dr. Kovach "has good grounds for his testimony, which is rooted in his extensive experience analyzing claims data for litigation, and thorough review of claims data produced in this action, and Messrs. Fischer and Miller's declarations and testimony." [Doc. No. 558 at 7]. Plaintiffs argue that they have put forth the publications and forecasts analyzed by Dr. Kovach, and "the widely accepted yardstick methodology he employed to calculate the vanishingly small probability that any class member TPP was uninjured by Takeda's restraint of the market for Amitiza and generic Amitiza." [*Id.* at 8].

Rule 702 of the Federal Rules of Evidence defines an expert witness as "a witness who is qualified as an expert by knowledge, skill, experience, training, or education." Fed. R. Evid. 702. To be permitted to testify, the following four requisites must be met: (1) "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;" (2) "the testimony is based on sufficient facts or data;" (3) "the testimony is the product of reliable principles and methods; and" (4) "the expert's opinion reflects a reliable application of the principles and methods to the facts of the case." *Id*. To be admissible, an expert's opinion must rest on more than a "subjective belief or unsupported speculation," and "an inference or assertion must be derived by the scientific method. Proposed testimony must be supported by appropriate validation—*i.e.*, 'good grounds,' based on what is known." *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993).

1. Dr. Kovach's Opinions Regarding Ascertainability

Defendants claim that Dr. Kovach does not have knowledge of Plaintiffs' methodology for ascertaining the class and should be prevented from offering any opinion that such methodology is administratively feasible. Their argument is based on Dr. Kovach's deposition testimony, in which he stated that he has no opinion regarding: (1) "The source of information Plaintiffs[] will use to ascertain the class;" (2) "Plaintiffs' approach to obtaining the data they will use to ascertain class members;" (3) "The cost of collecting data to ascertain the classes;" (4) "Plaintiffs' methodology to identify and exclude self-funded federal and state entities; and" (5) "Whether Plaintiffs will be required to use certifications." [Doc. No 546-1 at 13-14]. I find that Dr. Kovach is aware of what methods Plaintiffs are proposing because he has offered opinions that support substantial aspects of Plaintiffs' methodology, including the sufficiency of TPP claims data and whether TPP claims data informs funding status. [Doc. No. 558-1 at 16]. Further, "[a]t the *Daubert* stage, EPPs are not required to prove that they can ascertain class based on [Dr. Kovach's] opinions, they need only demonstrate that those opinions are reliable." *In re Generic Pharms. Pricing Antitrust Litig.*, No. 16-cb-27242, 2024 WL 4980784, at *25 (E.D. Pa. Dec. 3,

2024), *on reconsideration in part*, No. 16-cb-27242, 2025 WL 478178 (E.D. Pa. Feb. 12, 2025). Dr. Kovach "need only provide good grounds" for his opinions, and he "is not required to put forth a methodology for ascertainability, which is EPPs' burden to prove at a later stage in litigation." *Id.*

Defendants argue that Dr. Kovach does not offer evidence supporting his opinions on ascertainability because he has not reviewed "the Rawlings data, and relies solely on the testimony of Mr. Fischer regarding what the data is, how it can be collected, and how it can be used." [Doc. No. 546-1 at 14–15]. Defendants also argue that Dr. Kovach's opinion that the data can easily be standardized using data dictionaries should be excluded because "he has not explained how this standardization would be carried out and does not provide evidence for his assumption that data dictionaries would be generally available." [*Id.* at 17].

Defendants are correct that "while an expert may . . . testify solely on the basis of experience . . . he must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." *McGovern ex. Rel. McGovern v. Brigham & Women's Hosp.*, 584 F. Supp. 2d 418, 426 (D. Mass. 2008) (citation omitted). However, Dr. Kovach does provide such information. Dr. Kovach opines that standardization is a "simple programming task" that can be easily done even if data fields contain different sets of codes. [Doc. No. 558-1 at 20]. This is a task Dr. Kovach has "personally undertaken and overseen in [his] nearly 20 years of experience working with prescription drug claims data for pharmaceutical litigation [that] could be done across all the claims datasets." [*Id.*]. Defendants also argue that "an expert is responsible for ensuring that his opinion is based on reliable data" and that "he may not blindly rely on his client's representations." *Cashman Dredging & Marine Contracting Co., LLC v. Belesimo*, 759 F. Supp.

3d 120, 156 (D. Mass. 2024) (citation omitted). In *Cashman*, however, the expert failed to "conduct his own analysis to form his opinion." *Id.* Here, Dr. Kovach's testimony is a combination of his own analysis and information provided by Plaintiffs' other experts.

Finally, Defendants claim that Dr. Kovach lacks any expertise in ascertainability, arguing that although Dr. Kovach has 20 years of experience working with litigation consultants, he has never been employed in the pharmaceutical or healthcare industry, nor has he ever been retained as an expert on class certification issues. I disagree. Dr. Kovach has worked for 20 years as an economist at a litigation consulting firm specializing in pharmaceutical antitrust litigation. [Doc. No. 558 at 14]. He has extensive experience performing economic analyses involving claims data, calculating damages, and drafting expert reports. [*Id.*]. He has co-authorized a book on the use of pharmaceutical data in litigation. [*Id.*]. Dr. Kovach need not be an expert specifically in "ascertainability" for his opinions to be reliably formed based upon his qualifications and specialization in pharmaceutical antitrust litigation and claims data analysis. *Microfinancial, Inc. v. Premier Holidays Int'l, Inc.*, 385 F.3d 72, 80 (1st Cir. 2004) ("Rule 702 is not so wooden as to demand an intimate level of familiarity with every component of a transaction or device as a prerequisite to offering expert testimony").

2. Dr. Kovach's Opinions That "All Or Virtually All" Class Members Were Injured

Defendants argue that Dr. Kovach lacks the proper qualifications to offer an expert opinion on class wide injuries as he is not an economist, does not hold degrees in economics, and has not published any peer-reviewed articles concerning economics or the pharmaceutical industry. [Doc. No. 546-1 at 21]. However, as discussed above, Dr. Kovach is sufficiently

qualified, and "that he holds no degree in economics does not disqualify him." *In re: Se. Milk Antitrust Litig.*, No. 2:08-mc-1000, 2010 WL 11462847, at *1 (E.D. Tenn. Dec. 9, 2010).[2]

Defendants further argue that Dr. Kovach's opinions regarding classwide antitrust impact are unreliable because they are not based on empirical evidence and lack quantitative foundation, citing to deposition testimony that Dr. Kovach could not answer a hypothetical question. [Doc. No. 546 at 22–23]. But as Plaintiffs point out, Dr. Kovach has "exhaustively outline[d] his empirical process." [Doc. No. 558 at 23]. Dr. Kovach reached his conclusion that "all or virtually all" members were injured based on an examination of reports and publications regarding the phenomenon that generic drugs enter the market at prices significantly lower than the brand drug, coupled with his examination of record evidence of forecasts done by Takeda and its generic competitors that projected that the Amitiza market would follow this standard course, and applying those assumptions to estimate the probability that any individual class member was injured based on a well-documented generic conversion rate of 80% to 90%. [*Id.*]. Dr. Kovach also addresses any criticisms of his methodology in his rebuttal report.

Takeda has the right to challenge any weaknesses in Dr. Kovach's methodology at trial with its own competing expert; but it has not met the standard to exclude Dr. Kovach's opinions.

[2] The cases Defendants cite are inapposite as they all involve engineering experts who did not have expertise to offer opinions regarding the products at issue. *See Safety Ins. Co. v. EcoWater Sys., LLC*, No. 22-cv-10887-MJJ, 2024 WL 3026805, at *3 (D. Mass. May 17, 2024) (disqualifying expert where engineering expert testified that he was not "offering any opinions to a reasonable degree of engineering certainty"); *Carlucci v. CNH Am. LLC*, No. 10-cv-12205, 2012 WL 4094347, at *4 (D. Mass. Sept. 14, 2012) (disqualifying engineer who did not have expertise to analyze the product defect at issue, holding that "where an expert lacks relevant experience, training, and education to testify about design defects, his testimony is inadmissible"); *Morse v. Ford Motor Co.*, No. 08-cv-11930, 2010 WL 2733607, at *3 (D. Mass. July 9, 2010) (disqualifying expert who had extensive experience in accident reconstruction but did not have an engineering degree or specialized knowledge to opine on "tie rod assemblies, airbag systems, or for that matter, the Ford Focus"); *Polaino v. Bayer Corp.*, 122 F. Supp. 2d 63, 68 (D. Mass. 2000) (similar).

For these reasons, Defendants' Motion to Exclude the Expert Opinion of Dr. Kovach, [Doc. No. 545], is DENIED.

IV. CLASS CERTIFICATION LEGAL STANDARD

Federal Rule of Civil Procedure 23 governs class certification. *See Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 346 (2011). Rule 23(a) requires that "(1) there be numerosity, (2) there be common questions of law or fact, (3) the class representative's claims be typical of the class, and (4) the representative's representation of the class be adequate." *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 522 F.3d 6, 18 (1st Cir. 2008). Rule 23(b)(3) requires that common questions "predominate" over individual questions, and that a class action be a "superior" method of adjudicating the controversy. *See id.* Rule 23 also implicitly requires that putative class members be "ascertainable" with reference to objective criteria. *See In re Nexium Antitrust Litig.*, 777 F.3d 9, 27 (1st Cir. 2015).

A plaintiff seeking class certification must "affirmatively demonstrate" by a preponderance of the evidence that the Rule 23 requirements are met. *See Wal-Mart Stores*, 564 U.S. at 350; *Nexium*, 777 F.3d at 27. A court must test the plaintiff's assertions with "rigorous analysis." *See General Telephone Co. of Southwest v. Falcon*, 457 U.S. 147, 161 (1982). This may require consideration of the merits. *See Amgen Inc. v. Conn. Ret. Plans and Tr. Funds*, 568 U.S. 455, 466 (2013). In considering the merits, a court may "test disputed premises," *Tardiff v. Knox Cnty.*, 365 F.3d 1, 4 (1st Cir. 2004), and "formulate some prediction as to how specific issues will play out," *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 298 (1st Cir. 2000).

V. CLASS CERTIFICATION ANALYSIS

A. Numerosity (Impracticability Of Joinder)

Under Rule 23(a), a class may be certified only if "the class is so numerous that joinder of all members is impracticable." Fed. R. Civ. P. 23(a). This district has held that while "[t]he first requirement of Rule 23(a)(1) is often referred to as 'numerosity,' [] it might more properly be called the 'impracticability' requirement, because the inquiry called for by Rule 23(a)(1) often involves more than merely counting noses." *McLaughlin v. Liberty Mut. Ins. Co.*, 224 F.R.D. 304, 307 (D. Mass. 2004); *In re Ranbaxy Generic Drug Application Antitrust Litig.*, 338 F.R.D. 294, 301 (D. Mass. 2021) ("[T]here is no requirement of a minimum number of plaintiffs"). Courts have generally held that classes exceeding forty plaintiffs are deemed sufficient, although courts within this circuit have certified classes with sizes similar to that presented here. *See, e.g.*, *In re Prograf Antitrust Litig.*, No. 1:11–cv–10344, 2013 WL 2395083, at *1 (D. Mass. Apr. 23, 2013) (Zobel, J.) (certifying a class of twenty-five pharmaceutical wholesalers); *In re Citigroup, Inc. Capital Accumulation Plan Litig.*, No. 00-cv-11912, 2010 WL 9067986, at *8–10 (D. Mass. Jan. 6, 2010) (Gertner, J.), *aff'd*, 652 F.3d 88 (1st Cir. 2011) (certifying a subclass of twenty participants in an employee stock compensation program). *In re Nexium (Esomeprazole) Antitrust Litig.*, 296 F.R.D. 47, 51 (D. Mass. 2013).[3]

"In determining whether joinder would be impracticable, district courts may consider the following non-exhaustive factors, in addition to the size of the class: judicial economy, the claimants' ability and motivation to litigate as joined plaintiffs, the financial resources of class

[3] Courts in this circuit have certified direct purchaser pharmaceutical classes. *See Nexium*, 296 F.R.D. at 51 (class of 24 or 29 members); *Prograf*, 2013 WL 2395083 (class of 25); *Ranbaxy*, 338 F.R.D. 294 (classes of 62, 51, and 39 members); *In re Solodyn (Minocycline Hydrochloride) Antitrust Litig.*, 2017 WL 4621777, at *1 (D. Mass. Oct. 16, 2017) (class of 48); *In re Intuniv Antitrust Litig.*, No. 16-cv-12653, 2019 WL 4645502 (D. Mass. Sept. 24, 2019) (class of 48); *In re Loestrin 24 Fe Antitrust Litig.*, 13-md-2472, 2019 WL 3214257, at *8 (D.R.I. July 2, 2019) (class of 47).

members, the geographic dispersion of class members, the ability to identify future claimants, and whether the claims are for injunctive relief or for damages." *Loestrin*, 2019 WL 3214257, at *8 (citation omitted). "Moreover, courts have certified smaller classes in generic suppression cases where judicial economy favors proceeding as a class action." *Id.* (citation omitted).

Plaintiffs argue that joinder is impracticable here for several reasons: First, when class certification is denied, claimants with low-value claims are not incentivized to bring their own actions; Second, the proposed class is too geographically dispersed to make joinder practicable; Third, certification of the proposed classes here promotes judicial economy, and; Finally, private antitrust actions should be given favorable treatment as a matter of public policy, and class action treatment of the alleged antitrust violations here is appropriate to achieve the policy purposes of the federal antitrust laws. Defendants argue that DPPs have not met their burden to show that joinder is impracticable. Primarily, Defendants argue that while DPPs identify 39 to 43 potential class members, when properly accounted for, the proposed class should only consist of 14 to 17 members, demonstrating that DPPs are "artificially inflat[ing] the number of claimants." [Doc. No. 292 at 17-18]. Additionally, Defendants argue that DPPs have not put forth non-speculative or non-hypothetical evidence that "smaller claimants here would not pursue joinder if class certification were denied." [*Id.* at 18]. Finally, Defendants argue that the other factors such as judicial economy and geographic dispersion do not weigh in favor of certification. I will address each of these arguments in turn.

1. The True Size Of The Class

Plaintiffs' expert Dr. Rena Conti has provided an analysis that proposes several scenarios for when generic Amitiza would have been available, and based on these scenarios, Plaintiffs posit that the class may vary between 39 members, 40 members, or 43 members. [Doc. No. 249-

2 at 36, ¶ 75; 47-48, ¶¶ 102-103]. The class under any scenario would include six assignees: Meijer Distribution, Inc. and Kinney Drugs, Inc. (the proposed class representatives), as well as Giant Eagle, Supervalu Inc., Discount Drug Mart, Inc., and Wegmans Food Markets, Inc. [Doc. No. 249-2 at 6 n.3]. Defendants argue that several groupings of members should be excluded for various reasons:

1. Thirteen members have only directly purchased Par's Amitiza AG product from other sources, not from "Takeda or any generic Amitiza manufacturer other than Par" as required by the class definition. [Doc. No. 292 at 19-20].

2. Ten members are brand-only purchasers that are uninjured.

3. Seven members are subsidiaries or affiliates of other proposed class members and should not be "double-count[ed]." [*Id.* at 21-22].

4. Six entities, including KPH and Meijer, were created through assignments from wholesalers McKesson and Cardinal which Defendants assert to be invalid.

5. Three entities, including Meijer, must arbitrate their claims.

6. CVS is a retail Plaintiff that is pursuing its own separate claim against Takeda arising out of the same facts.

I will address each of these arguments in turn.

i. The Thirteen Generic-Only Purchasers

Thirteen proposed class members are entities that exclusively purchased Par's Amitiza AG product from Dr. Reddy's Laboratories ("DRL") and Sun, distributors who sold Par's AG product under distribution agreements with Sucampo and Takeda (the "generic-only purchasers"). [*See* Doc. No. 292-7 at 2].[4] Defendants believe these members should be excluded from the class because: (1) they do not fall within DPPs' initial proposed class definition, and,

[4] These members are Alpine Health LLC, Bluepax Pharmaceuticals, CityMedRx LLC, CVS, Guardian Pharmacy, Hospital Pharmaceutical Consulting, Hygen, Independent Pharmacy Cooperative, Keysource Medical, NDC Distributors LLC, Oak Drugs Inc., Primed Pharmaceuticals, and Republic Pharmaceuticals. [Doc. No. 249-2 at 49].

(2) even if these members did qualify under DPPs proposed definition, this Court's previous order on Takeda's motion to dismiss bars the generic-only purchasers under the principles of *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977) ("*Illinois Brick*").

Plaintiffs' initial class definition included all entities that "***directly purchased*** brand Amitiza and/or generic Amitiza in any form ***from Takeda or any generic Amitiza manufacturer other than Par***." [Doc. No. 248]. In their Reply, Plaintiffs amended this class definition to include all entities that "***directly purchased*** brand Amitiza and/or generic Amitiza in any form ***from*** Takeda, ***DRL, Sun,*** Teva, Amneal, or Zydus, or their subsidiaries or affiliates." [Doc. No. 319 at 9]. On October 25, 2024, Defendants filed a motion to strike Plaintiffs' amended class definition. [Doc. No. 365]. To determine which class definition controls, I must address this court's previous order dismissing members who only purchased AG product from Par and did not purchase generic Amitiza directly from Defendant Takeda.

On December 27, 2022, Judge Stearns granted in part Takeda's motion to dismiss plaintiffs who purchased only an AG product from Par. Judge Stearns held that "decisions of the First Circuit and district courts within it 'establish a rule . . . that so long as the selling member of the alleged antitrust conspiracy (here, Par as to the AG product) is joined as a defendant, the first purchaser outside of the conspiracy has direct purchaser standing.'" [Doc. No. 61 at 11 (quoting Doc. No. 49 at 37)]. Because Plaintiffs dismissed its claims against Par, the "selling member of the alleged antitrust conspiracy" was "no longer a defendant in the action, thereby eliminating *Illinois Brick* standing." [*Id.* at 12]. The court thus only allowed "so much of Takeda's motion as [was] premised on generic sales." [*Id.*]. I find that Judge Stearns's reasoning, as it applied to Par, applies equally here to members who only purchased generic product from DRL and Sun.

Illinois Brick found that plaintiffs who had purchased concrete blocks indirectly from the manufacturer defendants lacked standing to pursue their antitrust claims, finding that the overcharge passed down the distribution chain and thus created a "serious risk of multiple liability for defendants." *Illinois Brick*, 431 U.S. at 731. The Supreme Court later clarified the *Illinois Brick* rule in *Apple Inc. v. Pepper*, 587 U.S. 273, 279 (2019). There, the Court stated:

> The bright-line rule of Illinois Brick . . . means that indirect purchasers who are two or more steps removed from the antitrust violator in a distribution chain may not sue. By contrast, direct purchasers—that is, those who are the immediate buyers from the alleged antitrust violators—may sue. For example, if manufacturer A sells to retailer B, and retailer B sells to consumer C, then C may not sue A. But B may sue A if A is an antitrust violator. And C may sue B if B is an antitrust violator. That is the straightforward rule of Illinois Brick.

Id. at 280. That is precisely the scenario here. The generic-only purchasers, (consumer C), are attempting to sue Takeda, (manufacturer A), who has sold its product to DRL and Sun, (distributor B). Consumer C cannot now sue manufacturer A for its indirect purchase. This is the same logic that applied when Judge Stearns ruled on the motion to dismiss, only in that scenario, distributor B was Par.

Plaintiffs argue that *Illinois Brick* was primarily concerned with allowing indirect purchasers to pursue claims that would result in double recovery. They argue that here, DRL and Sun were not "purchasers in the marketplace that were harmed by Takeda's actions that kept *more* sellers of lubiprostone from the market, and so neither suffered harm from Takeda's anticompetitive conduct." [Doc. No. 319 at 26]. Plaintiffs contend that if the court were to exclude these members, then Takeda would avoid "all liability for the millions of dollars in overcharges caused by Takeda's actions on units sold by DRL and Sun." [Doc. No. 380 at 6]. But Plaintiffs have not cited to any case that would permit these indirect purchasers to recover under this theory, and the cases they do cite are inapposite. *Namenda* stands for the proposition

that "[i]ndirect purchasers are those who buy from the customers of a defendant – from people to whom the defendant sold product." *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 212 (S.D.N.Y. 2018). There, the court found that the Non-Forest Generic Purchasers were not *Illinois Brick* "indirect purchasers" because they purchased from competitors of the Defendant and thus were "neither direct nor indirect" purchasers in relation to the Defendant. *Id. Ranbaxy* is inapposite as it did not involve a resold AG product or address *Illinois Brick*. 338 F.R.D. at 298–299.

Plaintiffs raised similar arguments when seeking reconsideration of Judge Stearns's ruling on the motion to dismiss. In denying that motion, Judge Stearns ruled that "[w]hile the court sympathizes with the position in which plaintiffs find themselves," Plaintiffs themselves conceded that "decisions within this Circuit 'establish a rule in this Circuit that so long as the selling member of the alleged antitrust conspiracy (here, Par as to the AG product) is joined as a defendant, the first purchaser outside of the conspiracy has direct-purchaser standing, regardless of whether the case involved price-fixing allegations.'" [Doc. No. 73 (citing Doc. No. 49 at 37)]. I agree that "Plaintiffs cannot now reverse course and argue an alternative construction of the law based on the same cases." [*Id.*].

Plaintiffs argue there was no undue delay that will prejudice Takeda because the amended definition is essentially the same as the initial definition. Not so. The initial definition permits members who directly purchased generic Amitiza from any ***manufacturer*** other than Par. This definition would thus exclude purchases from ***distributors***, such as Par, DRL, Sun, or others, who are reselling Takeda or Sucampo manufactured Amitiza. The amended definition includes members who directly purchased generic Amitiza from DRL, Sun, Teva, Amneal, or

Zydus which excludes the limiting term "manufacturer," thereby failing to address the principles of *Illinois Brick*.

Given that at the time of the class certification briefing, three years had passed since the filing of the initial complaint and two years had passed since this court's order on the motion to dismiss, and that the new definition would require additional discovery, I GRANT Takeda's motion to strike and find that the thirteen generic-only purchasers of DRL and Sun must be excluded from the class.

ii. The Ten Brand-Only Purchasers

Ten proposed class members only purchased brand Amitiza during the class period (the "brand-only purchasers").[5] Defendants argue that these class members are uninjured under DPPs' damages theory, which is based on "purported overpayments on brand Amitiza purchases that would have been generic purchases in the 'but for world.'" [Doc. No. 292 at 26]. Plaintiffs argue that brand-only purchasers were injured because "[a]lthough these purchasers did not directly purchase generics after they became available, their purchasing patterns show they stopped or dramatically reduced brand purchases after generic entry and there is evidence that they purchased generics from other sources." [Doc. No. 343 at 22 (citing Doc. No. 343-5 at 15-16)]. Plaintiffs' expert Dr. Rena Conti explains that brand-only purchasers are injured at the point of sale; i.e., when they are forced to pay for supra-competitive prices. [Doc. No. 343-5 at 15, ¶¶ 33-36]. She opines that:

> Due to the rapid shift to purchasing the generic instead of brand Amitiza after generic entry, brand-only direct purchasers would either have switched to purchasing the generic had it become available earlier, or would have stopped purchasing altogether in the but-for world. This is consistent with the theory of harm I present above. These brand-only purchasers could not purchase generic

[5] These proposed class members include Burlington Drug Company, Cardinal Health P.R., Cesar Castillo Inc., H.D. Smith, Harvard Drug Group, J.M. Blanco, Miami-Luken Inc., Rochester Drug Cooperative, Smith Medical Partners, and Valley Wholesale drug Company. [Doc. No. 249-2 at 48-49].

> Amitiza due to the alleged suppression in competition. Whether that means they would have purchased generic Amitiza absent the alleged delay, or that they would have purchased less or no brand Amitiza, they were still forced to pay supra-competitive prices for brand Amitiza.

[*Id.* at 15, ¶ 34]. This is consistent with what other courts have held, including the cases that Defendants cite to. *See In re Celebrex Antitrust Litig.*, 2017 WL 3669604, at *8 (E.D. Va. July 28, 2017) (the "overcharge" is the difference between what they actually paid and what they would have paid after generic entry") (quoting *Meijer, Inc. v. Warner Chilcott Holdings Co. III*, 246 F.R.D. 293, 304 (D.D.C. 2007) ("[A]ntitrust injury occurs and is complete when the defendant sells at the illegally high price")).[6]

Exclusion of these ten brand-only purchasers also requires a predominance analysis under Rule 23(b)(3). Having found that the ten purchasers were injured and should be included in the class, I will discuss further why common issues regarding injury and damages predominate as in Section V.e.2.

iii. The Seven Subsidiaries And Affiliates

Defendants argue that seven proposed class members should be excluded because they have been double counted as related corporate entities. Defendants' expert opines that adjusting for corporate affiliates would result in the exclusion of three subsidiaries of Amerisource Bergen, two subsidiaries of Cardinal Health, and one of two affiliates who are subsidiaries of an entity not identified as a potential class member, decreasing the number of proposed class members by 6-7. [Doc. No. 292 at 22]. However, Plaintiffs have shown that these companies are "separately incorporated, separately listed in the manufacturers' transactional data, and, most importantly,

[6] While Defendants rely on *Celebrex* for the proposition that certain brand-only purchasers were found to have been uninjured, there, two brand-only purchasers were excluded because they made brand purchases only after generic entry and thus "received the full benefit of brand-name discounts that resulted from generic entry" and there was "insufficient evidence to show they paid an overcharge as a result of the antitrust conduct alleged." *Celebrex*, 2017 WL 3669604, at *9.

separately purchased (and were overcharged for) the[] product" and therefore, whether "related or not," each class member "suffered independent injury." *In re Namenda Direct Purchaser Antitrust Litig.*, 331 F. Supp. 3d 152, 207 (S.D.N.Y. 2018) (citation omitted). While Defendants argue that Plaintiffs have provided no evidence that these corporate subsidiaries or affiliates suffered independent injury, Plaintiffs have put forth such evidence. [*See* Doc. No. 249-2 at 88-93; Doc. No. 343-5 at 6-7, ¶¶ 12-13 ("all the DPP class members appear in the manufacturer data as individual entities and have transactions that are individually attributable to them")].

By permitting the inclusion of these entities, even if related, I join with other courts that have considered this issue and have ruled that where there is distinct and separate injury, a corporate relationship with another class member does not defeat individual member status. *Namenda*, 331 F. Supp. 3d at 207; *see also Solodyn*, 2017 WL 4621777, at *4 ("Defendants have provided no legal support for their argument that class members with common corporate parents should not be considered distinct entities for class certification purposes. On the other hand, DPPs argue that separately incorporated companies are distinct entities that should be treated as separate class members to vindicate their own antitrust injuries"); *Celebrex*, 2017 WL 3669604, at *8 ("Here, there is evidence to suggest that the subsidiaries made direct purchases of brand-name or generic Celebrex distinct from the purchases of their parent companies, and thus, would have suffered independent injury under the theory alleged").

iv. The Six Assignees

Defendants argue that six entities, including the two proposed class representatives—Meijer and KPH—were created through questionable assignments.[7] "[U]nless there is evidence that the class plaintiffs are seeking to artificially inflate the number of claimants, partial

[7] The four other entities include Giant Eagle, Supervalu Inc., Discount Drug Mart, Inc., and Wegmans Food Markets, Inc. [Doc. No. 292 at 23 n.79].

assignees may properly be treated as class members." *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 252 (3d Cir. 2016), *as amended* (Sept. 29, 2016); *In re Vitamin C Antitrust Litig.*, 279 F.R.D. 90, 102 (E.D.N.Y. 2012) ("[T]here is no rule prohibiting the assignment of class membership"). Defendants proffer several arguments regarding the terms and timing of the assignments to support that the assignments were created in order to artificially inflate the number of claimants. [*See* Doc. No. 292 at 23-25]. None of these theories support that the assignments were actually entered into for the purpose of inflating the number of claimants. *See Modafinil*, 837 F.3d at 250 (permitting assignees to be included in the class even where three assignees were added during the pendency of the litigation). Defendants' other arguments are circular. [Doc. No. 292 at 23 (arguing that the "creation of six class members by partial assignments . . . itself suggests that DPPs are seeking to artificially inflate the number of claimants")]. Accordingly, I find that these six entities may be included in the class.

v. The Three Members Who Must Arbitrate

Takeda contends that three entities must arbitrate their claims and therefore cannot be included in the class. These entities include one of the proposed class representatives, Meijer, as well as Cesar Castillo Inc. ("CCI") and Drogueria Betances, Inc. ("DBI"). Plaintiffs argue that Takeda has waived its rights to compel arbitration of any of these class members by waiting more than three years after the filing of the case to raise the issue of arbitrability. While the parties both rely on and incorporate arguments from the briefing for Takeda's Motion to Compel Arbitration against Meijer, *see* [Doc. No. 252], I have since granted that motion and issued a stay of this matter as to Meijer only, pending resolution of the arbitration proceedings. [*See* Doc. No. 491]. Accordingly, Meijer cannot be included in the class and cannot act as a class representative.

As for CCI and DBI, Plaintiffs argue that Takeda has waived its right to arbitrate those claims. Here, there are no motions to compel arbitration of CCI or DBI. The only argument on this issue is briefed in Plaintiffs' motion to require Takeda to withdraw letter to absent class members. [Doc. No. 295]. Given that almost a year has gone by since the filing of that motion and no motions to compel have been filed, I find it appropriate to permit CCI and DBI to remain as members of the class. *In re Citigroup, Inc.*, 376 F.3d 23, 26 (1st Cir. 2004) ("If arbitration is invoked in response to a lawsuit, it must be done early on in the case so resources are not needlessly deployed"). Accordingly, Plaintiffs Motion to Require Takeda to Withdraw, [Doc. No. 295], is GRANTED, in part, to the extent that Takeda must withdraw those letters. The motion is otherwise DENIED to the extent that it seeks an overbroad prohibition against Takeda to communicate with the absent class members as to any issue involving this case. While "[m]isleading or coercive communications with potential class members that could or are intended to undermine participation in a class or collective action are of great concern," I do not find that further "communications are more likely to be coercive." *Davine v. Golub Corp.*, 14-cv-30136, 2014 WL 5427006, at *3 (D. Mass. Oct. 24, 2014). "Courts should impose only such restrictions as are required to prevent serious abuses or remedy the harm from such abuses because restrictions can limit expression, implicating First Amendment issues." *Id.* As such, a broad prohibition on communications is unnecessary here.

vi. CVS

Finally, Defendants argue that CVS must be excluded because it has filed its own, separate action against Takeda arising out of the same facts and circumstances. *See CVS Pharmacy, Inc. v. Takeda Pharma. Co. Ltd., and Takeda Pharma. U.S.A., Inc.*, No. 1:24-cv-10223-MJJ, ECF No. 1 (D. Mass. Jan. 29, 2024). "But Defendants supply no authority for the

proposition that the existence of parallel actions should automatically reduce the number of prospective class members for purposes of the class certification inquiry." *MacNamara v. City of New York*, 275 F.R.D. 125, 142 (S.D.N.Y. 2011)." Though Defendants cite to an October 8, 2024 letter from CVS confirming that it "intends to opt out of the Direct Purchaser Plaintiff class, should it be certified," [*see* Doc. No. 361 at 4], "the mere possibility that members of a potential class may choose to opt out in the future is not enough to preclude a finding of numerosity," *MacNamara*, 275 F.R.D. at 142 (citation omitted). Even if CVS were to opt-out after certification, the class would remain sufficiently numerous to satisfy the requirements of Rule 23(a)(1).

*** * ***

The exclusion of the generic purchasers and Meijer would reduce the size of the class to 25-29. I find that class is still sufficiently numerous to grant class certification. *Nexium*, 296 F.R.D. at 51-53 (certifying class of 24 or 29 members); *Asacol*, 2017 WL 4118967, at *1 (26-member class); *Prograf*, 2013 WL 2395083, at *1 (25-member class). Having determined that the class size ranges from 25 to 29 members, I turn now to Defendants' argument that DPPs have failed to put forth sufficient evidence that joinder is impracticable.

2. Evidence Of Impracticability

i. Defendants' Motion To Strike The Sobol Declaration

Prior to addressing Defendants' remaining arguments regarding impracticability, I must resolve Defendants' motion seeking to strike Sections I-V of the Declaration of Thomas M. Sobol, (the "Sobol Declaration"), [*see* Doc. No. 290], as Plaintiffs rely on the statements in this declaration to support their arguments that numerosity has been met. The Motion is DENIED.

As an initial matter, the parties dispute whether Rule 56(c)(4) or Rule 12(f) is the appropriate governing rule. Rule 56(c) governs motions for summary judgment, and states that "[a]n affidavit or declaration used to support or oppose a motion must be made on personal knowledge, set out facts that would be admissible in evidence, and show that the affiant or declarant is competent to testify on the matters stated." Fed. R. Civ. P. 56(c)(4). Rule 12(f) governs pleadings, and states that the court "may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). While neither party has presented cases that are directly on point under either standard explicitly, the cases that have considered similar issues within this circuit persuade me that the Rule 12(f) standard is appropriate and Rule 56's "rigor is uniquely appropriate to declarations offered at summary judgment." *Rossello v. Avon Prods., Inc.*, No. 14-cv-1815, 2015 WL 3890403, at *4 (D.P.R. June 24, 2015), *report and recommendation adopted,* No. 14-cv-1815, 2015 WL 5693018 (D.P.R. Sept. 28, 2015). As such, I need only determine whether the Sobol Declaration is redundant, immaterial, impertinent, or scandalous. I find that it is not.

Further, the Sobol Declaration need not be admissible for the purposes of class certification. In *Marrero-Rolon*, the court denied a motion to strike based on defendants' argument that a Senate Commission Report that Plaintiffs relied upon for class certification was "fraught with evidentiary problems." *Marrero-Rolon v. Autoridad de Energia Electrica*, No. 15-cv-1167, 2018 WL 8805484, at *1 (D.P.R. Aug. 22, 2018). There, the court held that at the class certification juncture, "the Court is not deciding whether the Report is admissible at trial" but "is merely deciding whether there are common questions of fact. Defendants have provided no case law for the proposition that, at the class certification stage, the Court may only consider evidence that would be admissible at trial. If such were the case, then Defendants' opposition could only

rely on depositions, for example, after showing compliance with Fed. R. Civ. P. 32." *Id.* Similarly here, the court will only rely on the Sobol Declaration to the extent it supports Plaintiffs' argument that joinder is impracticable. As such, I "will not require that plaintiffs' evidence be essentially trial-ready." *Rossello*, 2015 WL 3890403, at *4.

Additionally, the Sobol Declaration does not contain improper legal argument but is rather a summary of relevant evidence that is publicly-available and that does not necessitate an analysis from an expert statistician. *Facey v. Dickhaut*, 91 F. Supp. 3d 12, 20–21 (D. Mass. 2014) ("Motions to strike have been denied even when the declarant did not personally experience the matters discussed in the affidavit, but did review business or public records and included information from those records with the affidavit"). Given that Mr. Sobol has extensive experience litigating class actions involving direct purchasers in generic-delay cases, his summary of facts based on his "own understanding and interpretation" of publicly available information is properly before me. *Mekonnen v. OTG Mgmt., LLC*, 394 F. Supp. 3d 134, 146 (D. Mass. 2019), *aff'd*, No. 19-1846, 2021 WL 1110915 (1st Cir. Mar. 23, 2021); *Marrero-Rolon* 2018 WL 8805484, at *1 (holding that the "vast majority of the [challenged] Declaration does not contain legal arguments, but merely summarizes the evidence supporting Plaintiffs' claims").

Finally, I do not find persuasive Defendants' arguments that Plaintiffs are using the Sobol Declaration to circumvent the local rules and the court-ordered page-limits as to the class certification briefing. On June 11, 2024, this court granted the parties' joint motion for leave to file excess pages in their class certification briefing. [Doc. No. 246]. In that motion, the parties acknowledged that the page limits would exceed the limits provided by Local Rule 7.1(b)(3) and (4). But Rule 7.1 governs motion practice, not declarations. In *Marrero-Rolon*, for example, the

court considered that the challenged declaration was "not a motion and, thus," the local rule was "inapplicable." 2018 WL 8805484, at *1. The same reasoning applies here.

For these reasons, the Motion to Strike the Sobol Declaration, [Doc. No. 290], is DENIED.

ii. Analysis Of Impracticability

"'Impracticability' does not mean 'impossibility,' but only the difficulty or inconvenience of joining all members of the class." *Solodyn*, 2017 WL 4621777, at *4 (D. Mass. Oct. 16, 2017) (quoting *Advert. Specialty Nat. Ass'n v. FTC*, 238 F.2d 108, 119 (1st Cir. 1956)). "Impracticability is a matter of discretion for the Court, *see Advert. Specialty*, 238 F.2d at 119, and courts have certified smaller classes in generic suppression cases where judicial economy favors proceeding as a class action, *see, e.g.*, *Nexium II*, 296 F.R.D. at 53 (certifying class of twenty-four or twenty-nine)." *Id.* When assessing practicability, this district considers (1) the ability and motivation of putative class members to bring their own actions if certification is denied; (2) geographic dispersion; and (3) judicial economy. *See*, *e.g.*, *Solodyn*, 2017 WL 4621777, at *5. Plaintiffs have put forth sufficient empirical evidence demonstrating that joinder is impracticable.

Defendants argue that evidence that class members in past cases chose not to pursue joinder is not *de facto* evidence that it was impracticable for them to do so. However, such evidence constitutes a valid predictor of whether it would be impracticable for class members here to pursue joinder, given the reasons underlying such impracticability, which are consistent across pharmaceutical antitrust cases.[8] Past experience shows that in the few cases where class

[8] Defendants' own expert admits that past behavior can provide some evidence of future behavior. [*See* Doc. No. 343-4 at 51 ("Q: Right. So whether someone filed in the past is indicative of whether they might file a joinder action here is your point, right? A: Yes. It provides some evidence.")].

certification was denied, in nearly identical generic entry pharmaceutical class actions, not all proposed class members filed joinder actions. [*See* Doc. No. 249-1 at ¶¶ 6-10; Doc. No. 249 at 15-17]. The Sobol Declaration outlines why members in class actions where certification was denied did not pursue joinder. [*See* Doc. No. 249-1]. DPPs' expert, Dr. Conti, has also explained that this phenomenon occurs because when class certification is denied, claimants with low-value claims are not incentivized to bring their own actions given the high costs of antitrust litigation. Similarly here, many of the class members have "negative value" claims, meaning that the expected individual recoveries will be smaller than the cost of bringing the action, given the costs of litigation and attorneys' fees. Based on Dr. Conti's analysis, 9-11 of the class members' individual recoveries will be below $1,000, and 15 of the class members' individual recoveries will be below $10,000. The fact that the Big Three wholesalers (McKesson, AmerisourceBergen, and Cardinal Health), account for 95% of the *claims* cuts in favor of class action, as smaller class members make up a majority of the *class*. *In re Solodyn*, 2017 WL 4621777, at *6 ("Such cases are the reason why the class action mechanism exists: there is no incentive for these parties to join in light of the litigation costs as compared to the damages at stake").

Compare *Modafinil*. There, the court found that the fact that the proposed class had three class members that made up 97% of the claims, was a factor which "could weigh in favor of class status *if* the remaining class members had very small claims." 837 F.3d at 258. Unlike here, there was evidence that many of the smaller class members had claims greater than $1,000,000, and that only six class members had claims lower than $1,000,000 each, making joinder economically feasible. *Id.* at 259. Here, Dr. Conti has put forth evidence that between 9 and 11 class members had damages with an expected value below $1,000; 15 class members had overcharge damages with an expected value below $10,000; 19 to 21 class members had

overcharge damages with an expected value below $100,000, and; 28 to 30 class members had overcharge damages with an expected value below $1,000,000. [*See* Doc. No. 249-2 at 51, ¶ 109]. This is sufficient evidence to support economic infeasibility.[9]

iii. Geographic Dispersion And Judicial Economy

The other subjective factors also weigh in favor of finding that numerosity is satisfied. First, Plaintiffs have shown that the proposed class is too geographically dispersed to make joinder practicable, "even when putative class members are corporate entities." *In re Solodyn*, 2017 WL 4621777, at *5. Defendants do not dispute that the class is geographically dispersed, only that post-COVID, such dispersion is irrelevant. The cases that Defendants cite to, however, do not find that dispersion is irrelevant but rather that geographic dispersion may be given less weight considering the technological advancements that have occurred since the COVID-19 pandemic. *Value Drug Co. v. Takeda Pharms., U.S.A., Inc.*, No. CV 21-3500, 2023 WL 2314911, at *13 (E.D. Pa. Feb. 28, 2023) (finding that while "[g]eographic dispersion slightly supports certification," the "impact geographic dispersion has on impracticality of joinder is discounted because of advancements in technology and our ability to conduct remote proceedings during and after the pandemic"); *In re Zetia (Ezetimibe) Antitrust Litig.*, No. 2:18-MD-2836, 2022 WL 1577219, at *16 (E.D. Va. Jan. 25, 2022), *report and recommendation adopted*, 342 F.R.D. 95 (E.D. Va. 2022) (finding geographic dispersion is "less probative in this

[9] While the parties' experts dispute each other's methodology regarding the expected recovery rate of the individual members, I find that numerosity has been met. Even if Professor Saravia's critiques regarding Dr. Conti's weighted-average damages recovery rate were true, Dr. Conti has put forth evidence in her rebuttal report that, when using Professor Saravia's methodology—which would apply a 31% recovery ratio as opposed to the 19% recovery ratio that Dr. Conti applied—there are still far more Plaintiffs who would recover smaller dollar amounts. [*See* Doc. No. 343-5 at 11, ¶ 25 (showing that between 4 to 6 class members have overcharge damages with an expected value below $1,000; 13 or 14 class members had overcharge damages with an expected value below $10,000; 17 to 20 members, depending on the scenario, had overcharge damages with an expected value below $100,000, and; 27 or 28 class members had overcharge damages with an expected value below $1,000,000)].

case because the Eastern District of Virginia has proven its ability to facilitate remote participation throughout the COVID-19 pandemic"). Further, the interests of judicial economy favor a class action here. *See Solodyn*, 2017 WL 4621777, at *5 ("Even accepting the Third Circuit's definition of judicial economy—focused on 'the administrative burden that multiple or aggregate claims place upon the courts," which "primarily involves considerations of docket control' . . . the factor weighs in DPPs' favor due to the difficulty of coordinating attorneys, scheduling and docketing for forty-eight clients") (citing *Modafinil*, 837 F.3d at 254, 257).

Considering that geographic dispersion and judicial economy weigh at least slightly in favor of a class action, and that many courts, including courts in this district, "have given favorable treatment to class actions in the private enforcement of antitrust laws," *Nexium*, 296 F.R.D. at 52 (citation omitted), I find that the factors weigh in favor of a finding that plaintiffs have met their burden to prove numerosity here.

B. Commonality

Commonality is not in dispute and is satisfied. Under Rule 23(a)(2), DPPs must show that "there are questions of law or fact common to the class." Fed. R. Civ. P. 23(a)(2). Here, the common issues concern whether purchasers were overcharged due to Defendants' anti-competitive conduct. These issues are found to be common in generic-delay cases. *Relafen*, 218 F.R.D. at 342 (finding commonality where factual issues were whether Defendants "engaged in the alleged anticompetitive conduct and whether and to what extent this conduct resulted in overcharges" and the legal questions common to the class members' claims include whether the Defendant violated the Sherman Act).

C. Typicality

Rule 23(a)(3) requires that "the claims or defenses of the representative parties are typical of the claims or defenses of the class." Fed. R. Civ. P. 23(a)(3). Rule 23(a)(3)'s typicality requirement has been liberally construed by courts. *In re Vitamins Antitrust Litig.*, 209 F.R.D. 251, 260 (D.D.C. 2002). "Rule 23(a)(3) does not require that a representative's claims be identical to those of his class; they only need be sufficiently similar to allow the court to conclude that: (1) the representative will protect the interests of the class; and (2) there are no antagonistic interests between the representative and the proposed class." Courts look at whether "claims or defenses of the class and the class representative arise from the same event or pattern or practice and are based on the same legal theory." *Intuniv Antitrust Litig.*, 2019 WL 4645502, at *6. Plaintiffs argue that they meet the requirements for typicality because its proposed class representatives are "direct purchasers of Amitiza who allege that Takeda impaired generic competition causing class-wide injury," and "they seek overcharge damages based on the same wrongful conduct as the rest of the class." [Doc. No. 249 at 24]. As I have already found that Meijer must arbitrate its claims thus cannot participate in the class or act as class representative, I will only address Defendants' arguments opposing typicality as they apply to KPH.

Defendants argue that typicality is not met because KPH is an assignee and is therefore subject to unique defenses. Specifically, Defendants argue that KPH's assignment is invalid due to lack of meaningful consideration, making them indirect purchasers of brand or generic Amitiza and thus unable to assert antitrust damages. Class certification is inappropriate when "a putative class representative is subject to unique defenses which threaten to become the focus of the litigation." *In re Railway Industry Employee No-Poach Antitrust Litig.*, 395 F. Supp. 3d 464, 500 (W.D. Pa. 2019). Conversely, typicality is not defeated when the unique defense is not

central to the litigation. *See Rodger v. Electronic Data Sys. Corp.*, 160 F.R.D. 532, 538–539 (E.D.N.C. 1995) (finding that the mere availability of certain defenses does not destroy typicality); *See also Riordan v. Smith Barney*, 113 F.R.D. 60, 63 (N.D. Ill. 1986) ("[I]t is only when a unique defense will consume the merits of a case that a class should not be certified.").

Whether KPH's assignment is valid is not a unique defense that is central to this litigation. Even if it were a unique defense, I find that KPH's assignment is valid. The face of the agreement states that the agreement is supported by consideration. [*See* Doc. No. 292-6 ("[I]n consideration of the above Recitals and mutual covenants contained in this agreement, and for other consideration . . . the parties agree as follows")]. This consideration "takes the form of ongoing business and goodwill with McKesson at the time of the assignment." [Doc. No. 319 at 14; *see also* Doc. No. 292-4 at 4, 27:1-5 ("Q: And you're not aware of any other consideration that was - - other than recited in the agreement that was given to McKesson by KPH in exchange for the assignment, correct? A: Correct")]. KPH's corporate representative testified that he was unaware of any *other* consideration, aside from what was already outlined in the agreement, that might have been exchanged. That is not an admission that *no* consideration was exchanged, as Defendants contend. Furthermore, a financial transaction is not necessary to find consideration in a valid contract. *Peterson v. Binnacle Cap. Servs. LLC*, 364 F. Supp. 3d 108, 115 (D. Mass. 2019) ("The definition of a benefit is extremely broad. Thus, even a very slight advantage is sufficient to constitute consideration.") (citations omitted). Accordingly, I find that KPH's claims are typical of the class.

D. Adequacy

Rule 23(a)(4) requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(3). "Although some courts of appeals have set a

high bar for adequacy by requiring that class representatives be active, well-informed, and able to direct the litigation, the First Circuit has not adopted so strict a standard." *Otte ex rel. Est. of Reynolds v. Life Ins. Co. of N. Am.*, 275 F.R.D. 50, 57 (D. Mass. 2011). "The controlling test still requires only that the moving party must show first that the interests of the representative party will not conflict with the interests of any of the class members, and second, that counsel chosen by the representative party is qualified, experienced and able to vigorously conduct the proposed litigation." *Id.* (citation omitted). As with the typicality analysis, I will only refer to Defendants' arguments regarding KPH's adequacy.

Defendants cite to certain testimony of KPH's corporate representative, Brian Scott, the Vice President of Pharmacy Supply Chain, to support its arguments that KPH's "complete deference to outside counsel, blindness to the relative (and potentially competing) financial interests among themselves and counsel, and their stark lack of involvement and familiarly with the case" renders it incapable of adequately representing the interests of the class. [Doc. No. 292 at 14]. Scott's testimony confirms that KPH did not have regularly scheduled meetings with its law firm or anyone else to discuss the litigation. [Doc. No. 292-4 at 7, 210:6-11]. Scott also testified that he was unaware of certain deadlines in this case, such as when fact and expert discovery ends and whether a trial date had been set. [*Id.* at 10-22, 225:10-12; 225:16-226:4]. Scott testified that he does not know whether any underlying factual basis was provided as part of the review of the complaint before it was filed. [*Id.* at 5, 71:13-17]. Scott testified that he was unaware that a motion to dismiss was filed, that a ruling was issued, or that certain claims were dismissed, but that KPH would rely on legal counsel to address these issues. [*Id.* at 7, 210:15-25]. Finally, Scott testified that he did not consult with KPH's legal department regarding whether there are any ongoing investigations of the company or make any other inquiries as to

whether there was anything that could make KPH unfit to be a class representative. [*Id.* at 5-5, 71:20–72:20].

None of this testimony supports that KPH is unable to serve as an adequate class representative. "With respect to [Scott's] knowledge of the case, all that is required of [him] is a general knowledge of the contours of the litigation and personal participation in discovery events." *Est. of Reynolds*, 275 F.R.D. at 57. Here, KPH produced over 16,000 pages of discovery and produced a 30(b)(6) witness, Scott, to sit for nearly 6 hours for a deposition. In preparation for his deposition, Scott reviewed the complaint, discovery responses, purchase data, and met with counsel. [Doc. No. 343-1 at 4-5, 11:18–12:20]. Scott also testified that he believed he understood an adequate class representative to "represent the class, represent them fairly, represent them adequately" and "keep them informed." [*Id.* at 21-22, 201:22-202:3]. And although he could not testify to the specifics, Scott testified that "an enormous amount of time and expense" has been invested into this litigation. [*Id.* at 10-11, 76:13–77:4].

"In complex actions such as this one, named plaintiffs are not required to have expert knowledge of all details of the case, ... and a great deal of reliance on the expertise of counsel is to be expected." *In re Relafen Antitrust Litig.*, 231 F.R.D. 52, 69 (D. Mass. 2005) (citation omitted). Here, "[a]lthough [Scott]'s grasp of the legal claims may be rudimentary, [he] was voluntarily deposed, knows who the parties are and the role of [his] attorneys, understands the nature of a class action suit, and is aware of the basic facts that led to" the suit. *Est. of Reynolds*, 275 F.R.D. at 57. "Courts rarely deny class certification on the basis of the inadequacy of class representatives, doing so only in flagrant cases, where the putative class representatives display an alarming unfamiliarity with the suit, display an unwillingness to learn about the facts underlying their claims, or are so lacking in credibility that they are likely to harm their case." *In*

re Pfizer Inc. Sec. Litig., 282 F.R.D. 38, 51 (S.D.N.Y. 2012) (citation omitted). That is not the case here, and therefore, KPH is an adequate representative.[10]

E. Predominance

DPPs must demonstrate that "questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). "To meet the predominance requirement, the party seeking certification must show that the fact of antitrust impact can be established through common proof and that any resulting damages would likewise be established by sufficiently common proof." *Nexium*, 777 F.3d at 18 (citation omitted). In the context of antitrust cases, there must be common proof demonstrating: (1) an antitrust violation, (2) injury resulting from the violation, and (3) the amount of damages sustained. *See e.g. In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 522 F.3d 6, 19 n.18 (1st Cir. 2008).

1. Antitrust Violation

All proposed class members allege injury from delayed generic entry and allege a violation of the Sherman Act. Defendants do not dispute that "common evidence including

[10] I also find that KPH's share of its aggregate damages relative to the potential fee recovery of class counsel does not warrant an inadequacy finding. Defendants argue that KPH stands to recover, at most, 0.25% of any class wide recovery, which is a "miniscule fraction of any reasonable estimate of a class wide contingent fee recovery for a matter in which aggregate damages are claimed to total over $1.2 Billion." [Doc. No. 292 at 14]. Defendants cite to *Intuniv*, 2019 WL 4645502, at *7, where FWK was held to be an inadequate class representatives given its "close business and personal relationship" with class counsel that "creates significant doubts about whether FWK could or would engage in an arm's length discussion about attorney fees with class counsel." There, Judge Burroughs held that this "concern is heightened because FWK's asserted share of the aggregate damages is a mere 0.3%, and as a result its recovery may prove to far less than the 10% share of Hagens Berman's fees that Mr. Vanek's firms stand to gain." *Id.* However, in that case, there were other concerns of potential conflict that are not present here. Specifically, Judge Burroughs held that "[e]ven without a direct interest in the referral agreement, the relationship between FWK and Mr. Vanek seems so close that the Court is unable to conclude that no conflict of interest is present." *Id.*; *see also id.* (finding that "FWK is functionally an investment vehicle that is the brainchild of class counsel Joseph M. Vanek").

expert testimony on Takeda's conspiracy to delay generic entry, class-wide antitrust injury, and calculation of aggregate damages, as well as testimony and documents from Takeda," will be offered at trial to support Plaintiffs' cause of action. Accordingly, Plaintiffs have proven that common issues regarding the antitrust violation predominate. *Celebrex*, 2017 WL 3669604, at *8 ("Courts deciding whether to certify a class in delayed-entry cases like this one frequently find that common questions of fact and law will predominate when there has been an alleged violation of antitrust law"); *In re Wellbutrin XL Antitrust Litig.*, No. 08-cv-2431, 2011 WL 3563385, at *1 (E.D. Pa. Aug. 11, 2011) ("If 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.").

2. Antitrust Injury

As for proof of antitrust injury, Plaintiffs' expert has provided common evidence that "all or nearly all members of the classes incurred at least some overcharge from impaired generic competition, and therefore suffered injury." [Doc. No. 249 at 28]. The common proof of overcharges includes "(a) academic and government research on the predictable, market-wide effects of generic competition, including empirical research showing that generic prices decline as additional competitors enter the market; (b) forecasts and other internal documents from Takeda and generic manufacturers analyzing the expected market-wide effects of generic competition for Amitiza, including the expected effect of inter-generic competition on prices and volumes; and (c) the actual experience with generic Amitiza competition." [*Id.*].

As discussed briefly above in Section V.A.1.ii., Defendants argue that because the brand-only purchasers did not purchase generic Amitiza after generic entry, individualized inquiry is required to "assess, among other things, each company's business model, policies, customer base

and changes to them over time" to determine whether brand-only purchasers were actually injured. [Doc. No. 292 at 34]. I agree with Plaintiffs that "whether brand purchasers were injured depends on common evidence including transactional data and forecasts," which predominates here because the injury to the brand-only purchasers occurred at the point where they made the purchase at a supra-competitive price, thus denying brand-only purchasers of the "*opportunity* to purchase Amitiza at a lower price." [Doc. No. 380 at 7-8 (emphasis in original)]. Therefore, "it is irrelevant to the injury inquiry whether those same companies (or other companies) would or would not have purchased generic Amitiza had it been available." [*Id.*].

Here, Dr. Conti "has proffered a credible opinion that the allegedly anticompetitive conduct caused all or nearly all putative class members to pay higher prices for [Amitiza], and he has therebefore shown that anticompetitive impact is capable of proof that is common to the class." *In re Intuniv Antitrust Litig.*, No. 1:16-CV-12653-ADB, 2019 WL 4645502, at *10 (D. Mass. Sept. 24, 2019); *Nexium*, 296 F.R.D. at 56 ("[G]eneric bypass cannot preclude recovery and that plaintiffs only need a "viable method" for demonstrating damages common to the class").[11]

3. <u>Antitrust Damages</u>

As for damages, the Supreme Court has "long recognized overcharges as the principal measure of damages for plaintiffs injured as customers." *Nexium*, 296 F.R.D. at 55 (citation omitted). Plaintiffs seek overcharges caused by the allegedly anti-competitive harm. "Overcharge damages are the difference between the actual prices that class members paid and the prices that would have been paid had generic competition not been impaired by the alleged conduct." [Doc.

[11] As I have already found that the thirteen generic-only purchasers lack standing to pursue their claims, I will not address the parties' arguments regarding predominance as they relate to the generic-only purchasers.

No. 249 at 31]; *Celebrex*, 2017 WL 3669604, at *8 (An overcharge "for the purposes of antitrust liability, is the increase in prices caused by the anti-competitive conduct"). Dr. Conti has provided a method to readily measure aggregate damages to the class using common evidence and methodology. Dr. Conti "uses sales data produced by Takeda and generic manufacturers to calculate the prices actually paid for each drug and determines the prices that each class member would have paid using yardsticks derived from sales data for the effects of generic entry for similar drugs. Dr. Conti then applies her overcharge calculation to the total purchases of each class member to calculate the aggregate overcharges suffered by each class member." [Doc. No. 249 at 31-32]. "Aggregate computation of class monetary relief is lawful and proper. Courts have not required absolute precision as to damages." *Nexium*, 296 F.R.D. at 58 (quoting 3 Herbert B. Newberg & Alba Conte, *Newberg on Class Actions* § 10.5, at 483–86 (4th ed. 2002)). I find that DPPs have met their burden of proving common damages under Rule 23(b)(3).

For all of these reasons, DPPs have met their burden of proving that common issues predominate under Rule 23(b)(3).

F. Superiority

To maintain class certification under Rule 23(b), a class action must be "superior" to any other forms of procedural device in insuring the "fair and efficient adjudication of the case." Fed. R. Civ. P. 23(b)(3). "The court considers four factors within the superiority inquiry: (A) the class members' interests in individually controlling the prosecution or defense of separate actions; (B) the extent and nature of any litigation concerning the controversy already begun by or against class members; (C) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (D) the likely difficulties in managing a class action. *Solodyn*, 2017 WL 4621777, at *21. "The Court here considers the alternatives to class action, conscious that

'[t]he policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights.'" *Id.* (citing *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 617 (1997)).

Defendants argue that a class action is not superior because some of the proposed class members have the capability to pursue their own claims individually. However, as already discussed above, Plaintiffs have put forth evidence that individual plaintiffs are unlikely to proceed individually, and that the principles of judicial efficiency and economy in avoiding the multiplicity of individual lawsuits and inconsistent results show that a class action is superior to other forms of litigation. *Id.* (citing *Relafen*, 221 F.R.D. at 288) ("Indeed, the consolidation of several related claims, from multiple districts and consisting of DPPs as well, within this court suggests "consistency would be best served by 'concentrating the litigation' in this forum").

Accordingly, DPPs' Motion for Class Certification is GRANTED.

VI. THE END-PAYORS

The EPPs have also moved for class certification. [Doc. No. 395]. The proposed EPP classes are comprised of thousands of third-party payors ("TPPs"), organizations that bear the insurance risk for their members' prescription drug purchases, including private health insurers like Premera, self-insured employes, and Taft-Hartley funds. The EPPs bring antitrust, consumer protection, and unjust enrichment claims under various state laws. On September 30, 2024, the court adopted the Magistrate Judge's Report & Recommendation and approved the dismissal of certain state-specific claims. [Doc. No. 87]. EPPs now seek certification of a Damages Class and an Unjust Enrichment Class:

(1) *Damages Class*: All entities that indirectly purchased or paid for some or all of the purchase price of Amitiza and/or AB-rated generic versions of Amitiza in Arizona,

California, Connecticut (7/10/2017 or later), District of Columbia, Florida, Hawaii, Iowa, Kansas, Maine, Maryland (10/1/2017 or later), Michigan, Minnesota, Nebraska, Nevada, New Mexico, New York, North Carolina, North Dakota, Oregon, Rhode Island, South Dakota, Tennessee, Vermont, and Wisconsin, from any of the Defendants or any other generic manufacturer, or their subsidiaries or affiliates, from October 1, 2016, through and until the anticompetitive effects of Defendants' conduct cease (the "Class Period")

(2) *Unjust Enrichment Class*: All entities that indirectly purchased or paid for some or all of the purchase price of Amitiza and/or AB-rated generic versions of Amitiza in Alabama, Arizona, California (11/30/2021 or later), Colorado (6/7/2023 or later), Connecticut (7/10/2017 or later), District of Columbia, Hawaii, Iowa, Kansas, Maine, Maryland (10/1/2017 or later), Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, Oregon, Rhode Island, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, from any of the Defendants or any other generic manufacturer, or their subsidiaries or affiliates, from October 1, 2016, through and until the anticompetitive effects of Defendants' conduct cease (the "Class Period")

(3) The following persons and/or entities are excluded from both Classes: (a) natural person consumers; (b) Defendants, their officers, directors, management, employees, subsidiaries, and affiliates; (c) all federal and state governmental entities except for cities, towns, municipalities, or counties with self-funded prescription drug plans; (d) all persons or entities who purchased Amitiza or its AB-rated generic for purposes of resale from any of the Defendants or any generic manufacturer; (e) fully insured health plans (i.e., health plans that purchased insurance covering 100% of their obligation to members); and (f) pharmacy benefit managers.

[Doc. No. 395]. Like the DPPs, the EPPs have detailed how their class satisfies the four factors of Rule 23(a) and 23(b)(3). The four factors of Rule 23(a) are not in dispute. Takeda primarily disputes that EPPs have satisfied the requirements for Rule 23(b)(3): ascertainability, predominance, and superiority. Specifically, Takeda argues that the EPP classes should not be certified because "(i) no administratively feasible mechanism exists for ascertaining the proposed classes prior to judgment, (ii) individual issues predominate over common issues, and (iii) individualized inquiry is necessary to distinguish whether a payor is a class member that was injured by the allegedly anticompetitive conduct." [Doc. No. 505 at 6].

A. Predominance

EPPs must show that common issues of law or fact predominate over any questions affecting only individual members. Fed. R. Civ. P. 23(b)(3). The First Circuit has outlined three principles guiding the predominance inquiry: "(1) 'the theory of liability is limited to the injury caused by defendants'; (2) 'the definition of the class must be 'definite,' that is, the standards must allow the class members to be ascertainable'; and (3) 'where an individual claims process is conducted at the liability and damages stage of the litigation, the payout of the amount for which the defendants were held liable must be limited to injured parties.'" *Solodyn*, 2017 WL 4621777, at *13 (citing *In re Nexium Antitrust Litig.*, 777 F.3d 9, 18–19 (1st Cir. 2015) ("*Nexium III*")). Defendants argue that EPPs have failed to show that the class is sufficiently ascertainable and have failed to put forth common proof of class-wide injury.

1. Ascertainability

"At the class certification stage, the court must be satisfied that, prior to judgment, it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members. The court may proceed with certification so long as this mechanism will be administratively feasible, and protective of defendants' Seventh Amendment and due process rights." *Nexium III*, 777 F.3d at 19 (citation omitted); *In re Asacol Antitrust Litig.*, 907 F.3d 42, 52 (1st Cir. 2018). EPPs must show that the class is "currently and readily ascertainable based on objective criteria." *Ranbaxy*, 338 F.R.D. at 307 (citing *Nexium III*, 777 F.3d at 19). "At the certification stage, it is unnecessary to identify every class member but the class must be sufficiently ascertainable to permit a court to decide and declare who will receive notice, who will share in any recovery, and who will be bound by the judgment." *Id.* (citing *Schonton v. MPA Granada Highlands LLC*, No. 16-cv-12151, 2019 WL 1455197, at *3 (D. Mass. Apr. 2, 2019)).

EPPs' proposed methodology for ascertaining the class is to reference readily available pharmaceutical transaction claims data that is available for all class members from the TPPs themselves, or through intermediaries such as Pharmacy Benefit Managers ("PBMs") and third-party administrators ("TPAs"), who administer pharmacy benefits for other TPPs. EPPs argue that these claims data detail each and every purchase of any given prescription drug, and that "EPPs can identify class members by reference to the objective criteria in the class definition: purchases of Amitiza and/or their AB-rated generic equivalents, not for resale; in applicable states; and during the relevant time period." [Doc. No. 396 at 25–26]. A declaration provided by Eric Miller, a claims administrator and executive vice president of A.B. Data, a class action administration company, explains that "the high level of detail contained within the data (purchase date, location of purchase, national drug code (NDC), quantity purchase, and amount paid), make processing TPP [class membership] claims straightforward." [*Id.* at 26 (citing Doc. No. 397-9 at 6)]. EPPs have also provided the opinions and testimony of Dr. Martin Kovach, EPPs' "ascertainability" expert, and a declaration of Mark Fischer, President of Rawlings Analytics, LLC, a company that provides pharmacy claims analytics services to TPPs and TPAs and has access to claims data on over 300 million Americans. EPPs proffer that class exclusions will be simple because "A.B. Data 'routinely employs standard techniques to ensure that persons and entities that are not within the class definition do not receive a payment from the recovery.'" [*Id.* at 27 (Doc. No. 397-9 at 7)]. EPPs also argue that "in each case for which a health plan retained Rawlings to identify claims for filing in TPP cases, Rawlings was able to 'differentiate[] between claims in which the client was acting as a self-funded plan sponsor and in which the client was operating in an administrative services capacity.'" [*Id.* at 28 (citing Doc. No. 397-8 at 4)].

Defendants argue that the class is not ascertainable primarily because (1) assurances that the data is available and can be analyzed later is not a methodology, (2), EPPs' proposed method of ascertaining the class is not administratively feasible, and (3) identifying excluded entities will require individual inquiry and EPPs cannot rely on certifications to do so.

First, I find that EPPs have proven that they have a methodology for identifying and excluding class members that is administratively feasible. Defendants argue that Plaintiffs' proposal to maintain or obtain receipts of claims data to establish ascertainability is insufficient because none of the supporting expert testimony or declarations submitted by Mr. Miller or Mr. Fischer actually explain how that methodology works. But that is not the standard. In *Nexium III*, for example, the First Circuit found a class ascertainable even where no mechanism for the exclusion of brand-loyalist consumers had been proposed, because "plaintiffs' expert made no concession that such a mechanism could not be developed, nor did defendants' expert say that it could not be developed." *Nexium III*, 777 F.3d at 20. The First Circuit held that it had "confidence that a mechanism would exist for establishing injury at the liability stage of this case, compliant with the requirements of the Seventh Amendment and due process." *Id.* at 21.

EPPs provide detailed testimony from: (1) Dr. Martin Kovach, who has extensive experience as an expert in pharmaceutical class actions and is the co-author of a book on pharmaceutical data litigation, (2) Eric Miller, who has 20 years of experience as a claims administrator and unique experience in administering pharmaceutical drug class actions utilizing claims data from TPP class members, (3) Mark Fischer, President of Rawlings Analytics, a company that provides pharmacy claims analytics services to TPPs and TPAs, and (4) Joey Coates, Director of Pharmacy and Clinical Consulting for named plaintiff Premera, who explained the nature of the data available to Premera in its role as a TPP and as a TPA for other

TPPs. EPPs have thus provided ample support for the feasibility of the methodology proposed. Indeed, other courts have routinely accepted the analysis of claims data as a proper method for ascertainability, including in cases where EPPs relied on testimony from Mr. Miller and Rawlings. *See, e.g., In re Generic Pharms. Pricing Antitrust Litig.*, No. 16-cb-27242, 2025 WL 754567, at *23 (E.D. Pa. Mar. 7, 2025) (certifying EPP class and finding, based on Mr. Miler's "significant experience as someone with decades in this field of work," that "third-party payers regularly produce this type of data during the claims administration process"); *In re Loestrin 24 FE Antitrust Litig.*, 410 F. Supp. 3d 352, 399 (D.R.I. 2019) (certifying EPP class and holding that "[p]rescription drug transactions are well documented and TPPs have the capability to retrieve information about the drugs they have purchased, the date on which they were purchased, and the price paid for the drugs").

Second, as to Takeda's "feasibility" argument, Takeda overstates the difficulty of processing the datasets here, as EPPs' expert has testified that obtaining and processing these datasets is a matter of "simple programming." [Doc. No. 527 at 25]. Further, EPPs have adequately addressed any gaps or inconsistencies in the Fischer, Miller, and Premera declarations, as well as Dr. Kovach's expert reports, and have shown that any individual inquiry required to address such inconsistencies is minimal. *See Solodyn*, 2017 WL 4621777, at *13 (crediting extensive experience of expert who opined that "in the pharmaceutical industry, data is collected and maintained at every level of the transaction," which makes "ascertaining class membership here administratively feasible"). Takeda's assertion that the proposed methodology would not take place until after liability is also unsupported. *Id.* at *16 ("EPPs propose that a mechanism can be developed to exclude them prior to judgment, which is all that is required at this time").

Finally, Defendants argue that EPPs' proposed methodology requires individual inquiry into claims data to determine which entities must be excluded. Defendants point to two specific examples: identification of fully insured plans, and identification of federal and state government entities. This argument does not hold water.

As for fully insured plans, "insurers are always able to differentiate between fully insured and self-funded plans." *Generics*, 2025 WL 754567, at *24. EPPs have provided testimony from Ms. Coates that "[w]hen operating as a TPA, Premera does, and by necessity must, maintain data that automatically differentiates its ASO's claims from its fully insured business. Further, this data does, and must, enable Premera to automatically identify which of its self-funding clients is responsible for each claim." [Doc. No. 527 at 26 (citing Doc. No. 397-10 at 3)]. Even if certain information is missing, such as funding type data, EPPs argue that the data can be easily produced if necessary. Additionally, "Mr. Miller testified that whether a plan is fully insured or self-funded 'is information that would be in our claim form and template and file accordingly.'" [Doc. No. 527 at 27 (citation omitted)].

As to federal and state government entities, Dr. Kovach has explained that those entities can be identified and excluded using multiple sources of objective data, including the plan sponsor's name, confirmation of this information in each insurer's "enrollment data base," and requests to Rawlings and/or TPPs to identify or exclude federal and state government entities among the plan sponsors in the claims data.[12] [*Id.* at 28]; *Loestrin*, 410 F. Supp. 3d at 401

[12] Defendants cite to *In re Niaspan Antitrust Litig.*, 464 F. Supp. 3d 678, 705 (E.D. Pa. 2020) to argue that excluding federal and state governmental entities based on plan name alone is insufficient. But that case is inapposite. There, EPPs presented an "individualized, *ad hoc* approach" that the court found could not address many of the class exclusions. As for federal and state entities, the EPPs stated those exclusions could be done because federal and government agencies are "facially obvious." *Id.* at 705. Defendants provided evidence that such plans were not facially obvious. *Id.* The court held that even if they were obvious, EPPs have not explained how they intend to apply that exclusion to its putative class. *Id.* Here,

(certifying class and finding sufficient that EPPs can "request that the PBMs remove federal and state plans from their dataset" and that EPPs' expert "will be able to identify them by name").

Mr. Miller has also explained that in the claims administration process, A.B. Data has each claimant certify that it is not a federal or state governmental entity. *See, e.g.*, *In re Namenda Indirect Purchaser Antitrust Litig.*, 338 F.R.D. 527, 549 (S.D.N.Y. 2021) ("Craft notes that PBMs processing the insurance claims would know the identity of any government entities . . . that they service . . . [i]nformation about state/federal insurance plans is also publicly available, and so whoever is analyzing the raw PBM data could use this information to apply the exclusion"). Even if some individual inquiry is required, any such inquiry would not prohibit a finding of ascertainability. *Soutter v. Equifax Info. Servs., LLC*, 307 F.R.D. 183, 197 (E.D. Va. 2015) ("[T]he time and effort required" to "determine the members of the class by reference to objective criteria . . . have no bearing on whether the individuals are or are not objectively ascertainable").

Relatedly, Defendants rely on *Asacol* to challenge EPPs' reliance on certifications that potential class members are eligible and do not fall within any excluded groups. 907 F.3d 42. Unlike here, in *Asacol*, EPPs sought to certify a class of individual consumers. *Id.* at 46. The First Circuit considered whether EPPs put forth a proper method for identifying and excluding uninjured brand-loyal class members. *Id.* at 51. EPPs proposed that a class administrator could evaluate each claim submitted by individual consumers, and then those members would have the opportunity to contest those calculations and make any changes it believes are necessary. *Id.* at 52. The First Circuit held that unlike *Nexium III*, which permits "unrebutted testimony" contained in affidavits as a mechanism for identifying injured and uninjured class members,

however, EPPs adequately describe and provide evidence in support of their methodology for handling these exclusions, and do not simply claim that such exclusions would be "obvious."

individual testimony from consumers could be "genuinely challenged." *Id.* at 53. Therefore, permitting certification based on such testimony would interfere with defendants' rights to challenge such affidavits.

That is not the case here, where EPPs propose to submit certifications from class members that they are neither fully insured nor governmental entities. This is information that can be readily verified by objective criteria, and "Defendants offer no convincing reason to think affidavits would be insufficient here, nor is there reason to believe the class members would not answer truthfully." *In re Xyrem (Sodium Oxybate) Antitrust Litig.*, No. 20-md-02966, 2023 WL 3440399, at *8 (N.D. Cal. May 12, 2023); *Gov't Emps. Health Ass'n v. Actelion Pharms. Ltd.*, 2024 WL 4122123, at *11 (D. Md. Sept. 6, 2024) (certifying class where proposed methodology included "a combination of detailed pharmaceutical data sets and affidavits contained in claims forms").[13]

2. Common Proof Of Injury

Defendants argue that individual issues overwhelm common questions of law or fact because a large number of class members are uninjured. Defendants argue that brand-loyal TPPs are uninjured because EPPs ignore the real-world evidence that shows that many TPPs never switched to generic Amitiza or stopped paying for Amitiza entirely before entry. Defendants also argue that generic-only TPPs were uninjured because the real-world evidence shows there was no correlation between the number of generic Amitiza competitors and generic Amitiza prices,

[13] *Lipitor* is inapposite. In *Lipitor*, EPPs' relied largely on the "say so of PBM executives' Declarations," and did not "provide the Court with evidence that the data provided from multiple different entities could be harmonized." *In re Lipitor Antitrust Litig.*, No. 3:12-cv-2389, 2024 WL 2865074, at *17 (D.N.J. June 6, 2024). Here, EPPs do not intend to rely on "PBM data alone" and have provided evidence that the data in their proposed methodology can be harmonized. *See also Generics*, 2025 WL 754567, at *23, 26 ("[T]he fact that EPPs have already demonstrated the existence and availability of that information differentiates it from *Lipitor*, wherein plaintiffs were only able to produce declarations that data existed without actual evidence that it could be obtained").

but rather, a fluctuation in the prices (both increases and decreases) following the launch of new generics. Both theories fail.

Injury occurs at the point of sale, where the overcharge occurs. *Ranbaxy*, 338 F.R.D. at 306 ("[A]ntitrust injury occurs at the moment of the overcharge regardless of later rebates or other offsets. That some TPPs may have ultimately paid more for generics is relevant to the amount of damages incurred but not for determining antitrust impact"). Dr. Kovach's report opines that "all or virtually all members of the Classes were injured by the alleged delay in generic entry." [Doc. No. 527 at 10 (citing Doc. No. 397-1 at 60)]. This is based on his analysis of real-world data to support the contention that when generic lubiprostone would have first entered in any of EPPs' but-for scenarios, it would have rapidly captured the great majority of the brand's prescriptions. Dr. Kovach has shown that in the real-world, the conversion rate for Amitiza was 80% after one year, 90% after two years, and 97% after 3 years. Dr. Kovach has provided evidence that these conversion rates would have been higher but-for the alleged anticompetitive conduct. Accordingly, there is a high probability that class members were overcharged. This theory of injury has been supported by other EPP class certification decisions. As the court held in *Solodyn*, "the likelihood that Defendants' arguments are inflating the number of uninjured members is even greater here . . . an insurer with brand-loyal members is only uninjured here if every one of its members would have been brand-loyal for all [Amitiza] purchases in each "but-for" scenario . . . [i]t is highly unlikely, therefore, that institutional payors were uninjured even if some of their members are brand-loyal or purchased the generic during the period in question." 2017 WL 4621777, at *18; *see also Loestrin*, 410 F. Supp. 3d at 402 ("The EPPs have demonstrated through Dr. French's sound analysis, by a preponderance of the evidence, that the TPPs that did not purchase generic Loestrin 24 and/or Minastrin in the actual

world were indeed injured because they would have made at least a single purchase of an AB-rated generic equivalent in the but-for world"); *Ranbaxy*, 338 F.R.D. at 306 (expert was able to show that "brand loyalty is doubtful among TPPs and that meaningful generic competition would likely cause all TPPs to purchase generics").

B. Superiority

Finally, Defendants argue that EPPs fail to demonstrate superiority because independent actions recently filed in state court by three major insurers, the Massachusetts ASOs, create a risk of duplicative claims and administrative burdens tied to identifying which entities remain in this class action. Specifically, Defendants argue that if the Massachusetts ASOs—who bring these claims on behalf of themselves, subsidiaries, and ASO customers—have standing to bring claims on behalf of those ASO customers, the claims administrator in this case will have to resolve duplicative claims and make individualized inquiries to determine which ASO customers are represented by these presumed opt outs.

EPPs have put forth evidence that A.B. Data is well-positioned to identify and remove duplicate claims, and Defendants have not put forth evidence to the contrary. As such, I find that "both fairness and efficiency support class certification, where otherwise the numerous individual class members would be forced to file suit individually, producing numerous identical issues in each case that would waste judicial resources and leave all parties vulnerable to unfair inconsistencies." *Solodyn*, 2017 WL 4621777, at *21 (citation omitted); *see also id.* ("To the extent that trial management difficulties arise in the future, they can and will be addressed by the Court through the structuring of the trial in this matter").

VII. CONCLUSION

For the above reasons, the Direct Purchaser Plaintiffs' Motion, [Doc. No. 248], is GRANTED in part and DENIED in part. Defendants' Motion to Strike Plaintiffs' Amended Class Definition, [Doc. No. 365], is GRANTED. I adopt Plaintiffs' initial class definition and exclude from the class Meijer and the thirteen AG-only purchasers who purchased directly from DRL and Sun. Plaintiffs' Motion to Require Takeda to Withdraw Letters to Absent Class Members, [Doc. No. 295], is GRANTED in part, to the extent that Takeda must withdraw those letters, but DENIED in part, to the extent that it requests prohibiting Takeda from further communicating with those class members. Defendants' Motion to Exclude the opinions of Dr. Conti, [Doc. No. 363], and Motion to Strike the declaration of Attorney Sobol, [Doc. No. 290], are DENIED. EPP's Motion for Class Certification, [Doc. No. 395; 23-cv-12918 Doc. No. 117], is GRANTED and Defendants' Motion to Exclude Certain Opinions of Dr. Martin E. Kovach, [Doc. No. 545; 23-cv-12918 Doc. No. 152], is DENIED.

SO ORDERED.

/s/ Myong J. Joun
United States District Judge