UNITED STATES DISTRICT COURT MIDDLE DISTRICT OF TENNESSEE NASHVILLE DIVISION

THE HOSPITAL AUTHORTIY OF)
METOPOLITAN GOVERNMENT OF)
NASHVILLE AND DAVIDSON)
COUNTY, TENNESSEE, d/b/a)
NASHVILLE GENERAL HOSPITAL) No. 3:15-cv-01100
and AMERICAN FEDERATION OF)
STATE, COUNTY AND MUNICPAL)
EMPLOYEES DISTRICT COUNCIL 37)
HEALTH & SECURITY PLAN,)
)
Plaintiffs,)
)
v.)
)
MOMENTA PHARMACEUTICALS,)
INC. and SANDOZ INC.,)
)
Defendants.)

MEMORANDUM OPINION

Pending before the Court is Nashville General Hospital ("NGH") and American Federation of State, County and Municipal Employees District Council 37 Health & Security Plan's ("DC 37") (collectively "Plaintiffs") Renewed Motion for Class Certification and Appointment of Class Counsel. (Doc. No. 349.) Momenta Pharmaceuticals, Inc. ("Momenta") and Sandoz Inc. ("Sandoz") (collectively "Defendants") have responded in opposition (Doc. No. 361) and also filed a Motion to Exclude the Report and Opinions of Plaintiffs' Expert Dr. Russell L. Lamb (Doc. No. 360). Plaintiffs filed both a reply in support of their renewed class certification motion (Doc. No. 369) and a response to Defendants' Motion to Exclude (Doc. No. 367). The Court held an evidentiary hearing on these motions on July 12, 2019. After the evidentiary hearing, the Court requested post-hearing briefs from the parties, which have been filed. (Doc. Nos. 384, 387.) At the Court's count, there have been no fewer than seven briefs regarding class certification, one aborted evidentiary hearing, amendment of the class definition, and one full evidentiary hearing. Needless to say, these issues are ripe and ready to be decided. For the reasons that follow, the Court will deny Defendants' Motion to Exclude the Report and Opinions of Plaintiffs Expert Dr. Russell L. Lamb and grant Plaintiffs' Renewed Motion for Class Certification.

A. <u>Procedural Background</u>¹

On October 14, 2015, NGH filed its initial complaint against the Defendants, alleging four separate counts under the Sherman Antitrust Act ("Sherman Act"). (Doc. No. 1.) NGH sought damages, as well as declaratory and injunctive relief. (Id. at 27.) NGH brought its claims on behalf of itself and a nationwide class of persons and entities, pursuant to the Class Action Fairness Act of 2005 ("CAFA") and Fed. R. Civ. P. 23(a) and (b). (Id. at 6, 21.) As explained in more detail in Section B infra, the alleged Sherman Act violations centered on the role that Defendants played in a conspiracy to monopolize the production and distribution of enoxaparin, a generic version of the drug Lovenox®. (Id. at 4-23.)

In response to the complaint, Defendants filed a motion to transfer the case to the District of Massachusetts and a Motion to Dismiss. (Doc. Nos. 65, 68.) Momenta additionally filed a separate Motion to Dismiss or Transfer for Improper Venue. (Doc. No. 62.) On September 29, 2016, Magistrate Judge Barbara Holmes entered a Report and Recommendation recommending that the motions be denied. (Doc. No. 114.) Defendants filed joint and separate objections to the Report and Recommendation. (Doc. Nos. 117, 119.) On March 21, 2017, the Court issued a

¹ The following procedural and factual background is largely drawn from the Court's prior Memorandum Opinion granting in part and denying in part Defendants' Motions to Dismiss. (See Doc. No. 253.) The Court reiterates this background information to properly contextualize the parties' class certification arguments.

Memorandum Opinion that adopted in part and declined to adopt in part the Report and Recommendation. (Doc. No. 134.) The Court dismissed NGH's Sherman Act claims on the ground that NGH did not have standing to seek damages under the "indirect purchaser rule." (<u>Id.</u> at 8-14.) However, NGH's Sherman Act claims were permitted to proceed on declaratory and injunctive theories of relief. (<u>Id.</u> at 16.)

Thereafter, NGH filed a motion for leave to file an amended complaint. (Doc. No. 140.) The amended complaint contained three primary changes: (1) the addition of DC 37 as a new representative plaintiff; (2) the addition of various state antitrust and consumer protection claims; and (3) the addition of new substantive allegations pertaining to Defendants' alleged anticompetitive conduct. (Doc. No. 141 at 5.) Defendants filed a response in opposition. (Doc. No. 148.) Ultimately, Magistrate Judge Holmes granted Plaintiffs' motion for leave to file an amended complaint, and Plaintiffs filed their amended complaint on December 21, 2017. (Doc. No. 191.) Defendants then filed three Motions to Dismiss under Federal Rules of Civil Procedure 12(b)(1), 12(b)(2), and (12)(b)(6). (Doc. Nos. 193, 195, 197.) The Court granted Defendants' Rule 12(b)(1) motion, denied the Rule 12(b)(2) motion, and granted in part and denied in part the 12(b)(6) motion. (See Doc. No. 253.) The net result of these rulings was that Plaintiffs' federal Sherman Act claims were dismissed but the majority of their state law antitrust claims were allowed to proceed. (See Doc. No. 254 at 1-2.) Defendants filed two Motions for Reconsideration of the Court's Rule 12(b)(2) ruling, both of which were denied. (See Doc. Nos 257, 258, 275, 276.)

The parties then proceeded to the class certification phase. After Plaintiffs' initial Motion for Class Certification (Doc. No. 243) was fully briefed, the Court determined that an evidentiary hearing was necessary and set the hearing for May 13, 2019. (See Doc. No. 283.) At the conclusion of the first day of the evidentiary hearing, the Court inquired into the Plaintiffs' objective criteria

for identifying members of the class. (See Doc. No. 329 at 172.) In response to this line of inquiry, Plaintiffs returned the next day with an amended class definition that contained substantial changes. (Doc. No. 330 at 12.) In light of this development, the Court continued the evidentiary hearing, denied Plaintiffs' initial Motion for Class Certification (Doc. No. 243) as moot, and allowed Plaintiffs leave to file a Motion to Amend the Class Definition (Doc. No. 318). Plaintiffs filed their Motion to Amend the Class Definition (Doc. No. 321), which the Court granted. (Doc. No. 340.) The parties then briefed the new class definition, the Court held another evidentiary hearing, and the matter is now ripe for disposition.

B. Factual Background

NGH is a metropolitan charity hospital that purchases certain drugs it administers, including the generic anticoagulant enoxaparin. (Doc. No. 191 at 6-7.) DC 37 is a non-profit health and welfare benefit plan covering public sector employees, retirees and their families. (<u>Id.</u>) Plaintiffs allege that they have, and will continue to, indirectly purchase or provide reimbursement for Lovenox® and enoxaparin. (<u>Id.</u> at 7-8.)

The drug at issue, enoxaparin, is used in the prevention and treatment of deep vein thrombosis and in the treatment of heart attacks. (<u>Id.</u> at 10.) Sanofi-Aventis ("Aventis"), a non-party to this lawsuit, brought enoxaparin to market in the United States under the brand name Lovenox® and held a patent on the drug, which was subsequently held to be unenforceable in 2007. (<u>Id.</u> at 10-11.)

However, Momenta is the assignee of a patent (the "886 Patent") for a chemical process used to test the quality of enoxaparin ("Method <207>"). (<u>Id.</u> at 13.) In 2003, Momenta entered into a collaboration agreement (the "Collaboration Agreement") with Sandoz, whereby Sandoz eventually began manufacturing and selling generic enoxaparin. (<u>Id.</u> at 11-14.) The Collaboration

Agreement provided for profit-sharing between Momenta and Sandoz regarding Sandoz's sales of its generic enoxaparin, so long as Defendants remained the sole source of generic enoxaparin in the United States. (Id. at 13.) Further, the Collaboration Agreement provided for Momenta to receive "milestone payments" if Sandoz remained the sole supplier of generic enoxaparin. (Id.) Essentially, the Collaboration Agreement provided Momenta with a powerful incentive to use whatever rights it had to prevent other parties from entering the generic enoxaparin market.

By 2007, Aventis had requested that the United States Pharmacopeial Convention ("USP") adopt criteria for enoxaparin that included a standardized test to assure that enoxaparin produced by drug companies in the United States met chemical criteria approved by the FDA.² (Id. at 16.) Aventis's proposed method for testing enoxaparin was Method <207>. (Id.) At that time, Aventis had a pending patent application for Method <207>. (Id. at 17.) Defendants, who participated in the relevant USP review panel, objected to Aventis having a patent that covered a standardized USP test, contending that the test, once adopted, should be free for anyone to use. (Id.) After discussions with USP, Aventis agreed to abandon its patent application. (Id. at 18.) However, unbeknownst to the USP panel, Momenta had its own patent application pending—the 886 Patent—that, when granted, would give Momenta patent rights that could be asserted against third parties that used Method <207>. (Id. at 18-19.) In December 2009, the USP approved and adopted Method <207> as the standardized test to assure enoxaparin quality, and the 886 Patent was issued shortly thereafter. (Id. at 13, 19.) Plaintiffs allege that, had Defendants disclosed their own application for the 886 Patent, the USP would have either required Momenta to abandon its patent

² The USP is a scientific nonprofit organization that sets standards for identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements that are manufactured, distributed, and consumed worldwide, and the USP standards are enforceable as binding by the United States Food and Drug Administration ("FDA"). 21 U.S.C. § 351(b).

rights, as it did with Aventis, or chosen an alternative test that would not have been subject to patent protection. (<u>Id.</u> at 19.)

Defendants became the first entities authorized by the FDA to produce generic enoxaparin. (Id. at 20.) Thereafter, Amphastar Pharmaceuticals, Inc. ("Amphastar"), a non-party to this case, received FDA approval to sell generic enoxaparin on September 19, 2011. (Id. at 21.) Upon approval, the FDA instructed Amphastar to use the USP compendium for enoxaparin, including Method <207>. (Id.) Two days later, Defendants sued Amphastar in the District of Massachusetts, contending that it was essentially illegal for Amphastar use Method <207> and produce generic enoxaparin because it could not do so without infringing on the 886 Patent. (Id.) After filing their complaint, Defendants obtained a temporary restraining order and preliminary injunction preventing Amphastar from selling enoxaparin. (Id. at 22.) However, the U.S. Court of Appeals for the Federal Circuit stayed the preliminary injunction in January 2012 and vacated it in August 2012. (Id.)

Plaintiffs, in their Amended Complaint, assert that Defendants' alleged anticompetitive activity violates numerous states' antitrust, consumer protection, and unjust enrichment laws. (Doc. No. 193 at 35-73.) As explained above, Plaintiffs now seek class certification.

C. Plaintiffs' Renewed Motion for Class Certification

Plaintiffs seek certification of the following class:

Hospitals, third-party payors, and people without insurance who indirectly purchased, paid for, and/or reimbursed some or all of the purchase price for, generic enoxaparin or Lovenox®, in Arizona, Arkansas, California, District of Columbia, Florida, Hawaii, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, South Dakota, Tennessee, Utah, Vermont, West Virginia, and Wisconsin, from September 21, 2011, through September 30, 2015 (the "Damages Class Period"), for the purpose of personal consumption by themselves, their families, or their members, employees, insureds, participants, patients, beneficiaries or anyone else.

With respect to third-party payors and people without insurance, the Damages Class only includes those, described above, who purchased, paid for, and/or reimbursed some or all of the purchase price for, generic enoxaparin or Lovenox® from a pharmacy.

Excluded from the proposed Damages class are:

- a. Defendants, their officers, directors, management, employees, subsidiaries, and affiliates;
- b. Federal and state governmental agencies except for cities, towns, municipalities, counties or other municipal government entities, if otherwise qualified;
- c. Payors that received 100% reimbursement on all transactions, such as fully insured health plans (i.e., plans that purchased insurance covering 100% of their reimbursement obligation to members); and
- d. Judges assigned to this case and any members of their immediate families.

(Doc. No. 349 at 2-3.)

D. Daubert Motion

As a preliminary matter, Defendants argue that Dr. Lamb's expert opinions should be excluded from consideration, pursuant to Federal Rule of Evidence 702 and <u>Daubert v. Merrell</u> <u>Dow Pharmaceuticals., Inc.</u>, 509 U.S. 579 (1993), because: (1) he did not perform a reliable empirical analysis; (2) the lack of empirical analysis led Dr. Lamb to rely on assumptions and vague "economic literature"; and therefore; (3) his opinion is not based on sufficient facts or data. (Doc. Nos. 360, 363 at 9-11, 387 at 21-22.)

Plaintiffs respond that the motion should be denied on the merits because Defendants have not met the standard to exclude Dr. Lamb's testimony under Fed. R. Evid. 702 and <u>Daubert</u>. (Doc. No. 367 at 2.) Plaintiffs contend that Defendants' arguments go to the weight of the evidence, rather than its admissibility. (<u>Id.</u>) Further, Plaintiffs note that the statistical regression analysis Defendants assert is missing is not necessary because the pharmaceutical industry is based on formulaic markups not individualized pricing schemes. (<u>Id.</u>)

First, the Court notes that Defendants' <u>Daubert</u> motion is subject to denial for noncompliance with the Court's Local Rules. The Court's Local Rules provide that "every motion that may require the resolution of an issue of law must be accompanied by a separately filed memorandum of law citing supporting authorities and, where allegations of fact are relied upon, affidavits, depositions, or other exhibits in support thereof." LR 7.01(a)(2). Defendants have included their <u>Daubert</u> motion arguments in their response to Plaintiffs' class certification motion (Doc. No. 363) and post-hearing brief (Doc. No. 401)—neither of which is a "<u>separately filed</u> <u>memorandum</u>" in support of their <u>Daubert</u> motion. <u>Id.</u> (emphasis added). Accordingly, Defendants' <u>Daubert</u> motion may be denied based on its failure to comply with the Court's Local Rules. <u>See Grove v. Wells Fargo Fin. California, Inc.</u>, 606 F.3d 577, 582 (9th Cir. 2010) (holding that denial of a motion as the result of a failure to comply with local rules is well within a district court's discretion).

Nevertheless, Defendants' <u>Daubert</u> motion also fails on the merits. Federal Rule of Evidence 702 governs the admissibility of an expert witness' testimony at trial. <u>Daubert</u>, 509 U.S. at 589. Under Rule 702:

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

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

(d) the expert has reliably applied the principles and methods to the facts of the case.

"[T]he trial judge has discretion in determining whether a proposed expert's testimony is admissible based on whether the testimony is both relevant and reliable." <u>Palatka v. Savage Arms,</u> <u>Inc.</u>, 535 Fed. Appx. 448, 453 (6th Cir. 2013) (quotation omitted). The Court's task is to assess "whether the reasoning or methodology underlying the testimony is scientifically valid and . . . whether that reasoning or methodology properly can be applied to the facts in issue." <u>Daubert</u>, 509 U.S. at 592–93.

The district court acts as the "gatekeeper" on opinion evidence, <u>Gen. Elec. Co. v. Joiner</u>, 522 U.S. 136, 142 (1997), and must exercise its gatekeeping function "with heightened care." <u>U.S. v. Cunningham</u>, 679 F.3d 355, 380 (6th Cir. 2012) (quotation omitted). The Court will not exclude expert testimony "merely because the factual bases for an expert's opinion are weak." <u>Andler v. Clear Channel Broad., Inc.</u>, 670 F.3d 717, 729 (6th Cir. 2012) (citations omitted). Indeed, rejection of expert testimony is the exception rather than the rule—the gatekeeping function established by <u>Daubert</u> was never "intended to serve as a replacement for the adversary system." <u>See Rose v. Matrixx Initiatives, Inc.</u>, Case No. 07-2404-JPM/tmp, 2009 WL 902311, at *7 (W.D. Tenn. 2009) (citing Fed. R. Evid. 702 advisory committee's note).

Rule 702 does not "require anything approaching absolute certainty." <u>Tamaraz v. Lincoln</u> <u>Elec. Co.</u>, 620 F.3d 665, 671–72 (6th Cir. 2010) (citing <u>Daubert</u>, 509 U.S. at 590). Under <u>Daubert</u>, experts are "permitted wide latitude in their opinions, including those not based on firsthand knowledge, so long as the expert's opinion has a reliable basis in the knowledge and experience of the discipline." <u>Dilts v. United Grp. Servs., LLC</u>, 500 Fed. Appx. 440, 445 (6th Cir. 2012) (quoting <u>Daubert</u>, 509 U.S. at 592) (internal quotation marks omitted). Expert testimony is reliable if it (1) is based on sufficient facts or data, (2) is grounded in reliable principles and methods, and (3) applies those principles and methods to the facts of the case in a reliable manner. Fed. R. Evid. 702. The Supreme Court in <u>Daubert</u> provided several non-exclusive factors for district courts to consider when evaluating the reliability of an opinion witness's testimony. 509 U.S. at 592–94. However, not all <u>Daubert</u> factors apply in every case. <u>Dilts</u>, 500 Fed. Appx. at 445. In <u>Kumho Tire</u> <u>Co. v. Carmichael</u>, the Supreme Court explained that "the law grants a district court the same broad latitude when it decides how to determine reliability as it enjoys in respect to its ultimate reliability determination." 526 U.S. 137, 141–42 (1999). When evaluating the reliability of non-scientific expert testimony, the district court may forgo these factors and focus on the reliability of the expert's personal knowledge or experience. <u>Thomas v. City of Chattanooga</u>, 398 F.3d 426, 431–32 (6th Cir. 2005). In this situation, the expert cannot ask a court simply to take his "word for it," but "'must explain how that experience leads to the conclusion reached . . . and how that experience is reliably applied to the facts." <u>Thomas</u>, 398 F.3d at 432 (quoting Fed. R. Evid. 702 adv. comm. note).

Here, Dr. Lamb's opinions, reports, and testimony are based on sufficient facts and data such that his expert opinion meets the threshold standard established by Rule 702 and <u>Daubert</u>. Dr. Lamb's expert report: (1) summarized his qualifications, the allegations, and background information on the pharmaceutical industry and enoxaparin; (2) performed a "back casting" analysis that purported to show the overcharges putative class members incurred from Defendants' alleged anticompetitive conduct and generic enoxaparin prices that would have manifested in a "but for" world absent Defendants' activity; (3) surveyed the economic literature concerning the effects of inter-generic competition; and (4) measured potential class-wide damages. (Doc. No. 303-1 at 6-90.) Dr. Lamb relies on a host of materials in coming to his conclusions, including wholesale pharmaceutical data, Defendant's internal documents, and economic literature. (<u>Id.</u>) To the extent that Defendants argue that Dr. Lamb's analysis is insufficient in the absence of any

statistical analysis, that argument goes to the weight afforded to his opinion, not its admissibility under Rule 702 and <u>Daubert</u>. Dr. Lamb's expert testimony and report are reliable because: (1) it is based on sufficient facts and data (wholesale pharmaceutical data, Defendants' internal documents, and the case record); (2) it is grounded in reliable principles and methods (back casting and deference to economic literature); and (3) applied reasonably to the facts of the case. Fed. R. Evid. 702. Perhaps Dr. Lamb's expert opinion would have been more convincing with a statistical regression analysis, but the absence of one does not render the opinion inadmissible under Rule 702 and <u>Daubert</u>. Dr. Lamb's qualifications as an expert, unchallenged by Defendants, are impressive and his opinion here is sufficiently reliable to survive this threshold challenge. Accordingly, Defendants' Motion to Exclude the Report and Opinions of Plaintiffs Expert Dr. Russell L. Lamb (Doc. No. 360) will be denied.

E. Applicable Law on Class Certification

To certify a class, the Court must be satisfied that Plaintiffs have met the requirements of both Rule 23(a) and Rule 23(b) of the Federal Rules of Civil Procedure. "A class action will be certified only if, after 'rigorous analysis,' the Court is satisfied that the prerequisites of Rule 23(a) have been met and also that the action falls within one of the categories under Rule 23(b)." <u>Castillo v. Envoy Corp.</u>, 206 F.R.D. 464, 467-68 (M.D. Tenn. 2002) (citing <u>Gen. Tel. Co. of Sw. v. Falcon</u>, 457 U.S. 147, 161 (1982)). The Sixth Circuit has recognized that district courts have broad discretion in deciding whether to certify a class, but that courts "must exercise that discretion within the framework of Rule 23." <u>Coleman v. Gen. Motors Acceptance Corp.</u>, 296 F.3d 443, 446 (6th Cir. 2002); <u>see also In re Am. Med. Sys., Inc.</u>, 75 F.3d 1069, 1079 (6th Cir. 1996).

The party seeking class certification bears the burden of showing that the requirements for class certification are met. <u>Bridging Communities Inc. v. Top Flite Fin. Inc.</u>, 843 F.3d 1119, 1124

(6th Cir. 2016). In evaluating whether class certification is appropriate, "it may be necessary for the court to probe behind the pleadings," as the issues concerning whether it is appropriate to certify a class are often "enmeshed" within the legal and factual considerations raised by the litigation. <u>In re Am. Med. Sys., Inc.</u>, 75 F.3d at 1079; <u>see also Wal-Mart Stores, Inc. v. Dukes</u>, 564 U.S. 338, 350-52 (2011) (explaining that a court's rigorous analysis will frequently entail "some overlap" with the merits of plaintiffs' underlying claim) (citing <u>Falcon</u>, 457 U.S. at 160). A party seeking to maintain a class action thus must be prepared to establish that Rule 23(a)'s numerosity, commonality, typicality and adequacy of representation requirements have been met. <u>Comcast v. Behrend</u>, 569 U.S. 27, 33 (2013). In addition, the party must satisfy, through evidentiary proof, at least one of Rule 23(b)'s provisions. <u>Id.</u> at 34. Plaintiffs rely on Rule 23(b)(3), which allows for certification of a Rule 23(a)-compliant class if:

the court finds that the questions of law or fact common to class members predominate over any questions affecting only individual members, and that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy. The matters pertinent to these findings include:

- (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.

Fed. R. Civ. P. 23(b)(3).

The Court will start with an examination of the Rule 23(a) factors then examine the Rule

23(b) predominance factor in terms of both the non-retail/hospital chain and the retail chain. The

Court then turns to an analysis of class-wide damages, Plaintiffs' standing to pursue out of state claims, and the superiority inquiry.

F. <u>Rule 23(a)</u>

1. Plaintiffs' Arguments and Defendants' Response

Plaintiffs assert that the class easily meets the requirements of Federal Rule Civil Procedure 23(a). (<u>Id.</u> at 8.) First, the proposed class consists of thousands of hospitals, insurers, and uninsured, satisfying numerosity. (<u>Id.</u>) Plaintiffs also assert that there are common questions of law and fact, namely the effect Defendants' alleged antitrust activity had on members of the class and the generic enoxaparin market. (<u>Id.</u> at 8-10.) Further, Plaintiffs' claims are typical of the class because they were injured in the same way as all members of the proposed class—they paid more for enoxaparin than they would have absent Defendants' alleged anticompetitive behavior. (<u>Id.</u> at 10.) Finally, Plaintiffs maintain that they are adequate class representatives because: (1) NGH and DC 37 (as well as all members of the proposed class) were harmed by paying more for enoxaparin than they otherwise would have absent Defendants' conduct; and (2) there are no fundamental intra-class conflicts sufficient to defeat certification. (<u>Id.</u> at 11-15.) Moreover, Plaintiffs contend that they are adequate class representatives because the statutes are materially the same. (<u>Id.</u> at 15-16.)

Defendants have two primary arguments regarding Plaintiffs' Rule 23(a) showing: (1) Plaintiffs are not adequate class representatives because their interests conflict with putative class members; and (2) Plaintiffs' claims are not typical of other putative class members. (<u>Id.</u> at 24-26.) Essentially, on the first point, Defendants argue that commercial insurers and hospitals have divergent economic interests in this class action, as hospitals have every incentive to claim that they absorbed enoxaparin overcharges, while commercial insurers (who pay some portion of the final hospital bill) have an incentive to claim the overcharge was passed on to them. (<u>Id.</u> at 25-26.) Defendants contend that this is a "quintessential class conflict" precluding certification. (<u>Id.</u> at 26.) On the second point, Defendants argue that NGH and DC 37's claims are not typical of other putative class members' claims because: (1) the proposed class includes commercial insurers and hospitals, leading to a conflict of economic interests; and (2) individualized differences between hospitals—billing differences, GPO suppliers, reimbursement policies—prevents any claim from being typical. (<u>Id.</u>)

2. Numerosity

The class must be so numerous that joinder of all members is impractical. Fed. R. Civ. P. 23(a)(1). According to Plaintiffs, this requirement is met because the proposed class contains thousands of members. Generally, the number of members of the proposed class, if more than several hundred, easily satisfies the requirements of Rule 23(a)(1). <u>Bacon v. Honda of Am. Mfg.</u>, Inc., 370 F.3d 565, 570 (6th Cir. 2004); <u>see also Bittinger v. Tecumseh Prods. Co.</u>, 123 F.3d 877, 884 n. 1 (6th Cir. 1997) (joinder of parties impracticable for class with over 1100 members and "[t]o reach this conclusion is to state the obvious"). Defendants do not appear to contest plaintiffs' position on numerosity. Given the vast number of hospitals, pharmacies, and uninsured patients that make up the class, joinder is impracticable and the requirements of Rule 23(a)(1) are met.

3. Commonality

Rule 23(a)(2) provides that "[o]ne or more members of a class may sue or be sued as representative parties on behalf of all members only if . . . there are questions of law or fact common to the class," Fed. R. Civ. P. 23(a)(2), and commonality requires the plaintiffs to demonstrate that the class members 'have suffered the same injury." <u>Dukes</u>, 131 S.Ct. at 2551 (quoting <u>Falcon</u>, 457 U.S. at 157). "[P]laintiffs must show that their claims 'depend upon a

common contention' that is 'of such a nature that it is capable of classwide resolution—which means that determination of its truth or falsity will resolve an issue that is central to the validity of each one of the claims in one stroke.'" <u>Dukes</u>, 131 S.Ct. at 2551. One common question is sufficient. Powers v. Hamilton County Pub. Defender Com'n, 501 F.3d 592, 619 (6th Cir. 2007).

In antitrust cases, the commonality requirement is often easily met. "Price-fixing conspiracy cases by their very nature deal with common legal and factual questions about the existence, scope, and extent of the alleged conspiracy." <u>In re Foundry Resins Antitrust Litig.</u>, 242 F.R.D. 393, 404–05 (S.D. Ohio 2007) (citing <u>In re Workers''Comp.</u>, 130 F.R.D. 99, 105 (D. Minn. 1990)). In this case, Plaintiffs argue that commonality is established because their claims are based on Defendants' allegedly anticompetitive conduct and its effects on the generic enoxaparin marketplace. (Doc. No. 353 at 9.) Defendants do not appear to challenge Plaintiffs' assertion that the commonality requirement has been met, and the Court finds that the requirements of Rule 23(a)(2) are satisfied.

4. <u>Typicality</u>

Rule 23(a)(3) requires plaintiffs to show 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). Often, "[t]he commonality and typicality requirements of Rule 23(a) tend to merge." <u>Dukes</u>, 131 S.Ct. at 2551 n. 5. There are differences, however. Commonality traditionally refers to characteristics of the class as a whole, while typicality "refers to the individual characteristics of the named plaintiff in relation to the class." <u>Prado–Steiman, ex rel. Prado v. Bush</u>, 221 F.3d 1266, 1279 (11th Cir. 2000). "[A] plaintiff's claim is typical if it arises from the same practice or course of conduct that gives rise to the claims of other class members, and if his or her claims are based on the same legal theory." <u>In re Am. Med. Sys., Inc.</u>, 75 F.3d at 1082. Typicality is ordinarily established in the

antitrust context when the named plaintiffs and all class members allege the same antitrust violation by defendants. <u>Thomas & Thomas Rodmakers, Inc. v. Newport Adhesives &</u> <u>Composites, Inc.</u>, 209 F.R.D. 159, 164 (C.D.Cal. 2002); (citing <u>In re Playmobil Antitrust Litig.</u>, 35 F. Supp. 2d 231, 244 (E.D.N.Y.1998)).

As stated, Defendants muster two primary arguments regarding typicality: (1) the proposed class includes commercial insurers and hospitals, setting up divergent economic incentives; and (2) no "typical" claim exists among hospitals based on the individual differences in billing, chargemasters, reimbursement, and GPO contracts. (Doc. No. 363 at 26.)

Defendant's arguments miss the mark. The focus of the typicality inquiry is to resolve whether the representatives claims arises from the same event or practice or course of conduct that gives rise to the claims of other class members. <u>In re Am. Med. Sys.</u>, 75 F.3d at 1082. Defendant's arguments are geared towards the predominance inquiry, which the Court will address below. As to typicality, the Plaintiffs and putative class members have claims that arise from the same course of conduct—the Defendants' alleged anticompetitive conspiracy to reduce generic competition in the enoxaparin market and reap the benefits of the resulting overcharges. These indirect purchasers rely on the same course of conduct and their claims are cognizable under the various state antitrust, consumer protection, and unjust enrichment laws. Accordingly, the typicality requirement, which is "not onerous," is satisfied. <u>UAW v. Ford Motor Co.</u>, No. 06-cv-10311, 2006 WL 1984363, at *19 (E.D. Mich. July 13, 2006); <u>see also In re Packaged Ice Antitrust Litig.</u>, 322 F.R.D. 276, 285 (E.D. Mich. 2017) (finding the typicality requirement met in an indirect purchaser suit where the putative members' claims were based on defendants' alleged anticompetitive conspiracy).

5. Adequacy

The final requirement of Rule 23(a) is that the representative parties must "fairly and adequately represent the interests of the class." Fed. R. Civ. P. 24(a)(4). "The two criteria for determining whether class representatives are adequate are '(1) the representatives must have common interests with unnamed members of the class, and (2) it must appear that the representatives will vigorously prosecute the interests of the class through qualified counsel." Ford Motor, 2006 WL 1984363, at *19 (quoting Senter v. General Motors Corp., 532 F.2d 511, 525 (6th Cir. 1976)).

Both NGH and DC 37's interests are aligned with the putative class members because they all possess the same interests and have suffered the same alleged injury i.e., they have each allegedly paid more for generic enoxaparin than they would have paid absent the alleged conspiracy. Essentially, Defendant's argument on this point is that hospitals (such as NGH) and commercial insurers (like BlueCross/BlueShield) will be pitted against each other because hospitals will have every economic incentive to exclude those insurers from asserting claims based on enoxaparin overcharge reimbursements those insurers may have absorbed in the hospital setting. (Doc. No. 363 at 24-26.). First, based on Plaintiffs' expert testimony from Dr. Lamb, the Court finds that, based on hospital billing practices, hospitals absorbed the enoxaparin overcharges, and, therefore, commercial insurers would not have these types of claims. Therefore, Defendants' argument asserts a merely speculative class conflict that is insufficient to challenge adequacy. See In re Solodyn (Minocycline Hydrochloride) Antitrust Litig., Case No. 14-md-002503, 2017 WL 462177, at *13 (D. Mass Oct. 16, 2017) (holding that merely speculative or hypothetical class conflicts are insufficient). Accordingly, the Court finds that: (1) NGH and DC 37 have common interests with unnamed class members because they have the same economic

interests and suffered the same alleged injury; and (2) DC 37 and NGH will vigorously prosecute the interests of the class through qualified counsel.

With that, Rule 23(a)'s requirements are satisfied.

G. <u>Rule 23(b)(3) Requirements: Predominance</u>

Meeting the predominance requirement of Rule 23(b)(3) demands more than common evidence that defendants colluded to raise prices for generic enoxaparin. Plaintiffs must also show that they can prove, through common evidence, that all class members were in fact injured by the alleged conspiracy. <u>Amchem</u>, 521 U.S. at 623–24. However, Plaintiffs are not required to demonstrate through common evidence the precise amount of damages incurred by each class member. <u>See Dukes</u>, 131 S.Ct. at 2558.

Rule 23(b)(3) tests "whether proposed classes are sufficiently cohesive to warrant adjudication by representation," <u>Amchem</u>, 521 U.S. at 623, but it is far more demanding than the commonality, typicality, and adequacy inquiries of Rule 23(a). <u>Comcast</u>, 133 S.Ct. at 1432; Amchem, 521 U.S. at 623–24. To satisfy Rule 23(b)(3), the questions in a class action that are subject to generalized proof, and thus applicable to the class as a whole, must predominate over questions that are subject only to individualized proof. <u>Beattie</u>, 511 F.3d at 560.

In conducting the predominance inquiry, courts must "take into account 'the claims, defenses, relevant facts, and applicable substantive law,' to assess the degree to which resolution of the class-wide issues will further each individual class member's claim against the defendant." <u>Klay v. Humana, Inc.</u>, 382 F.3d 1241, 1254 (11th Cir. 2004), <u>abrogated on other grounds by Bridge v. Phoenix Bond & Indem. Co.</u>, 553 U.S. 639 (2008) (quoting <u>Castano v. Am. Tobacco Co.</u>, 84 F.3d 734, 744 (5th Cir. 1996)). "If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable." <u>In re Hydrogen Peroxide Antitrust</u>

<u>Litig.</u>, 552 F.3d 305, 311 (3d Cir. 2008) (citing <u>Newton v. Merrill Lynch, Pierce, Fenner & Smith,</u> <u>Inc.</u>, 259 F.3d 154, 172 (3d Cir. 2001)). Although individual treatment of the essential elements of a case precludes certification, it is not necessary that all questions of fact be common, but only that some questions are common and that they predominate over individual questions. <u>Id.</u>

A "close look" must be taken at whether common questions predominate over individual ones and a "rigorous analysis" must be conducted that may "entail overlap with the merits of the plaintiff's underlying claim." <u>Comcast</u>, 133 S.Ct. at 1432 (internal quotations omitted). Free-ranging merits inquires are not permitted at the certification stage, however. <u>Amgen</u>, 133 S.Ct. at 1194–95. "Merits questions may be considered to the extent—but only to the extent—that they are relevant to determining whether the Rule 23 prerequisites for class certification are satisfied." <u>Id.</u> at 1195.

The predominance inquiry begins with the elements of the underlying cause of action. <u>Erica</u> <u>P. John Fund, Inc. v. Haliburton Co.</u>, 563 U.S. 804, 809 (2011). As set forth above, Plaintiffs have alleged an overarching antitrust conspiracy that violates various states' antitrust, unjust enrichment, and consumer protection laws. To prevail on their antitrust claims based on allegations of a conspiracy, plaintiffs must demonstrate (1) a violation of antitrust laws (i.e. the conspiracy), (2) direct injury (or impact) from the violation, and (3) measurable damages. <u>See Hydrogen</u> Peroxide, 552 F.3d at 311.

1. Plaintiffs' Arguments and Defendants' Response

Plaintiffs argue that common questions predominate, satisfying Rule 23(b)(3). (<u>Id.</u> at 16.) Plaintiffs acknowledge that they must demonstrate that they can prove through common evidence that all class members were in fact injured by the alleged antitrust conspiracy and assert that such common proof of injury is available. (<u>Id.</u> at 18-19.) Specifically, they assert that Dr. Lamb's expert report and testimony at the evidentiary hearing establish this common proof. (Id. at 19.) Plaintiffs explain that Dr. Lamb's analysis establishes that after Amphastar's actual entry into the enoxaparin market, prices declined and class members paid less for generic enoxaparin than they did before a second generic entered the market. (Id.) Plaintiffs argue that Dr. Lamb's opinion is also confirmed by Defendants' own expert Dr. Pierre Cremieux, who opined that wholesalers, retail pharmacies, and pharmacy benefit managers (PBMs) contract in such a way that overcharges for acquisitions of drugs (like enoxaparin) are passed on to third-party payors (TPPs)/uninsured patients in the retail channel and hospitals in the non-retail channel. (Id. at 19-20.) The Court finds that Defendants' arguments quibble with the data set relied by Dr. Lamb, rather than his ultimate conclusions, which go to the weight of the evidence, not its suitability for use on a class-wide basis. (Id. at 20-21.)

As to the non-retail/hospital component of predominance, Plaintiffs contend that individual analysis of hospitals' enoxaparin transactions is not necessary (and therefore does not defeat predominance) because Dr. Lamb's benchmark analysis demonstrates that hospitals paid more for enoxaparin than they otherwise would have absent Defendants' conduct. (Id. at 22.) Once the fact of damages has been established, Defendants argument as to the quantum of damage cannot defeat certification. (Id. at 22-23.) Further, Plaintiffs note that the differences between the claims in the various states antitrust, consumer protection, and unjust enrichment laws does not require individualized inquiry because those differences are immaterial and can be resolved using common evidence on a class-wide basis. (Id. at 24-29.) Finally, Plaintiffs argue that the class mechanism is superior to alternative methods, especially considering that individual class members would be disincentivized from bringing suit because of the high cost of suit and small amount of available

monetary relief. (<u>Id.</u> at 29-30.) Plaintiffs then propose a notice plan and schedule to be instituted after certification is granted. (<u>Id.</u> at 30-31.)

Defendants first contend that individualized questions regarding who was injured will predominate over common questions, making class certification inappropriate. (Id. at 13.) Defendants explain that indirect purchaser cases such as this one are complicated because Plaintiffs bear the burden of proving not only that direct purchasers paid an inflated cost but that this inflated cost was passed through to the indirect purchasers. (Id. at 13-14.) Further, for hospitals, Plaintiffs must show that the hospital absorbed the inflated cost rather than passing it on to patients or insurers. (Id. at 14.) Defendants maintain that Dr. Lamb has not empirically demonstrated either of these propositions. (Id.) Instead, he simply assumes that hospitals never passed any of these inflated costs on to insurers or patients (i.e., they always absorbed the inflated costs on to TPPs and uninsured in the form of higher prescription prices. (Id.) However, Defendants maintain that a rigorous analysis (as performed by their expert Dr. Cremieux) reveals that individualized inquiry is required to demonstrate antitrust impact and exclude uninjured class members, making class certification inappropriate. (Id. at 15-16.)

Defendants contend that, in the hospital channel, individualized inquiry is necessary to determine whether any particular hospitals would have paid less for enoxaparin if Amphastar had not been enjoined from entering the market. (<u>Id.</u> at 16.) In fact, given NGH's contract with its group purchasing organization ("GPO"), from whom it purchased enoxaparin, Defendants maintain that NGH would not have paid less for enoxaparin in a but-for world, as it was already receiving the benefit of a lower price based on a prior renegotiation. (<u>Id.</u> at 17.) Defendants argue

that these types of individualized inquiries are necessary for each hospital, which makes class certification inappropriate. (<u>Id.</u> at 18.)

Similarly, Defendants assert that individualized inquiry is required to demonstrate antitrust impact and to exclude uninjured class members in the retail pharmacy chain. (Id. at 20.) Defendants explain that a "bottom level" analysis is necessary to demonstrate that pharmacies always passed the overcharges to TPPs and uninsured purchasers, Dr. Lamb failed to conduct a "bottom level" analysis showing this pass through, and, therefore, without individualized inquiry, many members of the proposed class suffered no injury. (Id. at 20-22.) Defendants stress that these individualized issues (both as to hospitals and the retail pharmacy channel) cannot be cured by adjusting aggregate damages because there is no common method to identify and exclude uninjured class members or to reduce Dr. Lamb's damages model to account for the varying levels of pass through. (Id. at 22-24.) Therefore, granting certification, even in light of an adjustment to the aggregate damages, would deprive Defendants of their ability to fairly defend this litigation. (Id. at 24.)

2. Antitrust Conspiracy

"Predominance is a test readily met in certain cases alleging . . . violations of the antitrust laws" and generally "proof of the conspiracy is a common question that is thought to predominate over the other issues of the case" <u>In re Scrap Metal Antitrust Litig.</u>, 527 F.3d 517, 532, 535 (6th Cir. 2008) (quoting <u>Amchem</u>, 521 U.S. at 625). Plaintiffs allege here that Defendants engaged in a single, market wide conspiracy to reduce competition in the sale of generic enoxaparin, which they will prove with evidence common to the class. "Courts have fairly consistently found . . . that common issues regarding the existence and scope of the conspiracy predominate over other questions affecting only individual members in antitrust price fixing cases." <u>In re Southeastern</u> <u>Milk Antitrust Litig.</u>, Case No.l 2:08-MD-1000, 2010 WL 3521747, at *9 (E.D. Tenn. Sept. 7, 2010). That makes sense because determination of the conspiracy issue will focus on the conduct of the Defendants, not the individual class members. <u>See Merenda v. VHS of Mich., Inc.</u>, 296 F.R.D. 528, 548 (E.D. Mich. 2013). The existence of a conspiracy is central to the claims of all putative class members and thus is appropriate for resolution generally on a class-wide basis. With this in mind, the parties have focused on the second element, impact, as that element poses the more serious impediment to certification, and, likewise, the Court focuses its attention there.

3. Impact

In recognition that Rule 23's predominance requirement is "more stringent" than other elements of the Rule, <u>Amchem</u>, 521 U.S. 591 at 609, the overwhelming focus of the briefing discusses whether Plaintiffs can show that common questions of fact or law predominate over those questions "affecting only individual members." <u>See</u> Fed. R. Civ. P. 23(b)(3). To carry their Rule 23(b)(3) burden, Plaintiffs offer the expert reports of Dr. Lamb. Defendants respond in kind, offering the expert reports of Dr. Cremieux.

Contrary to Defendants' protestations, at this stage of the litigation, Plaintiffs' burden as it relates to predominance is "not to prove [(for example)] the element of antitrust impact." <u>In re</u> <u>Hydrogen Peroxide</u>, 552 F.3d at 311. Plaintiffs must instead show that the essential elements of their claims are "<u>capable</u> of proof at trial through evidence that is common to the class rather than individual to its members." <u>Id.</u> at 311–12 (emphasis added). This inquiry necessarily requires this Court to form "some prediction as to how specific issues will play out" in terms of trial proof, particularly when a class certification decision is made on the basis of an incomplete discovery record. <u>In re New Motor Vehicles Canadian Exp. Antitrust Litig.</u>, 522 F.3d 6, 20, 27 (1st Cir. 2008). The predominance inquiry gauges whether a proposed class is cohesive enough to "warrant adjudication by representation." <u>Beattie</u>, 511 F.3d 554 at 564.

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Plaintiffs' approach to showing that impact is capable of proof using evidence common to the class involves a two-step process. Because Plaintiffs are indirect purchasers (i.e., they purchased enoxaparin from wholesalers who purchased it from Defendants) Plaintiffs must prove that: (1) the conspiracy resulted in higher prices for Defendants' customers (the wholesalers who purchased directly from Defendants); and (2) this initial overcharge was passed through the non-retail (hospital) and retail channels and was included in the final price they paid for the enoxaparin. See In re Polyurethane Foam Antitrust Litig., 314 F.R.D. 226, 276 (N.D. Ohio 2014) (explaining the impact burden plaintiffs have in indirect purchaser actions).

a. <u>Non-Retail/Hospital Chain</u>

In support of their assertion that Defendants' antitrust conspiracy resulted in higher prices for enoxaparin and these overcharges were passed down the supply chain, Plaintiffs primarily rely on Dr. Lamb's expert reports and testimony. To show that the alleged antitrust conspiracy resulted in higher prices, Dr. Lamb uses a method known as "backcasting." (Doc. No. 303-1 at 82-88.) Put simply, Dr. Lamb starts with the "actual world" prices that existed for enoxaparin—taking into account Defendants' alleged anticompetitive activity in excluding Amphastar's entry from the generic enoxaparin marketplace. (<u>Id.</u> at 82.) Dr. Lamb then "backcasts" and shifts Amphastar's entry into the generic enoxaparin market four months earlier (from February 2012 to October 2011), which he asserts would have occurred absent Defendants' alleged conduct. (<u>Id.</u> at 83-85.) The difference between the actual world and but-for world price results in the "overcharge" that wholesalers incurred and subsequently passed on to hospitals. (<u>Id.</u>) Dr. Lamb, in his original expert report, estimated class-wide damages for indirect purchasers to be around \$298 million, but, as a result of Plaintiffs amended class definition, he reduced the damages estimate to approximately \$234 million. (Doc. No. 353-4 at 3.) Defendants do not take issue with Dr. Lamb's backcasting analysis or the proposition that the alleged antitrust activity resulted in higher generic enoxaparin prices, rather, Defendants target the second part of the analysis—whether the initial overcharge was passed through the retail and non-retail channels and whether these overcharges can be proven through proof common to the class.

Defendants' argument on this point can be summarized in two words: individualized inquiry. (Doc. No. 363 at 16-22.) Relying on Dr. Cremieux's expert reports and testimony, Defendants contend that there is simply no way to calculate through common proof whether putative class members suffered an overcharge in the first instance or suffered an overcharge and passed it on downstream—either of which would exclude putative plaintiffs from the class. (<u>Id.</u>)

In his expert report, Dr. Cremieux criticizes Dr. Lamb for failing to perform a pass-through analysis showing the overcharges incurred by putative class members. (Doc. No. 363-1 at 8.) Dr. Cremieux opines that: (1) some hospitals pass on their acquisition costs to patients and insurance companies and some do not; (2) Dr. Lamb has not identified a common method to determine which hospitals pass on the overcharges and which ones absorb that cost; (3) this failure results in an aggregate damages calculation that is unreliable and overstated; (4) conversely, Dr. Lamb, without any statistical analysis, assumes that pharmacies act as resellers and pass 100% of any overcharge on to downstream purchasers (uninsured and TPPs); and (5) individualized inquiry is required to determine how and at what point in the process the overcharge was borne and by whom. (Id. at 11.) Defendants maximal focus on whether the overcharge was offset by the hospital passing on the overcharge misses the point.

"[A]ntitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset." <u>In re Nexium Antitrust Litig.</u>, 777 F.3d 9, 27 (1st Cir. 2015) (citing <u>Adams v. Mills</u>, 286 U.S. 397, 407 (1932); <u>Hawaii v. Standard Oil Co. of Cal.</u>, 405 U.S. 251, 262 n. 14 (1972). "If a class member is overcharged, there is an injury, even if that class member suffers no damages." <u>Id.</u> Accordingly, in the hospital channel, the proper focus is on whether the hospital incurred an overcharge in the first instance. Even if individualized inquiry is required to see if the hospitals passed on that overcharge, as Defendants contend, such an inquiry is not necessary to determine if the putative hospital claimant suffered actual antitrust impact, which is all that is required in the predominance inquiry.

Thus, the Court must look to whether Plaintiffs, through Dr. Lamb, have demonstrated that by common proof whether hospitals incurred overcharges in the first instance. In his expert report, Dr. Lamb claims that the common proof showing hospitals bore these overcharges consists of: (1) an extensive body of published research showing that direct and indirect purchasers realize significant costs savings when generics enter the market; (2) Defendants' documents, testimony, and forecasts confirming that when generics enter the market there is a significant cost savings for purchasers; and (3) IMS data on sales of generic enoxaparin that confirm that competition among generic manufacturers would have led to significantly lower prices. (Doc. No. 353-1 at 60-61.) Here, if a class member is overcharged, there is an injury, even if that class member suffers no damages. Relying on economic literature, Dr. Lamb opines that:

[T[he price differential (generic versus the brand name drug) and the generic's share of unit sales increase over time following generic entry. Other studies show that this price differential increases as additional generic manufacturers enter the market, particularly with respect to the impact on generic price when a second generic manufacturer (including an authorized generic) competes in a market against a generic that otherwise would have been the only generic in that market.

(<u>Id.</u> at 61.) Similarly, Dr. Lamb cites to Defendants' own internal documents and materials, all of which are common to the class, demonstrating that Defendants realized that additional generic entry would result in significant price erosion. (<u>Id.</u> at 63.) These internal memoranda show that Defendants acutely understood the significant profits that could be realized by capturing an

extended exclusivity period for generic enoxaparin during which time consumers would be willing

to pay an anticompetitive price because the drug had no alternatives. (Id. at 65-67.) Finally, using

the IMS data, Dr. Lamb concludes that:

Sandoz began selling generic Enoxaparin in July 2010 and Amphastar and Winthrop (Sanofi's authorized generic) entered in October 2011. As shown, in the retail channel, Sandoz's share of the market relative to the other generics decreased from 100 percent in September 2011 to approximately 49 percent in September 2012. In the non-retail channel, Sandoz's share of the market relative to the other generics decreased from 100 percent in September 2011 to approximately 49 percent in September 2012. In the non-retail channel, Sandoz's share of the market relative to the other generics decreased from 100 percent in September 2011 to approximately 66 percent in September 2012.

The substitution of Sandoz's generic Enoxaparin for the generic Enoxaparin sold by other manufacturers is evidence, common to the proposed Class as a whole, that if another generic manufacturer had entered the market earlier, proposed Class members would have purchased generic Enoxaparin at a lower price.

Thus, data on sales of Lovenox and A-rated generic Enoxaparin demonstrate that competition among generic manufacturers in the actual world resulted in lower prices for generic Enoxaparin following Amphastar's entry into the market. That is, in preventing a second or third generic manufacturer from entering the market, Defendants' alleged misconduct caused purchasers to be overcharged because the prices for both Lovenox and A-rated generic Enoxaparin were higher than they would have been had there been no impediment to entry by a second or third generic manufacturer. In other words, the price-based competition between generic manufacturers that would have occurred absent Defendants' alleged misconduct would have allowed all or nearly all proposed Class members to pay less for Lovenox and A-rated generic Enoxaparin than they actually did.

(<u>Id.</u> at 67-71.)

The Court finds that Dr. Lamb's analysis and examination of this evidence sufficiently demonstrates that there is common evidence capable of demonstrating the fact of antitrust impact. Defendants' individual inquiry arguments are a red herring, as, in reality, the real issue is their concern that the Court's certification of the class will include persons who have not been injured by the alleged anticompetitive conduct. However, the Defendants' speculative concern will not defeat certification. As the Seventh Circuit has explained:

[A] class will often include persons who have not been injured by the defendant's conduct. Such a possibility or indeed inevitability does not preclude class certification, despite statements in some cases that it must be reasonably clear at the outset that all class members were injured by the defendant's conduct.

<u>Kohen v. Pacific Inv. Mgmt. Co. LLC</u>, 571 F.3d 672, 677 (7th Cir. 2009) (citations omitted). The Court agrees with <u>Kohen</u> and with other courts that "have routinely observed that the inability to show injury . . . does not defeat class certification where the plaintiffs can show widespread injury to the class." <u>In re Cardizem CD Antitrust Litig.</u>, 200 F.R.D. 297, 320–21 (E.D. Mich. 2001) (citing <u>In re NASDAQ Market–Makers Antitrust Litig.</u>, 169 F.R.D. 493, 523 (S.D.N.Y. 1996)). As to the non-retail/hospital channel, the Court is persuaded that Dr. Lamb's analysis and testimony shows that, based on Defendants' alleged antitrust activity, the price for generic enoxaparin was sold to non-retail putative class members (hospitals) at an anticompetitive price during the class period. Although this finding is sufficient for Rule 23(b)(3) purposes, the Court separately examines Defendants and Dr. Cremieux's other arguments for completeness of the record.

Before considering Dr. Cremiuex's reports and testimony in-depth, the Court pauses to note that, in the discretion afforded by the Sixth Circuit, it ascribes little, if any, weight to these reports and testimony. <u>See Deal v. Hamilton Cty. Bd. of Educ.</u>, 392 F.3d 840, 851 (6th Cir. 2004) ("Furthermore, this Court is not in the business of dictating to district courts the amount of weight they must give certain expert opinions.") The Court gives little weight to Dr. Cremieux's opinions because: (1) there were manifest contradictions between his original and supplemental expert reports; and (2) he was forced to admit significant error in his supplemental report on cross-examination during the certification hearing. The Court places particular emphasis on the latter incident. In brief, Dr. Cremieux stated in his supplemental report that Sanofi and Medassets (a GPO from whom NGH purchased enoxaparin) had an agreement to reduce the price of generic enoxaparin as early as September 2011. (Doc. No. 363-1 at 16.) Dr. Cremieux links this

"agreement" with his ultimate opinion that this "agreement" would have resulted in a price decline in generic enoxaparin even absent the Defendants' alleged antitrust activity. (Id. at 17.) However, on cross-examination, Dr. Cremieux was forced to admit that no such agreement existed in September 2011, and, in fact, when MedAssets was considering Sanofi's price reduction, Defendants' alleged anticompetitive activity (enjoining Amphastar from entering the generic enoxaparin marketplace) was already occurring. (Doc. No. 396 at 260-62.) The Court also finds a significant negative change in Dr. Cremieux's demeanor at this point. This admission of error not only substantially undermines Dr. Cremieux's expert opinion on this particular issue, but also casts serious doubt on his credibility and the remainder of his opinions. Accordingly, the Court ascribes Dr. Cremieux's testimony little, if any, weight because the Court does not find Dr. Cremieux credible.

In Defendants' brief, they argue that NGH itself was not injured by the alleged anticompetitive activity based on the Sanofi-MedAssets September agreement. (See Doc. No. 363 at 17.) However, based on the Dr. Cremieux's fatal admission in his testimony during cross-examination, the evidentiary record before the Court does not support such an argument. Defendants' arguments that individualized inquiry is necessary to determine how the particular hospitals set their charges, reimbursement, insurer contracts, and patient circumstances is also incorrect. In the non-retail/hospital chain, the Court is concerned with the purchase by the hospitals in the first instance. The insurer contracts, patient charges, and charge-setting practices have no effect on the hospital's <u>initial</u> purchase of generic enoxaparin, which is the only inquiry that matters for antitrust impact.

At bottom, Plaintiffs' evidence has shown, by a preponderance of the evidence, that the vast majority of non-retail/hospital class members were most likely injured, based on how the

generic enoxaparin supply chain is structured. "Rigorous analysis" of the evidence does not show, by a preponderance of the evidence, that the number of uninjured class members is more than *de minimis*. This Court is well within its discretion to find that the Plaintiffs have presented a sufficient showing of common antitrust impact to the putative non-retail/hosptial class. Defendants' speculation, built on the back of an unreliable expert opinion, cannot defeat the Plaintiffs' showing. <u>See Messner v. Northshore Univ. HealthSystem</u>, 669 F.3d 802, 825 (7th Cir. 2012) (once plaintiffs had shown broad antitrust impact, certification could not be denied just because defendants pointed to a class of uninjured members but "[gave] no indication how many such individuals actually exist").

b. <u>Retail/Pharmacy Chain</u>

As to the retail class, Plaintiffs assert that common proof of injury is clearly available. (Doc. No. 353 at 19.) Plaintiffs point to: (1) Dr. Lamb's certification testimony that pharmacies are resellers, and, therefore, the anticompetitive price they paid for generic enoxaparin was automatically passed on to TPPs and uninsured consumers; and (2) the IMS data definitively shows that pharmacies paid an anticompetitive price. (Id.) Plaintiffs acknowledge that Defendants take issue with Dr. Lamb's reliance on the IMS data, but argue that such an assertion goes to the weight of the evidence, rather than its admissibility or its ability to satisfy the predominance inquiry. (Id. at 21.)

Indeed, Defendants' arguments as to the retail/pharmacy chain of the class definition largely focus on the alleged deficiencies in the IMS data used by Dr. Lamb. (See Doc. No. 363 at 20-22.) Defendants argue that the IMS data only shows the prices paid by pharmacies and provides no insight on what price the end-consumers (TPPs and uninsured patients) paid for generic enoxaparin when they obtained it from said pharmacies. (Id. at 20-21.) Therefore, because Dr.

Lamb failed to use an approach that accounted for the price paid at the "final level," Defendants argue that there is no common proof available to show that the TPPs and uninsured patients were injured. (<u>Id.</u>) Defendants also argue that the pass-through rate for pharmacies is less than 100%, meaning it would require individualized inquiry to ascertain whether the TPP or uninsured patient suffered antitrust impact by actually paying an inflated price. (<u>Id.</u> at 21-22.)

Again, it bears repeating, the Court places little, if any, weight on Dr. Cremieux's report or opinion testimony, given his blatant contradictory testimony at the certification hearing. In his initial report, Dr. Lamb summarized how pharmaceuticals, including generic enoxaparin, are distributed in the retail chain and how anticompetitive prices at the top-end of the chain affect prices at the consumer level:

Manufacturers of prescription drugs, including brand-name drugs and generics, sell directly to drug wholesalers, and in some circumstances, directly to retail pharmacy chains, mail order and specialty pharmacies, hospital chains, and health plans. As described in Momenta's 2012 SEC Form 10-K, "[g]eneric pharmaceutical products are sold through various channels, including retail, mail order

Drug manufacturers determine the Wholesale Acquisition Cost ("WAC"), which is typically the 'baseline price at which wholesale distributors purchase products.' Drug wholesalers purchase prescription drugs from manufacturers and resell them to retail pharmacies, mail-order pharmacies, hospitals, long-term care and other medical facilities. In turn, retail pharmacies purchase prescription drugs from wholesalers, and, in some cases, directly from the manufacturers, and ultimately sell those drugs to their customers holding prescriptions. Some retailers also purchase prescription drugs directly from the manufacturers.

(Doc. No. 353-1 at 18.) In his reply report, Dr. Lamb elaborates, stating that as a matter of economics, pharmacies would pass through higher costs of generic enoxaparin to their customers, including uninsured patients and TPPs. (Doc. No. 353-2 at 68-69.) Dr. Lamb notes that the retail supply chain is simple—manufacturers sell to wholesalers who sell to pharmacies who sell to end users (TPPs and uninsured patients)—such that any increase in the acquisition cost invariably must be passed to the final level. (Id.) He also explains that economic literature supports his conclusion

that pass through in the retail chain occurs because in markets that suffer from monopoly overcharges, a high degree of pass on almost always occurs and is likely to manifest rapidly. (<u>Id.</u> at 69.) Dr. Lamb notes that, based on the back casting, showing that a higher price was paid by wholesalers because of Defendants' alleged activity, and principles of economics, which suggest that some percentage of a price increase (overcharge) is invariably passed to end consumers, common proof available to the class supports the finding that TPPs and uninsured patients suffered antitrust impact. (<u>Id.</u> at 69-70.)

Admittedly, Dr. Lamb's expert report, testimony, and supporting evidence for antitrust impact in the retail channel is very thin. However, Plaintiffs' burden is limited, even in the predominance inquiry. "Antitrust plaintiffs have a limited burden with respect to showing that individual damages issues do not predominate. Plaintiffs do not need to supply a precise damage formula at the certification stage of an antitrust action. Instead, in assessing whether to certify a class, the Court's inquiry is limited to whether or not the proposed methods are so insubstantial as to amount to no method at all." In re Potash Antitrust Litig., 159 F.R.D. 682, 697 (D. Minn. 1995). "This relaxed standard flows from the equitable notion that the wrongdoer should not be able to profit by insistence on an unattainable standard of proof." Id. (citation omitted). "Moreover, the fact that the damages calculation may involve individualized analysis is not by itself sufficient to preclude certification when liability can be determined on a class-wide basis." Id.

Simply put, the Court believes that Dr. Lamb's opinion and testimony, supported by economic literature and the IMS data, provides enough evidence to demonstrate antitrust impact in the retail channel. To be clear, the Court finds Dr. Lamb credible and Dr. Cremieux not credible. Accordingly, Plaintiffs have established antitrust impact as to both the retail and non-retail

channels of their class definition, and, therefore, the Rule 23(b)(3) predominance requirement is satisfied.

H. Class-Wide Damages

The Court also finds that, as to the issue of class-wide damages, Plaintiffs, through Dr. Lamb, have presented a proper methodology to measure class-wide damages. Based on the above analysis, the Court is satisfied that an injury-in-fact impacted the proposed class members. As with all other issues in this case, the parties disagree as to the <u>quantum</u> of damages. However, at this point, the Court need not provide any definitive answer to this issue. In re Loestrin 24 Fe Antitrust Litig., Case No. 13-2472-WES-PAS, 2019 WL 3214257, at *5 (D. R. Isl. Jul. 2, 2019) (holding that, on the issue of class-wide damages, "[w]hile Defendants fashion a colorable argument on this score, the [Plaintiffs] have satisfied their burden to produce a 'scientifically sound and methodologically reliable' opinion . . . [and] [i]t will be up to the jury to determine which party's theory wins the day."). As discussed above, that Dr. Lamb's damages model may include a purchaser that was uninjured does not render his analysis unsound. It is for the jury to determine whether the potential class members were injured, and if so, to what extent; or to determine that they were not. Id. at *6. At bottom, Dr. Lamb has produced a viable, methodologically sound opinion as to the calculation of damages, and, at this stage, that is all that is required.

I. State Law Differences and Standing

Plaintiffs argue that, to the extent there are differences between the 30 state laws they are bringing claims under, those differences can be resolved using common evidence on a class-wide or state-wide basis, and, in any event, most of the differences are immaterial. (Doc. No. 353 at 24.) Defendants argue that Plaintiffs lack standing to bring claims on behalf of class members in the majority of class states because they did not suffer injury in those states and the material state law differences in those states' statutes prevent certification. (Doc. No. 363 at 27-29.)

Threshold individual standing is a prerequisite for all actions, including class actions. See O'Shea v. Littleton, 414 U.S. 488, 494 (1974). A potential class representative must demonstrate individual standing vis-as-vis the defendant; he cannot acquire such standing merely by virtue of bringing a class action. Fallick v. Nationwide Mut. Ins. Co., 162 F.3d 410, 423 (6th Cir. 1998) (citing Brown v. Sibley, 650 F.2d 760, 770 (5th Cir. 1981)). As the Sixth Circuit has made clear, however, "once an individual has alleged a distinct and palpable injury to himself he has standing to challenge a practice even if the injury is of a sort shared by a large class of possible litigants." Id. (quoting Senter v. Gen. Motors Corp., 532 F.2d 511, 517 (6th Cir. 1976)). Once his standing has been established, whether a plaintiff will be able to represent the putative class, including absent class members, depends solely on whether he is able to meet the additional criteria encompassed in Rule 23 of the Federal Rules of Civil Procedure. Id. (citing Cooper v. Univ. of Texas at Dallas, 482 F. Supp. 187 (N.D. Tex. 1979); Herbert B. Newberg & Alba Conte, Newberg on Class Actions § 2.05 (3d ed. 1992)). Here, the Court has previously determined that NGH and DC 37 have standing to sue Defendants under the states in which they were harmed (i.e. where they purchased enoxaparin)-Tennessee and New York, respectively. (See Doc. No. 253.) However, the Court deferred deciding the issue of whether Plaintiffs had standing to pursue claims based on other state laws and statutes. (Id. at 20.) The Sixth Circuit's decision in Fallick suggests that this standing inquiry turns on whether Plaintiffs have satisfied the Rule 23(a) factors. 162 F.3d at 423-25. As demonstrated above, the Court finds that Plaintiffs have satisfied the Rule 23(a) factors, and, therefore, under Fallick, Plaintiffs have standing to assert claims under the various state statutes on behalf of absent class members.

Also, the Court looks to the First Circuit Court of Appeals' decision in <u>In re Asacol</u>, 907 F.3d 42, 49 (1st Cir. 2018), for guidance. In <u>Asacol</u>, the First Circuit focused on the "basic Article III requirement that a plaintiff possess 'such a personal stake in the outcome of the controversy as to assure . . . concrete adverseness." 907 F.3d at 49 (quoting <u>Baker v. Carr</u>, 369 U.S. 186, 204 (1962)). "So the question of standing is not: Are there differences between the claims of the class members and those of the class representative? Rather, the pertinent question is: Are the differences that do exist the type that leave the class representative with an insufficient personal stake in the adjudication of the class members' claims?" <u>Id.</u>

Here, as in Asacol, the Court likewise concludes that "success on the claim under one state's law will more or less dictate success under another state's law." Id. Although both Fallick and Asacol approach the standing inquiry in differently, the end result is the same: does the nature of Plaintiffs' injury give it a sufficient incentive to adequately litigate claims that are similar, but not identical, to those of absent class members? The answer to that inquiry is a yes. Under these parallel laws, all plaintiffs who were forced to pay a higher price in the absence of generic competition have a substantial and shared interest in proving that the higher price was the result of unlawful monopolizing conduct that is redressable by an award of damages. "[T]he fact that judgments for some class members will nevertheless enter under the laws of states other than the states under which any of the class representative' judgments will enter, where those laws are materially the same, has no relevant bearing on the personal stake of the named plaintiffs in litigating the case to secure such judgments." Id. The Court has reviewed the differences in the state statutes that Plaintiffs assert claims under, and, contrary to Defendants' arguments, the differences are not material. Moreover, in any event, the fundamental issues under these statutes remains the same—proving that putative plaintiffs were forced to pay a higher price in the absence

of generic enoxaparin competition. Finding Article III standing otherwise satisfied in this case is in accord with the decisions of other circuits that have considered similar issues. <u>See Langan v.</u> <u>Johnson & Johnson Consumer Cos.</u>, 897 F.3d 88, 92-96 (2d Cir. 2018) (holding that named plaintiffs had standing to assert claims under various state laws). Accordingly, the Court finds that Plaintiffs have standing to bring claims under the various state statutes in the jurisdictions identified in the class definition.

J. Superiority

Finally, to earn certification, a putative class must establish that a class action is "superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). In undertaking this analysis, the Court examines four factors:

(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.

Defendants do not dispute that superiority is met here. (See Doc. No. 363.) In the instant case, three of the four factors weigh in favor of a certifying the case as a class action. First, the relatively small amount of individual damages and the similarity of claims give class members little interest in individually controlling separate actions. Second, concentration of these claims in this Court is desirable, as it will streamline the resolution of the claims and conserve judicial and litigation resources. Finally, the Court is aware of no particular difficulties associated with the management of this class action, especially given the current stage of the litigation. Thus, for purposes of Rule 23(b)(3), a class action is superior to other methods of adjudication in the instant case. With that, the Plaintiffs have carried their burden in establishing that their proposed class should be certified under Rule 23(a)(1) and (b)(3) under the Federal Rules of Civil Procedure.

K. Conclusion

For the reasons stated above, the Plaintiffs' Renewed Motion for Class Certification and Appointment of Class Counsel (Doc. No. 349) is **GRANTED** and Defendants' Motion to Exclude the Report and Opinions of Plaintiffs Expert Dr. Russell L. Lamb (Doc. No. 360) is **DENIED**. The Court further **APPOINTS** NGH and DC 37 as class representatives. Additionally, after considering the factors set out in Federal Rule of Civil Procedure 23(g)(1)(A), the Court determines that Lieff Cabraser is qualified to represent the class and, therefore, **APPOINTS** Lieff Cabraser as Class Counsel.

An appropriate order will enter.

D. Crens

WAVERLY ()/CRENSHAW, JR. () CHIEF UNITED STATES DISTRICT JUDGE