

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

**In re: PROGRAF ANTITRUST
LITIGATION**

MDL No. 2242

Master File No. 1:11-cv-02242 RWZ

THIS DOCUMENT RELATES TO:

ALL INDIRECT PURCHASER ACTIONS:

*Louisiana Health Service Indemnity
Company d/b/a Bluecross/Blueshield of
Louisiana v. Astellas Pharma US, Inc., No.
11-cv-12326*

*Janet M. Paone v. Astellas Pharma US, Inc.,
No. 11-cv-11647*

**INDIRECT PURCHASER PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF
THEIR MOTION TO LIFT THE STAY AND FOR LEAVE TO FILE FOR
PRELIMINARY APPROVAL OF CLASS ACTION SETTLEMENT
WITH ASTELLAS PHARMA, US, INC. ("ASTELLAS")**

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I. INTRODUCTION

Indirect Purchaser Plaintiffs¹ and the class of indirect purchasers certified pursuant to Federal Rule of Procedure 23(c)(4) (the “Class”) (collectively, the “Plaintiffs”) respectfully submit this Memorandum of Law in support of their Motion to Lift the Stay and for Leave to File their Motion for Preliminary Approval of the Proposed Class Action Settlement with Astellas Pharma, US, Inc. (“Astellas”), the defendant in *In re Prograf Antitrust Litigation*, Civil Action No. 1:11-md-10344-RWZ (the “Class Action”).

In exchange for Astellas’s agreement to pay Plaintiffs \$13,250,000.00, plus interest earned while in escrow, the proposed settlement releases Astellas from all claims by Plaintiffs in the Class Action (the “Settlement”). Plaintiffs respectfully request that the Court enter a preliminary approval order, substantially in the form annexed to Plaintiffs’ Motion for Preliminary Approval as **Exhibit 1**, by which the Court will preliminarily approve the Settlement between Plaintiffs and Astellas as embodied in the Settlement Agreement, attached to the Declaration of J. Gerard Stranch, IV (“Stranch Decl.”) as **Exhibit 2**. Astellas does not oppose the relief requested in Plaintiffs’ motion for preliminary approval, but it does not join in this Memorandum.

II. PROCEDURAL AND FACTUAL BACKGROUND

Plaintiffs in the Indirect Purchaser Class Action alleged, among other things, that Astellas filed a baseless citizen petition with the United States Food and Drug Administration to delay approval of generic versions of the prescription drug Prograf (tacrolimus), in violation of the antitrust, unfair competition, consumer protection, and unjust enrichment laws of certain states. Plaintiffs further alleged that they incurred damages as a result of these actions. Astellas

¹ Indirect Purchaser Plaintiffs are Louisiana Health Service Indemnity Company d/b/a Bluecross/Blueshield of Louisiana (“BCBSLA”) and Janet M. Paone (“Paone”).

denies Plaintiffs' allegations, asserts defenses to Plaintiffs' claims, asserts that its petition to the FDA had scientific merit and raised legitimate medical concerns, asserts that the petition cannot be the basis for antitrust liability in light of the First Amendment to the United States Constitution, and asserts that the conduct challenged by Plaintiffs did not delay the market entry of any generic product or cause any injury or damage. The Court is familiar with the parties' factual and legal positions, having ruled on significant motion practice including Astellas's motion to dismiss, Astellas's motion for summary judgment, various discovery disputes, and extensive pretrial briefing. The parties have aggressively litigated this Class Action for close to five years.

On January 18, 2013, the Indirect Purchaser Plaintiffs filed their Motion to Certify Class, asserting that the following liability issues were common to all members of the class: "(1) whether Astellas delayed or prevented generic manufacturers from coming to market in the United States; (2) whether Astellas' citizen petition to FDA during FDA's review of ANDAs for generic tacrolimus was objectively baseless; (3) whether Astellas unlawfully maintained monopoly power by delaying generic entry; (4) whether direct proof of Astellas' monopoly power is available and, if so, whether it is sufficient to prove Astellas' monopoly power without the need to also define a relevant market; and (5) to the extent a relevant market or markets must be defined, what that definition is or what those definitions are."²

On June 4, 2013, defendant Astellas filed its opposition to Motion to Certify Class of the Indirect Purchaser Plaintiffs,³ with hearing held on August 6, 2013. On December 17, 2013, the Court denied the Motion for class certification,⁴ yet articulated that "the criteria for membership

² See Dkt. No. 153-155.

³ See Dkt. No.249.

⁴ See Dkt. No. 350. The Court denied certification, concerned that "proof of plaintiffs' antitrust

in the proposed class are objective”⁵ and hence, ascertainable, and furthermore that “common issues predominate with respect to the first element [of plaintiffs’ antitrust claims], violation of antitrust law.”⁶

On January 3, 2014, the Indirect Purchaser Plaintiffs moved for reconsideration of denial of certification, seeking “certification of a class only as to the issue of Astellas’s alleged antitrust conduct.”⁷ On June 10, 2014, the Court allowed the Indirect Purchaser Plaintiff’s motion seeking partial class certification on the issue of antitrust violation, finding specifically that “all IPP class members, as well as the certified class of direct purchaser plaintiffs,⁸ present the same allegations and proof of misconduct by Astellas.”⁹ On June 24, 2014, Astellas sought an interlocutory appeal of the Court’s class certification decision under Fed. R. Civ. P. 23(f), which was accepted by the United States Court of Appeals for the First Circuit on March 4, 2015.¹⁰ That appeal has been fully-briefed and the Court of Appeals has heard oral argument but has yet to issue its ruling. On December 3, 2014, during the intervening period between class

injury ... [would] depend on individual issues rather than common ones. *Id.*, at p. 44.

⁵ Dkt. No. 350 at 7.

⁶ Dkt. No. 350 at 21

⁷ Dkt. 371 at 2.

⁸ On January 22, 2015, Astellas and Direct Purchaser Plaintiffs in this Multi-district Litigation submitted their Motion for Preliminary Approval of Proposed Class Action Settlement. See Master File No. 1:11-md-02242-RWZ, Dkt. No. 652. The parties urged settlement based upon clarification of the issues that resulted from discovery that included the review of “more than 317,700 documents and almost three million pages,” took “nineteen depositions,” and “retained and worked with expert witnesses in evaluating scientific, regulatory and economic issues relating to liability and damages.” (See Dkt. 653, p. 6). On May 20, 2015, the Court granted the Motion for Settlement. See Doc. 678).

⁹ Dkt. No. 450 at 4.

¹⁰ See Dkt. No. 664.

certification and the appeal, the Court issued a stay order in the Indirect Purchaser action.¹¹

III. DESCRIPTION OF THE SETTLEMENT

After intensive arms'-length negotiations, fact and expert discovery including, among other things, the production and inspection of hundreds of thousands of pages of documents, depositions of Astellas's employees, Astellas's experts, and third-party witnesses, substantial briefing on the legal issues (including motions to dismiss, summary judgment, *Daubert*, and motions *in limine*), consultation with economic, scientific and regulatory experts regarding numerous relevant legal, evidentiary, and economic issues, successfully defeating a motion for summary judgment filed by Astellas, preparing the case for trial, and having fully-briefed and argued Astellas's Rule 23(f) petition to the First Circuit Court of Appeals, Plaintiffs, on behalf of the Indirect Purchaser Class, agreed, subject to the Court's approval, to settle their claims against Astellas on behalf of the following class of indirect purchasers ("Settlement Class"):

All persons ("Consumers") or entities ("Third Party Payors") in the United States and its territories who purchased and/or paid for some or all of the purchase price for branded Prograf capsules and/or any of its AB-rated generic equivalents in any form in the states of Arizona, California, Delaware, District of Columbia, Florida, Georgia, Idaho, Illinois, Iowa, Kansas, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, Nevada, New Hampshire, New Mexico, New York, North Carolina, North Dakota, Oregon, Pennsylvania, Puerto Rico, Rhode Island, South Dakota, Tennessee, Vermont, West Virginia and Wisconsin, for consumption by themselves, members of their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, at any time during the period from April 15, 2008 until December 31, 2010 (the "Class Period"). For purposes of the Settlement Class definition, persons and entities "purchased" or "paid for" Prograf and/or any of its AB-rated generic equivalents if they paid, or reimbursed someone who paid, some or all of the dispensing pharmacy's price for such drug.

Excluded from the Settlement Class are:

- a) Astellas and its officers, directors, management, employees, parents, subsidiaries, and affiliates;

¹¹ See Dkt. 640.

- b) All federal governmental entities (except for government-funded employee benefit plans);
- c) All persons or entities who purchased Prograf and/or any of its AB-rated generic equivalents for purposes of resale or directly from Astellas or its affiliates;
- d) All fully insured health plans (*i.e.*, plans that purchased insurance from another entity covering 100% of the plan's reimbursement obligations to its members);
- e) All "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment share of the dispensing pharmacy's price did not vary between brand-name and generic drug purchases; and
- f) The judges in this case and any members of their immediate families.

The proposed Settlement Agreement, which is attached to the Stranch Decl. as Ex. 2, provides for Astellas to pay \$13,250,000.00 (Thirteen Million Two-Hundred Fifty Thousand Dollars) to be distributed among the Settlement Class as outlined in the Settlement Agreement in exchange for a full and complete settlement and release of all claims that Plaintiffs have asserted or could have asserted in the Indirect Purchaser Class Action.¹² The Settlement includes the full and complete cost of Settlement Class members' benefits and compensation, settlement notice and claims administration, and Class Counsel's attorneys' fees and expenses (that may be approved by this Court).

The parties have further agreed that Class Counsel will ask the Court to appoint Allocation Counsel to represent Third-Party Payor members of the Settlement Class and Consumer members of the Settlement Class, respectively, for the purpose of negotiating and

¹² The release, as set forth in Paragraphs 14-15 of the Settlement Agreement, specifically excludes all claims arising in the ordinary course of business between Plaintiffs or any Settlement Class members and Astellas arising under Article 2 of the Uniform Commercial Code, the laws of negligence or product liability or implied warranty, breach of contract, breach of express warranty, or personal injury, or other claims unrelated to the allegations made in this Action.

recommending to the Court a plan of allocation detailing what portion of the Net Settlement Funds (as defined in the Settlement Agreement) will be used to pay each sub-group's authorized claims. At the conclusion of these negotiations, Class Counsel will seek the Court's approval of the negotiated plan of allocation if it has a reasonable basis.

The Settlement provides that Class Counsel intend to seek, solely from the Settlement Fund, a Court-awarded Fee and Expense Award consisting of attorneys' fees of up to one-third of the total Settlement Fund plus the reimbursement of reasonable costs and expenses incurred in the prosecution of the Indirect Purchaser Class Action to date plus interest thereon, and incentive awards for the Indirect Purchaser Class Representatives. It also establishes the procedures for obtaining Court approval of such awards.

The first step in the settlement approval process is Plaintiffs' request to lift the stay effectuated by the Court's December 3, 2014 Order for the sole purpose of allowing Plaintiffs to contemporaneously seek leave of the Court to submit the proposed Settlement to the Court for preliminary approval. If the Court grants Plaintiffs' motion to lift the stay and grants preliminary approval, a schedule will be established for submitting a notice plan and plan of allocation for approval by the Court. Plaintiffs will proceed to work with the selected Settlement Administrator to formulate a notice plan so that the terms of the proposed Settlement may be communicated to the Settlement Class members. Additionally, after preliminary approval, Astellas shall deposit the Settlement Amount monies with the approved Escrow Agent, and the selected Allocation Counsel shall then negotiate, at arms' length, an agreement (the "Allocation Agreement") concerning the allocation of the net Settlement Fund between these two groups within the Settlement Class. Finally, the Court will schedule the Fairness Hearing and deadlines for filing motions for final approval and Plaintiffs' counsel's applications for an award of attorneys' fees, expenses, and incentive awards. The Action will be stayed in all

other respects.

Accordingly, this motion seeks entry of the proposed Preliminary Approval Order attached to the Stranch Decl. as **Exh. 1**, which provides for: (i) certification of a Fed. R. Civ. P. 23(b)(3) class for settlement purposes only (“Settlement Class”); (ii) preliminary approval of the Settlement set forth in the Settlement Agreement between the parties as within the range of fairness and in the best interests of the Settlement Class; (iii) appointment of separate counsel to represent Third Party Payor members of the Settlement Class and to represent Consumer members of the Settlement Class for the purpose of negotiating, at arms’ length, an agreement (the “Allocation Agreement”) concerning the allocation of the Net Settlement Fund (as defined herein) between these two groups; (iv) approval of a reasonable deadline for Allocation Counsel to negotiate and reach the Allocation Agreement and submit it to the Court for preliminary approval, along with Plaintiffs’ proposal for a notice plan; (v) appointment of a Claims Administrator to administer claims submitted by members of the Settlement Class; (vi) appointment of an Escrow Agent; (vii) establishment of a schedule for a hearing before the Court after the notice period has expired to consider objections to the Settlement, to approve the Settlement if appropriate, and to consider Plaintiffs’ counsel’s applications for attorneys’ fees and expenses and incentive awards as set forth in the Settlement Agreement (the “Fairness Hearing”); and (viii) a stay of all proceedings in the Action, other than those incident to the settlement process, until such time as the Court renders a final decision regarding the approval of the Settlement.

IV. PRELIMINARY APPROVAL SHOULD BE GRANTED

“Settlement agreements enjoy great favor with the courts as a preferred alternative to

costly, time-consuming litigation.”¹³ Approval of a class action settlement under Fed. R. Civ. P. 23(e) involves a two-step process. First, counsel submits the proposed terms of settlement and the court makes a preliminary fairness evaluation.¹⁴ In this preliminary evaluation of a proposed settlement, the court determines only whether the settlement has “obvious deficiencies” or whether “it is in the range of fair, reasonable, and adequate.”¹⁵ In this Circuit and elsewhere, settlements are favored, particularly of class actions.¹⁶

“At the preliminary approval stage, the Court need not make a final determination regarding the fairness, reasonableness and adequateness of a proposed settlement; rather the Court need only determine whether it falls within the range of possible approval.”¹⁷

“Ultimately, the more fully informed examination required for final approval will occur in connection with the Final Fairness Hearing, where arguments for and against the proposed settlement will be presented after notice and an opportunity to consider any response provided by the potential Class Members.”¹⁸

If the Court finds that the parties reached the settlement as a result of good-faith negotiations and after sufficient discovery, then a presumption of fairness attaches to the

¹³ *Fid. & Guar. Ins. Co. v. Star Equip. Corp.*, 541 F.3d 1, 5 (1st Cir. 2008).

¹⁴ See *Federal Judicial Center, Manual for Complex Litigation* §21.632 (4th ed. 2004) (hereafter “Manual”); see also 4 *Newberg on Class Actions* §11:25, at 38-39 (4th ed. 2002) (endorsing two-step process).

¹⁵ *In re M3Power Razor Sys. Mktg. & Sales Prac. Litig.*, 270 F.R.D. 45, 52 (D. Mass. 2010) (Woodlock, J.) (citing *Manual* §21.632).

¹⁶ *In re Lupron Mktg. & Sales Practices Litig.*, 228 F.R.D. 75, 88 (D. Mass. 2005) (citing *City P’ship Co. v. Atl. Acquisition Ltd. P’ship*, 100 F.3d 1041, 1043 (1st Cir. 1996)).

¹⁷ *In re Puerto Rican Cabotage Antitrust Litig.*, 269 F.R.D. 125, 140 (D. Mass. 2010) (Dominguez, J.) (citations omitted).

¹⁸ *In re M3 Power Razor Sys.*, 270 F.R.D. at 62.

settlement.¹⁹ Courts in this Circuit have looked to four factors to determine whether a settlement is entitled to such a presumption: “(1) the negotiations occurred at arm’s length; (2) there was sufficient discovery; (3) the proponents of the settlement are experienced in similar litigation; and (4) only a small fraction of the class objected.”²⁰ As explained below, this settlement more than satisfies the relevant criteria for preliminary approval.

A. The Court Should Certify the Proposed Class for Purposes of Settlement

Preliminary certification of the Settlement Class is appropriate in this case because the four requirements of Rule 23(a) are met, the necessary parts of Rule 23(b) are satisfied, and the Settlement Class is sufficiently defined. The “district court must conduct a rigorous analysis of the prerequisites established by Rule 23 before certifying a class,”²¹ “however, despite this heightened scrutiny . . . the law favors class action settlements.”²²

1. The Settlement Class is ascertainable, and satisfies all requirements of Rule 23(a).

The Court previously found that the Class is ascertainable, specifically that “criteria for membership in the proposed class are objective” and that the exclusions, too are “based on objective criteria.”²³ The Court previously found that the Settlement Class also satisfies Rule 23(a) requirements of (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation.²⁴ There has been no material change to the Settlement Class definition which

¹⁹ See *In re Pharm. Indus. Avg. Wholesale Price Litig.*, 588 F.3d 24, 32-33 (1st Cir. 2009).

²⁰ *In re Lupron Mktg. & Sales Pracs. Litig.*, 345 F. Supp. 2d 135, 137 (D. Mass. 2004) (Stearns, J.). The fourth factor is more often relevant for purposes of final approval, after notice has issued and class members have been given an opportunity to object to a settlement.

²¹ *Smilow v. Southwestern Bell Mobile Sys.*, 323 F.3d 32, 38 (1st Cir.2003).

²² *In Re Relafen*, 231 F.R.D. 52, 68 (D. Mass. 2005) (*quoting In Re Lupron Mktg. And Sales Practices Litig.*, 228 F.R.D. 75, 88 (D.Mass.2005)) (internal quotations omitted)

²³ Dkt. 350 at 7-8.

²⁴ Dkt. 350 at 8-11; see also *Smilow v. Southwestern Bell Mobile Sys.*, 323 F.3d 32, 38 (1st Cir.

should impact this analysis.

(a) Numerosity

Fed. R. Civ. P. 23(a)(1) requires that members of a class be “so numerous that joinder of all members is impracticable.” The Rule does not impose a precise numerical threshold, but classes of forty or more are generally deemed sufficient.²⁵ “District courts ‘may draw reasonable inferences from the facts presented to find the requisite numerosity.’”²⁶ Here, the size of the proposed Class easily meets the numerosity requirement. As stated by Plaintiffs in their prior briefing in support of class certification,²⁷ and as recognized by the Court’s decision on Class Certification, class members from the numerous states number in the tens of thousands, and hence numerosity “is easily satisfied.”²⁸

(b) Commonality

Fed. R. Civ. P. 23(a)(2) requires “questions of law or fact common to the class.” The First Circuit has described commonality as a “low bar” with a “permissive application.”²⁹ Commonality asks whether there are “questions of law or fact common to the class.” Fed. R.

2003).

²⁵ *E.g., Sparkle Hill, Inc. v. Interstate Mat Corp.*, No. 11-10271-RWZ, 2012 U.S. Dist. LEXIS 178793, at *4 (D. Mass. Dec. 18, 2012) (Zobel, J.); *Connor B. ex rel. Vigurs v. Patrick*, 272 F.R.D. 288, 292 (D. Mass 2011); *In re Relafen Antitrust Litig.*, 218 F.R.D. 337, 342 (D. Mass. 2003).

²⁶ *In re Volkswagen & Audi Warranty Extension Litig.*, 273 F.R.D. 349, 352 (D. Mass. 2011) (quoting *McCuin v. Sec’y of Health & Human Servs.*, 817 F.2d 161, 167 (1st Cir. 1987)).

²⁷ See Dkt. No. 155 at 13-14.

²⁸ See Dkt. No. 350 at 8-9.

²⁹ *In re New Motor Vehicles*, 522 F.3d at 19; accord *In re McKesson Governmental Entities Average Wholesale Price Litig.*, 767 F. Supp. 2d 263, 269 (D. Mass. 2011); *Connor B.*, 272 F.R.D. at 293; *Campbell v. First Am. Title Ins. Co.*, 269 F.R.D. 68, 74 (D. Me. 2010).

Civ. P. 23(a)(2). It requires the party seeking certification to show a “common contention . . . that 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.” *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2551 (2011). Even a single common question can be enough to satisfy Rule 23(a)(2). *Id.* at 2556. The Court previously found commonality, having identified numerous questions of law and fact common to the Class, including: “(1) whether Astellas delayed or prevented generic manufacturers from coming to market in the United States; (2) whether Astellas’s citizen petition to FDA during FDA’s review of ANDAs for generic tacrolimus was objectively baseless; (3) whether Astellas unlawfully maintained monopoly power by delaying generic entry; (4) whether direct proof of Astellas’s monopoly power is available and, if so, whether it is sufficient to prove Astellas’s monopoly power without the need to also define a relevant market; (5) to the extent a relevant market or markets must be defined, what that definition is or what those definitions are; and (6) whether Astellas’s conduct caused injury to Plaintiffs and Class members and, if so, the appropriate measure of damages.”³⁰

(c) Typicality

Fed. R. Civ. P. 23(a)(3) requires that “the claims or defenses of the representative parties are typical of the claims or defenses of the class.” “The typicality requirement is fulfilled when the plaintiffs’ claims arise from the same course of conduct and are based on the same legal theory as the class claims.”³¹ “[C]lass representatives’ claims can be considered typical even

³⁰ Dkt. 155 at 16.

³¹ *In re Evergreen Ultra Short Opportunities Fund Secs. Litig.*, 275 F.R.D. 382, 389 (D. Mass. 2011); accord *In re Pharmaceutical Indus. Average Wholesale Price Litig.*, 277 F.R.D. 52, 58 (D. Mass. 2011).

where there is some factual variation among the claims of different class members.”³² As the Court previously recognized in finding the typicality requirement satisfied, “the claims of each named plaintiff and those of the class arise from the same course of conduct (Astellas’s allegedly anti-competitive actions) and are based upon the common legal theories of monopolization, deceptive trade practices, and unjust enrichment. All plaintiffs and members of the proposed class assert that Astellas’s alleged misconduct resulted in an overcharge for tacrolimus products or unjust enrichment at their expense.”³³

(d) Adequacy of Representation

Fed. R. Civ. P. 23(a)(4) requires that “the representative parties will fairly and adequately protect the interests of the class.” Adequacy has two aspects: “(1) the attorneys representing the class must be qualified and competent; and (2) the class representatives must not have interests antagonistic to or in conflict with the unnamed members of the class.”³⁴

With regard to class counsel, Plaintiffs are capably represented by well-recognized class action firms. The Court previously appointed Branstetter Stranch & Jennings PLLC and the Dugan Law Firm as interim co-lead counsel for the class.³⁵ As recognized by the Court, these firms have “extensive experience in pharmaceutical class action lawsuit and have vigorously and capably represented the putative class throughout the course of this litigation.”³⁶ Class counsel have already put tremendous resources toward this case over the course of four plus years and

³² *In re Evergreen*, 275 F.R.D. at 390; *see also Connor B.*, 272 F.R.D. at 296 (“[T]he fact that the harms alleged by named Plaintiffs may differ in some respects from those suffered by unnamed Plaintiffs does not undermine typicality.”).

³³ Dkt. 350 at 9-10.

³⁴ *Andrews v. Bechtel Power Corp.*, 780 F.2d 124, 130 (1st Cir. 1985).

³⁵ Dkt. 69.

³⁶ Dkt. 350 at 10-11.

have demonstrated their willingness to see it through trial.

With regard to class representatives, “[o]nly conflicts that are fundamental to the suit and that go to the heart of the litigation prevent a plaintiff from meeting the Rule 23(a)(4) adequacy requirement.”³⁷ There is no question that Plaintiffs BCBSLA and Paone have diligently and faithfully represented the Class in all respects. They initiated this litigation and have continued to vigorously pursue it through appeal on class certification and up to the eve of trial. They belong to the Class, and their interests fully align with the interests of other Class members. All paid supracompetitive prices for tacrolimus and suffered the same type of injury. For example, Paone has demonstrated through both testimony and documentary evidence that she made co-payments of 20% of the price for brand Prograf under Medicare Part B during the relevant period, which are purchases that suffered an overcharge according to Plaintiff’s economic model.³⁸ Ms. Paone also testified that she paid this amount from her own bank account during this period.³⁹ This evidence demonstrates that Ms. Paone made at least one “co-insurance” payment for Prograf under Medicare Part B during the relevant period that contained an overcharge, which is sufficient to demonstrate the same type of antitrust injury as that alleged on behalf of the Class.⁴⁰

As the Court previously recognized, Plaintiffs are part of the Class, alleged the same

³⁷ *Matamoros v. Starbucks Corp.*, 699 F.3d 129, 138 (1st Cir. 2012) (quotations omitted).

³⁸ See Dkt. 272 at 28-29. Defendant’s health care expert Ms. Fox-Smith confirmed that Ms. Paone’s prescriptions during this period were covered under Medicare Part B and that her supplemental insurance did not cover prescription drugs, which leads to the unavoidable conclusion that Ms. Paone paid these cost herself out of pocket. *Id.* at 28, FN 10 (identifying documents stating that Ms. Paone’s Blue Cross Blue Shield Senior Gold plan did not provide prescription drug coverage during this time.).

³⁹ *Id.*

⁴⁰ It has not been disputed in this litigation that for the purposes of determining adequacy under Fed. R. Civ. P. 23(a)(4), BCBSLA has demonstrated the same type of overcharge injury alleged on behalf of the Class. See Dkt. 249 at 12.

injury as the Class, and have demonstrated that their interests align with absent class members, thus demonstrating that the adequacy requirement has been met.⁴¹

2. The Settlement Class satisfies Rule 23(b)(3).

Class certification is appropriate under Rule 23(b)(3) if “questions of law or fact common to the class members predominate over any questions affecting only individual members” and if “a class action is superior to any other available methods for fairly and efficiently adjudicating the controversy.”

(a) Variations in State Laws

Plaintiffs submitted comprehensive briefing on class certification justifying why they satisfied the requirement of predominance despite the existence of differences between Plaintiffs’ state law theories of recovery. The Court agreed, finding specifically that “plaintiffs have demonstrated sufficient commonality among the relevant antitrust and consumer protection laws” such that it does not “preclude a finding of predominance,”⁴² and that “the same core elements form the basis for unjust enrichment claims in all the named jurisdictions and largely predominate over the various differences among them.”⁴³ Plaintiffs would refer the Court to its briefing and the Court’s findings on this issue in support of its argument for certification of the Settlement Class.

(b) Predominance of Common Questions of Law or Fact

The predominance inquiry “tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation.”⁴⁴ Common questions may predominate despite the

⁴¹ Dkt. 350 at 10-11.

⁴² *Id.* at 15-16.

⁴³ *Id.* at 19.

⁴⁴ *Amchem Products, Inc. v. Windsor*, 521 U.S. 591, 623 (1997).

existence of individual differences, as long as “a sufficient constellation of common issues binds class members together.”⁴⁵ As the Supreme Court recently explained: “Rule 23(b)(3) . . . does *not* require a plaintiff seeking class certification to prove that each ‘elemen[t] of [her] claim [is] susceptible to classwide proof,’” but rather that “common questions ‘*predominate* over any questions affecting only individual [class] members.’”⁴⁶ Accordingly, Plaintiffs must make a “showing that questions common to the class predominate, not that those questions will be answered, on the merits, in favor of the class.”⁴⁷

In its Memorandum and Order denying Plaintiffs’ Motion for Class Certification, the Court agreed with Plaintiffs’ undisputed argument that common issues predominated on the issue of whether Astellas committed an antitrust violation,⁴⁸ a holding it reiterated in its order granting Plaintiffs’ Motion for Reconsideration when it granted partial-certification to an issue-only class.⁴⁹ However, the Court’s Order expressed concern that Plaintiff’s proof of class-wide damages through their expert, Dr. Meredith Rosenthal, did “not show injury to each of its members – that is, her methodology fails to show that all (or nearly all) class members paid supra-competitive prices for Prograf or generic tacrolimus, or that this determination can be made with common proof,”⁵⁰ and thus found that Plaintiffs did not satisfy predominance on this element of their claim.

⁴⁵ *Waste Mgmt. Holdings v. Mowbray*, 208 F.3d 288, 296 (1st Cir. 2000).

⁴⁶ *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 133 S. Ct. 1184, 1196 (2013).

⁴⁷ *Id.* at 1191.

⁴⁸ Dkt. 350 at 21; *see also Id.* at 15-16 (Court stating that evidence of Astellas’s “unlawful monopolistic practices and its deceptive conduct directed at the FDA” is “common to all class members.”)

⁴⁹ *See* Dkt. 450 at 4 (“[A]ll IPP class members, as well as the certified class of direct purchaser plaintiffs, present the same allegations and proof of misconduct by Astellas.”); 9-10.

⁵⁰ Dkt. 350 at 35.

Barely one year after the Court issued its Order denying class certification in this matter, the First Circuit Court of Appeals issued its opinion in another pharmaceutical antitrust case involving indirect purchasers, *In re Nexium Antitrust Lit.*, 777 F.3d 9 (1st Cir. 2015), which spoke directly to the predominance issues that so concerned this Court on the original class certification. Applying the analysis in *Nexium* (a decision that directly addressed how a district court can properly certify a class of indirect drug purchasers for all purposes, including antitrust injury), Plaintiffs demonstrate below that the factual record shows the proposed Settlement Class sought here is fully capable of certification on all issues in the case, including impact and damages.

The holding in *Nexium* is founded in earlier controlling precedent, both in the First Circuit and the U.S. Supreme Court which recognize that individual questions of damages raising the possibility of uninjured class members does not preclude certification. These precedents leading up to *Nexium* make clear that where “most,”⁵¹ or even just “a very substantial number,”⁵² of proposed class members can prove injury at trial, the possibility that some number of class members may have escaped the defendants’ conduct unscathed does not justify depriving the class as a whole of the benefits of the class action mechanism.

⁵¹ *Tardiff v. Knox County*, 365 F.3d 1,6 (1st Cir. 2004) (“[U]ndue complications as to liability [were] limited . . . If there was in fact a rule, custom or policy of strip searching every arrestee or a substantially overlarge category, then it is a fair guess that *most* arrestees so classed were strip searched on this basis.”); *Mowbray*, 208 F.3d at 297 (noting that “*most* class members’ claims were unaffected” by “idiosyncratic” statute of limitations issues, affirming certification because “the mere fact that such concerns may arise and may affect different class members differently does not compel a finding that individual issues predominate over common ones”).

⁵² *Gintis v. Bouchard Transp. Co.*, 596 F.3d 64, 67 (1st Cir. 2010) (Souter, J.) (vacating and remanding district court’s denial of class certification and stating that “on remand, the focus will be on the plaintiffs’ claim that common evidence will suffice to prove injury, causation and compensatory damages for *at least a very substantial portion of the claims* that can be brought by the putative class members”).

i. **Nexium Sustained the Lower Court’s Finding of Predominance Despite the Presence of Uninjured Class Members and Individualized Damages Issues**

In *Nexium*, the district court concluded that plaintiffs met the predominance requirement, “despite finding that the certified class included *some number* of uninjured class members,” and it certified a Rule 23(b)(3) class of end payors who bought Nexium.⁵³ In an opinion issued after the district court certified an issue class here, the First Circuit explicitly confirmed that the presence of uninjured members in the class does not preclude class certification, citing “the obvious utility of allowing the inclusion of some uninjured class members . . . and the lack of harm in doing so.”⁵⁴

The *Nexium* holding was rooted in three conclusions: (1) the plaintiffs’ aggregate recovery was limited to the amount of the injury caused by defendants, (2) the class was definite, and (3) the defendants ultimately would be required to pay damages only to injured parties. *Id.* at 18-21. The First Circuit explained:

[I]t is difficult to understand why the presence of uninjured class members at the preliminary stage should defeat class certification. Ultimately, the defendants will not pay, and the class members will not recover, amounts attributable to uninjured class members, and judgment will not be entered in favor of such members. Some number of uninjured members will receive a class notice, but the district court can easily assure that defendants will not pay for notice to uninjured members. At worst the inclusion of some uninjured class members is inefficient, but this is counterbalanced by the overall efficiency of the class action mechanism. Moreover, excluding all uninjured class members at the certification stage is almost impossible in many cases, given the inappropriateness of certifying what is known as a “fail-safe class”—a class defined in terms of the legal injury.⁵⁵

⁵³ 777 F.3d at 18.

⁵⁴ *Id.* at 23

⁵⁵ *Id.* at 21-22 (footnote omitted).

The First Circuit thoroughly analyzed the record on its way to rejecting the defendants' arguments that the presence of uninjured class members precluded class certification.

First, it determined that the presence of some "brand-loyal" customers—who would purchase branded Nexium regardless of whether less expensive alternatives existed, and therefore, allegedly were not injured by any delay—did not compel the conclusion that the defendants would be forced to pay damages to uninjured parties. *Id.* at 20.

Second, it acknowledged that the defendants asked for the impossible—the exclusion of all uninjured class members at the class certification phase. It recognized the "almost inevitable tension" involved in the effort to craft a class definition that included no uninjured parties while simultaneously excluding no injured parties; the Court correctly concluded that it was impossible to entirely separate the uninjured from the injured at the class certification stage. *Id.* at 22. Given the impossibility of the defendants' request—which, if honored, would result in almost all class actions being rejected—the First Circuit observed that the defendants' objection to certifying a class that included uninjured members "run[s] counter to fundamental class action policies," because "[t]he plaintiff class members in this case"—prescription drug end payors—"appear to be the very group that Rule 23(b)(3) was intended to protect" since "the actual overcharge to each class member was generally a small amount per prescription and too small to warrant individual litigation." *Id.* at 23. The First Circuit also noted, as it had in *In re New Motor Vehicles Litig.*, 522 F.3d 6 (1st Cir. 2008), that the failure to certify a class where individual claims are small may deprive plaintiffs of the only realistic mechanism to vindicate meritorious claims. *Id.*

The First Circuit concluded that the possibility of some uninjured members in the class did not violate the defendants' Seventh Amendment rights or eliminate plaintiffs' standing. The Court held that certifying a class that could potentially include uninjured members would not violate the Seventh Amendment as long as there is "a mechanism to establish injury."⁵⁶ Since the named plaintiffs had paid supracompetitive prices on "at least one . . . transactions" during the proposed damages period, they had standing.⁵⁷

ii. **Nexium Is Consistent With First Circuit Precedent**

The First Circuit's holding in *Nexium* was an affirmation of prior precedents ruling that the predominance inquiry should not be allowed to subvert Rule 23's overriding goal of vindicating in an efficient and economic manner those numerous small and individual claims which are otherwise meritorious. In *AWP (In re Pharm. Indus. Average Wholesale Price Litig., 588 F.3d 24 (1st Cir. 2009))* a class action on behalf of TPPs alleging a fraudulent pricing scheme for prescription pharmaceuticals, defendant AstraZeneca argued that the need for each class member to prove that it was injured by AstraZeneca's pricing practices should have precluded class certification and the classwide damages award should be set aside.⁵⁸ AstraZeneca contended that the district court's failure to require individualized proof of injury and damages for class member violated its "'fundamental right' to defend against each class member's claim of injury and damages."⁶⁰ The First Circuit panel disagreed and upheld the

⁵⁶ *Id.* at 21.

⁵⁷ *Id.* at 32.

⁵⁸ 582 F.3d at 190, 197.

⁵⁹ AstraZeneca also argued that the class mechanism "depriv[ed] AstraZeneca of its opportunity to raise individual defenses against each class member," (citing *Amchem* and the Rules Enabling Act) and that "the classwide judgment deprived the company its opportunity to litigate individualized issues of . . . injury as to absent class members." *Id.* at 191. The First Circuit did not find these arguments persuasive, noting that "it would quickly undermine class-action

classwide damages award, observing that the possibility that some class members may have evaded injury by the defendants' fraudulent scheme did not prevent the application of the class action mechanism, or render a class action unfair.⁶¹

In *In re Neurontin Mktg. & Sales Practices Litigation*, the First Circuit considered the grant of summary judgment and denial of class certification of a proposed class of TPPs who paid for Neurontin, and suggested that class members did not need to individually establish injury by looking at their purchases prescription by prescription.⁶² The First Circuit vacated and remanded a denial of class certification after rejecting the argument that class plaintiffs had to adduce individual evidence to prove they were injured. The Court, focusing on the availability of classwide evidence of Neurontin's ineffectiveness to treat class members' ailments, found the district court should not have denied class certification based on the defendants' argument that plaintiffs' claims required "the individual, subjective ineffectiveness of each off-label prescription in order to establish injury."⁶³

mechanism were we to find that a district court presiding over a class action lawsuit errs every time it allows for proof in the aggregate." *Id.* at 191, 195.

⁶⁰ *Id.* AstraZeneca also argued that the class mechanism "depriv[ed] AstraZeneca of its opportunity to raise individual defenses against each class member," (citing *Amchem* and the Rules Enabling Act) and that "the classwide judgment deprived the company its opportunity to litigate individualized issues of . . . injury as to absent class members." *Id.* at 191. The First Circuit did not find these arguments persuasive, noting that "it would quickly undermine class-action mechanism were we to find that a district court presiding over a class action lawsuit errs every time it allows for proof in the aggregate." *Id.* at 191, 195.

⁶¹ *Id.* at 197.

⁶² *In re Neurontin Mktg. & Sales Practices Litigation*, 712 F.3d 60, 69 (1st Cir.) (Lynch, C.J.) cert. denied sub nom. *Pfizer Inc. v. Kaiser Found. Health Plan, Inc.*, 134 S. Ct. 786, (2013).

⁶³ *Id.* *Neurontin* is one of a trio of decisions, all of which favorably cited the analysis of Professor Rosenthal, the same expert put forward by the Settlement Class in this case. *In re Neurontin*

The First Circuit thus spoke clearly well before *Nexium*: the presence of individual questions of damages raising the possibility that class members that ultimately may be found uninjured does not defeat class certification.

iii. The Settlement Class Satisfies Predominance Under *Nexium*

This Court did not have the benefit of *Nexium* at the time of its first certification ruling, but *Nexium* provided important guidance as to some of the precedents the district court relied on in its initial order denying class certification and from which the Court can comfortably conclude the Settlement Class does, as a matter of fact, satisfy the predominance inquiry.

For example, in initially denying full class certification, the district court relied upon *New Motor Vehicles* for the dispositive proposition that: “[i]n antitrust actions, common issues do not predominate if . . . the fact of antitrust cannot be established through common proof.”⁶⁴ But *Nexium* explains: “[t]o the extent that *New Motor Vehicles* is read to impose such a requirement,^[65] it has been overruled by the Supreme Court’s *Halliburton* decision.”⁶⁶

Without the guidance of *Nexium*, the district court’s original ruling denying class certification also lacked the First Circuit’s precedential application of *Amgen Inc. v. Conn. Retirement Plans & Trust Funds*, 133 S. Ct. 1184 (2013)—which established that a single

Mktg. & Sales Pracs. Litig., 712 F.3d 21, 41-45 (1st Cir. 2013) (Lynch, C.J.); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 51, 56, 58-59 (1st Cir. 2013) (Lynch, C.J.); *Neurontin*, 712 F.3d at 68 (1st Cir. 2013).

⁶⁴ Dkt. 350 at 21.

⁶⁵ The precise issue framed by the First Circuit on this holding was: “[d]efendants argue that this court in *New Motor Vehicles* held that to obtain class certification, plaintiffs must establish at class certification that ‘each class member was harmed by the defendants’ practice.’”).

⁶⁶ *Nexium*, 777 F.3d at 24.

element of a cause of action could not be dispositive of the predominance analysis.⁶⁷ As *Nexium* clarified, predominance may be satisfied by the presence of a vast majority of common questions, and disavowed the notion expressed by the outdated dicta in *New Motor Vehicles* that antitrust impact—alone—was dispositive of predominance.⁶⁸

Under *Nexium* and its founding precedents, the accepted facts show the proposed Settlement Class here should be certified on all issues in the case, including impact and damages. First, though Court did not have the benefit of the First Circuit’s *Nexium* decision at the time of its class certification decisions, the Court *de facto* addressed the three factual requirements the *Nexium* Court emphasized in affirming certification of an antitrust drug indirect purchaser class:

The class is definite. The Court considered and rejected Astellas’s challenge to ascertainability based on Astellas’s claim that individualized investigation would be required to identify potential members.⁶⁹ The class is defined using objective criteria.

Aggregate recovery is limited to the amount of the injury. Professor Meredith Rosenthal, Professor of Health Economics and Policy at the Harvard School of Public Health, developed “yardsticks” based on actual prices and quantities after the entry of generic tacrolimus in August 2009.⁷⁰ She then applied those yardsticks to an earlier time frame, April 2008, when generic entry would have occurred but for the alleged antitrust violation.⁷¹ In this manner, Professor Rosenthal constructed a “but-for world” and estimated what prices of the drug would have been for class members during the class period “but-for” Astellas’s anticompetitive conduct.⁷² She concluded that delayed generic entry through the fourth quarter of 2009 injured class members.⁷³ Professor Rosenthal’s calculations

⁶⁷ *Nexium*, 777 F.3d at 21 (“Rule 23(b)(3) ‘does not require a plaintiff seeking class certification to prove that each element of her claim is susceptible to classwide proof.’”) (quoting *Amgen*, 133 S. Ct. at 1196)).

⁶⁸ Dkt. 350 at 22.

⁶⁹ *Id.* at 7

⁷⁰ *Id.* at 24.

⁷¹ *Id.* Plaintiffs later adjusted the but-for generic entry date to September 3, 2008, based on the opinion of their causation expert. See Pltfs.’ Resp. to Statem. of Facts ¶ 1 (Dkt. No. 346).

⁷² *Id.* at 24-25.

⁷³ *Id.* at 26.

provide the total damages to the class; Astellas will never have to pay more than that amount, no matter how allocation ultimately breaks down between individual class members. It is entirely appropriate to enter an aggregate damages judgment for the class, followed by a post-judgment claims process, or, in this case, follow up proceedings to prove impact *and* damages. “The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself.”⁷⁴ The court did not find that the aggregate overcharge damage methodology was in error. The court only found that the end payors’ methodology did not show *injury* for *every* member of the class.⁷⁵

Only injured parties will recover. Ultimately, should a jury find Astellas liable and specify an aggregate damages award, then the Plaintiffs, pursuant to the proposed trial plan submitted with full class certification briefing (Dkt. No. 155-3), would cull uninjured class members (if any) based upon the submission of payment records. The process would be, as a practical matter, the same as that endorsed in for the pharmaceutical end payor claims in *AWP*, *Neurontin*, and *Nexium*. TPP class members would obtain purchase records (patient identifiers, prescription units, pharmacy or provider states, fill dates, and amounts paid by the patient versus the TPP) for each prescription. Such information is commonly maintained in one database by either the TPP or its PBM. For consumers, pharmacy and payor records are available to consumer class members, and additional cost-sharing details—such as copay level and effective deductible—are tracked in consumers’ typical explanation of benefits package provided by insurers. For uninsured cash-payer claimants, damage allocation can use receipts and pharmacy records (pharmacies are required by law to maintain prescription records), in addition to the sworn affidavit.⁷⁶ Although the damage allocation process involves a review of class member data, “the need for some individualized determinations at the liability and damages stage does not defeat class certification.”⁷⁷ Uninjured class members will not recover here.

No Seventh Amendment concern. In certifying the issues class (and the separation it contemplates between proof of violation as opposed to the economic consequences to individual class members), the district court weighed and rejected Astellas’s argument that uninjured members of the class would violate the Seventh Amendment.⁷⁸

⁷⁴ *AWP*, 582 F.3d at 197.

⁷⁵ *Id.* at 40.

⁷⁶ See *Mullins v. Direct Digital, LLC*, No. 15-1776, 2015 WL 4546159, *12-13 (7th Cir. July 28, 2015) (affirming class certification and noting that “treason, under Article III of the U.S. Constitution, is the only type of case in which testimony of a ‘witness is legally insufficient to prove a fact.’”).

⁷⁷ See *Nexium*, 777 F.3d at 21.

⁷⁸ Dkt. 450 at 7.

No standing concern. The district court also evaluated and rejected Astellas’s argument that some class members lacked Article III standing. The District Court observed that Astellas did not challenge the standing of BCBSLA, and that so long as one class representative had standing, the case may proceed.⁷⁹

Plaintiffs present proof of widespread impact to consumers. As clarified by the First Circuit, a plaintiff does not have to actually prove impact on every class member at the class certification stage.⁸⁰ A plaintiff’s methodology does not have to rule out the possibility of any uninjured class members. *Id.* at 25. Professor Rosenthal explained that her methodology for showing impact “could be uniformly applied to all of the Class members.” Dkt. 154-1 at 11. She opined that “the vast majority of Class members were injured.”⁸¹ She also expressly addressed Astellas’s misplaced criticism that peculiar generic penetration rates were dispositive of class impact in this case:

[E]ven with Prograf’s more modest generic penetration, payers paid more absent generic competition than after it occurred[.] And, more importantly, payers were deprived of savings at an earlier time because of the alleged generic foreclosure by the Defendant, which delayed generic entry for more than a year.⁸²

When dispensing with Astellas’s expert’s pontifications regarding the problems with mathematical averages, she answered, “[t]here is no question that there exists variability within pharmaceutical markets and variation in prices paid by payers. Averages are useful indicators when there is variation.”⁸³ Averages are only problematic in an applied economic analysis when

⁷⁹ Dkt. 450 at 7-8.

⁸⁰ *Nexium*, 777 F.3d at 24 & n.20.

⁸¹ Dkt. 273-1 at 12; *see also Id.* at 11 (“[V]irtually all third-party payors were injured.”). A plaintiff does not have to actually prove impact on every class member at the class certification stage. *Nexium*, 777 F.3d at 24 & n.20. A plaintiff’s methodology does not have to rule out the possibility of any uninjured class members. *Id.* at 25.

⁸² Dkt. 273-1 at 5.

⁸³ Dkt. 273-1 at 8.

they mask substantial variation; here, that is not the case. As another court explained when analyzing Professor Rosenthal's methodology:

*The use of averages in this case does not mask meaningful variations in overcharges, and it provides a reliable method to provide a reasonable estimate of the damages based on relevant purchase data.*⁸⁴

Furthermore, to the extent the Court was concerned on the original motion for class certification with "offsets" to overcharge transactions eliminating antitrust injury for some class members,⁸⁵ this has been deemed incorrect as a matter of law and should not preoccupy the Court in certifying the Settlement Class. Relying on well-settled antitrust law from the Supreme Court, the First Circuit rejected this exact same argument in *Nexium*:

[D]efendants incorrectly assume that if a class member offsets an overcharge through later savings attributable to the same or related transaction, there is no injury. But antitrust injury occurs the moment the purchaser incurs an overcharge, whether or not that injury is later offset.⁸⁶

Thus *Nexium*, and the seminal Supreme Court cases that it relied upon, hold that a single overcharge constitutes impact, even if a class member is only injured for part of the class period.⁸⁷

The same approach applies to any concerns regarding so-called brand loyalists being included in the Settlement Class.⁸⁸ In *Nexium*, the First Circuit stated the "defendants incorrectly

⁸⁴ *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 144 (E.D. Pa. 2011).

⁸⁵ See Dkt. 350 at 39, FN 34 ("[Astellas] claims that where a class member received reduced prices for some transactions that outweigh any overcharges for other transactions during the same damages period as the result of the same alleged violation, the resulting offset means that class member has suffered no antitrust injury....I am inclined to agree with Astellas on this point of contention.").

⁸⁶ *Nexium*, 777 F.3d at 27; see also *id.* at 39.

⁸⁷ *Nexium*, 777 F.3d at 27.

⁸⁸ See Dkt. 350 at 37, 41.

assume that a class member who is injured for only a part of the class period did not suffer injury.”⁸⁹ The First Circuit acknowledged that some brand loyalists were likely not injured by the defendants’ conduct, but rejected the argument that this was more than a *de minimis* amount, in part because “a consumer was injured if he or she would have purchased generic *even once* during class period,” and that given that Nexium is a “maintenance drug,” there is a high likelihood that a consumer would purchase a generic at least once.⁹⁰ The *Nexium* Court then credited Professor Rosenthal’s observation that defendants had not presented evidence but were relying on the mere hope that there is a “likelihood of there being a substantial number of consumers who *only* purchases during the entire Class Period were brand purchases.” and concluded that “[t]he defendants’ speculation cannot defeat the plaintiffs’ showing” that “the vast majority of class members were probably injured.”⁹¹

Here, similar to the defendant in *Nexium*, the hypothetical existence of a transplant patient who may have once bought the brand after generic entry does not defeat the fact of injury. Prograf, like Nexium, is a maintenance drug so repeated transactions for a given consumer increase the likelihood of generic purchasing for at least *one* transaction. Even more importantly, here, like *Nexium*, “brand loyalists” paying the retail price of Prograf *do* suffer injury for a substantial time during the class period, as evidenced Professor Rosenthal’s uncontroverted finding that brand prices in fact went down after generic entry. Dkt. 154-1 at 13-15.

⁸⁹ *In re Nexium*, 777 F.3d at 27.

⁹⁰ *Id.* at 30.

⁹¹ *Id.* at 30-31 (emphasis in original).

As Plaintiffs demonstrate, the First Circuit's *Nexium* decision should ameliorate any concerns that the Settlement Class satisfies the test for predominance and should be certified as to all issues, in a manner consistent with First Circuit precedent.

3. The Settlement Class is Superior to Alternative Forms of Adjudication

Rule 23(b) also sets forth a requirement that "a class action [be] superior to other available methods for fairly and efficiently adjudicating the controversy." Fed.R.Civ.P. 23(b)(3). This superiority requirement is designed to ensure that the class action will "achieve economies of time, effort, and expense, and promote . . . uniformity of decision as to persons similarly situated, without sacrificing procedural fairness or bringing about other undesirable results."⁹² In this manner, the Rule aims to provide for the "vindication of the rights of groups of people who individually would be without effective strength to bring their opponents into court."⁹³ Further, the Rule itself provides a non-exhaustive list of factors which the Court may consider in determining whether the requirement of superiority is fulfilled:

(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 proposed Settlement Class meets the superiority prong of the Rule 23(b)(3) inquiry. The proposed settlements in the instant case will present a solution to the all indirect purchasers of Prograf and generic tacrolimus against Defendant in the instant case. Because the parties have

⁹² *Amchem*, 521 U.S. at 615.

⁹³ *Id.* at 617 (internal quotation omitted).

agreed to resolve the case on a class-wide basis involving the establishment of a settlement fund, this will save class members (not to mention the entire judicial system) the large sums of time and resources they would have to invest in trying individual damages cases, even if the currently-certified issue class obtained a ruling that Astellas engaged in antitrust activity.

In cases such as this, where a defendant's wrongdoing resulted in class-wide impact, but individual losses are small, the class action mechanism is superior to other methods of adjudication. Without the use of the class mechanism, the reality is the majority of the consumers and smaller third-party payors lack the resources and the financial incentive necessary to pursue individual actions to their conclusion.⁹⁴ Realistically, the alternative to a class action is that a Defendants' conduct will largely go unchallenged and Class members will go uncompensated, as the claims of individual Class members are, on balance, too small to justify complex antitrust litigation against pharmaceutical giants represented by some of the best law firms in the country. Accordingly, the Court should find that the superiority requirement of Rule 23(b)(3) is met.

Class members have no incentive to control separate actions because they all have common claims and interests. The work of Plaintiffs and Class Counsel inure to the benefit of all. Plaintiffs are not aware any other indirect purchaser actions relating to the same case and controversy that is not already before this Court. Finally, consolidation and resolution on a class basis in this single forum reduces unnecessary expenses and the possibility of conflicting rulings. Without a class action, thousands of class plaintiffs would have to prove the same set of facts in case after case.

⁹⁴ Even as to the TPPs, many "are small Taft-Hartley plans without the resources to litigate in hard fought battles with the pharmaceutical manufacturers." *See In re Pharm. Indus. Average Wholesale Price Litig.*, 252 F.R.D. at 107.

4. Manageability concerns are irrelevant in the settlement certification context.

“Confronted with a request for settlement-only class certification, a district court need not inquire whether the case, if tried, would present intractable management problems, *see* Fed. R. Civ. P. 23(b)(3)(D), for the proposal is that there be no trial,” *Amchem*, 521 U.S. at 620.

* * *

For the foregoing reasons, the End-Payor Class Representatives respectfully request that this Court certify the Settlement Class under Rule 23(b)(3) and that the End-Payor Class Representatives be certified as representatives of the Class.

B. The Proposed Settlement Is the Product of Good Faith, Extensive, Arm’s-Length Negotiations

The proposed Settlement resulted from extensive arm’s-length negotiations undertaken in good faith between Plaintiffs, Class Counsel, and Astellas, respectively.

The parties’ settlement negotiations did not begin until after over four years of litigation, after significant discovery and motion practice on Plaintiff’s motion for class certification, Astellas’s summary judgment motion, *Daubert* motions, and extensive pretrial briefing. The negotiations commenced in the midst of the parties’ briefing on Astellas’s Rule 23(f) appeal to the First Circuit and did not resolve until after oral argument, but before the court issued its opinion. As a result, the parties have had the opportunity to scrutinize the strengths and weaknesses of the pending claims and defenses, and to consider, among other issues, liability, causation, damages, and the viability of the Action moving forward on a class basis. Ultimately, the narrowing of issues that naturally occurred during pretrial motion practice and discovery, along with a thorough understanding of the parties’ respective positions on the class certification appeal, enabled the parties to reach the proposed Settlement. Because of the extensive, arm’s-length bargaining involved, there is no issue (or even a suggestion) of any collusive aspect to the

proposed Settlement.

C. There Was More Than Sufficient Discovery and Investigation for Class Counsel for the Class to Make an Informed Decision

Prior to filing suit, Class Counsel undertook a comprehensive investigation of the facts and law giving rise to the claims alleged. This investigation included, among other things, meeting with the named Class representatives, reviewing transactional data related to the purchase of Prograf, and conducting extensive industry, legal, regulatory, scientific, and economic research.

Subsequent discovery in this case spanned over two years. In all, Plaintiffs reviewed and analyzed more than 317,700 documents and almost three million pages produced by Astellas and various non-parties. Armed with this written and electronic discovery, counsel for the Indirect Purchaser Class deposed Astellas's current and former executives and employees, experts, and various non-parties, nineteen depositions in all. Plaintiffs also retained and worked with expert witnesses in evaluating scientific, regulatory and economic issues relating to liability and damages. As a result, issues relating to liability, causation and damages have been developed sufficiently for counsel for the Indirect Purchaser Class to make an informed decision regarding the proposed Settlement. Plaintiffs' counsel were heavily involved in preparing this case for trial and were stayed by the Court only a few weeks before trial was set to commence.

D. The Proponents of the Settlement Are Highly Experienced in Antitrust Litigation

Class Counsel believes that this is a fair settlement and is in the best interests of the Class. The Class is represented by lawyers who have extensive antitrust class action experience, and who this Court appointed based on that experience. Co-Lead Counsel and the other firms representing the Indirect Purchaser Class are well-established figures in antitrust litigation and complex litigation generally, and specifically in Hatch-Waxman indirect purchaser antitrust

actions. Other courts have also recognized Class Counsel's expertise in this field and have been repeatedly adjudged class counsel adequate under Rule 23(a)(4) and 23(g).⁹⁵ Thus, Class counsel are well-versed in both prosecution and settlement of this type of litigation.

Accordingly, Class counsel's recommendations are entitled to great weight. Indeed, courts have repeatedly and explicitly deferred to the judgment of experienced counsel who have conducted arm's-length negotiations in approving proposed class settlements.⁹⁶ The presumption in favor of such settlements reflects courts' understanding that vigorous, skilled negotiation protects against collusion and advances the fairness interests of Rule 23(e).

E. The Proposed Settlement is in the Best Interest of the Class

Having evaluated the strength of Plaintiffs' claims and the merits of Astellas's anticipated defenses, Counsel for Plaintiffs feel strongly that the consideration offered by Astellas in the settlement is fair and that the settlement is in the best interests of the Class. Although the Court here granted partial class certification on the single issue of antitrust violation (which is presently the subject of an appeal to the First Circuit), Plaintiffs would not be seeking recovery of any class-wide damages at trial. Therefore, even if Plaintiffs established that Astellas engaged in antitrust conduct at the class trial on this single element of their cause of action, the named Plaintiffs and every other member of the class would still have to proceed to a second phase of litigation in which they must prove that Astellas' conduct caused economic injury (i.e.

⁹⁵ *Id.*

⁹⁶ See, e.g., *Rolland* 191 F.R.D. at 10 ("When the parties' attorneys are experienced and knowledgeable about the facts and claims, their representations to the court that the settlement provides class relief which is fair, reasonable and adequate should be given significant weight."); *Bussie v. Allmerica Fin. Corp.*, 50 F. Supp. 2d 59, 77 (D. Mass. 1999) ("The Court's fairness determination also reflects the weight it has placed on the judgment of the parties' respective counsel, who are experienced attorneys and have represented to the Court that they believe the settlement provides to the Class relief that is fair, reasonable and adequate.") *Manual* § 30.42; 4 *Newberg on Class Actions*, § 11.41.

antitrust overcharge), as well as the amount of any such injury. The quantum of damage incurred by the class members would be highly dependent on the jury's findings on Sandoz's hotly-disputed "but-for" generic entry date. Under Plaintiffs' model, Sandoz would have entered in September 2008, for overcharge damages to the class states of approximately \$24,000,000. Astellas, on the other hand, submitted expert opinion modeling generic entry just before it actually occurred. If the jury accepted Astellas's model, damages would have been negligible. Weighed against these risks, the \$13.25 million recovery for the benefit of the Settlement Class is eminently reasonable and the best result for the class members under the circumstances.

Accordingly, based on the above factors, this Court should grant preliminary approval of the proposed Settlement.

V. PLAINTIFFS SEEK APPROVAL FOR THE APPOINTMENT OF ALLOCATION COUNSEL

Plaintiffs seek approval to appoint allocation counsel to negotiate on the appropriate division of settlement funds among third-party payer and consumers, thus assuring that settlement proceeds are distributed fairly and equitably amongst class members. The Net Settlement Fund will be apportioned in accordance with the determination of allocation counsel negotiating on behalf of third-party payors and consumers, and will be distributed to class members *pro rata* based on their purchases during the class period, and thus does not grant preferential treatment to any class member.

To determine a reasonable allocation between consumers and TPPs, Class Counsel would appoint Kenneth A. Wexler (on behalf of consumers), and Christopher M. Burke, two attorneys experienced in pharmaceutical antitrust litigation, to serve as Allocation Counsel and to negotiate with one another. Mrs. Wexler and Burke will negotiate a separate agreement ("Allocation Agreement") which shall be presented to the Court for preliminary approval as part

of the Motion for Preliminary Approval of Allocation Agreement and Notice Plan as set forth in Paragraph 5 of the Settlement Agreement.⁹⁷ The Allocation Agreement shall be negotiated at arms'-length between Allocation Counsel, informed to the extent they deem appropriate, by the expert reports, affidavits, declarations, and depositions in the Action by Dr. Meredith Rosenthal and Dr. Pierre Cremieux.⁹⁸ At least thirty (30) days prior to the Fairness Hearing, counsel for Plaintiffs and the Settlement Class will submit to the Court a proposed plan of final distribution of the Settlement Fund, including the method by which the net Settlement Fund will be distributed among the Consumer members of the Settlement Class and among the Third Party Payor members of the Settlement Class (the "Allocation Plan").⁹⁹

Kenneth A. Wexler is the founder of Wexler Wallace, which is recognized nationally as a leading firm in complex class action and multidistrict litigation. Among other types of litigation, Mr. Wexler and Wexler Wallace have held leadership positions in a number of pharmaceutical overpricing and Hatch-Waxman antitrust cases. A number of the courts in which Mr. Wexler has practiced have recognized him and other attorneys at Wexler Wallace for their professional, vigorous advocacy on the behalf of class members and their experience in the prosecution of complex class action claims. More information can be found in the Wexler Wallace Firm Resume, attached hereto as **Exhibit 3** to the Stranch Decl.

Christopher M. Burke chairs Scott + Scott's competition practice, and his particular area of concentration is complex antitrust litigation. Currently, Mr. Burke is lead counsel in a number of antitrust cases, including *In Re: Foreign Exchange Benchmark Rates Antitrust Litigation*, 13-cv-7789 (S.D.N.Y.); and *Alaska Electrical Pension Fund v. Bank of America*

⁹⁷ See Stranch Decl., Exh. 2 (S.A.) at ¶9.

⁹⁸ *Id.*

⁹⁹ *Id.*

Corporation, No. 14-cv-7126 (JMF) (S.D.N.Y), and serves on the Executive Committee in *In re Lithium Ion Batteries Antitrust Litig.*, No. 13-md-2420-YGR (DMR) (N.D. Cal.), and *In re: Aetna, Inc. Out of Network "UCR" Rates Litigation*, MDL No. 2020 (D.N.J.). Mr. Burke is well-versed in pharmaceutical antitrust cases and the interplay between consumer and third-party payor members in a class settlement, having previously served as Allocation Counsel for the end-payor pharmaceutical antitrust case *In re: Skelaxin (Metaxalone) Antitrust Litigation*, No. 12-md-02343 (E.D.Tenn.). More information can be found in the Scott+Scott Firm Resume attached hereto as **Exhibit 4** to the Stranch Decl.

VI. PLAINTIFFS SEEK APPROVAL FOR THE APPOINTMENT OF CLASS ADMINISTRATOR AND ESCROW AGENT

Plaintiffs request that the Court approve the selected settlement administrator, Garden City Group, Inc. (“GCG”), a well-known and highly respected expert in the field of settlement notice and administration. See Declaration of Stephen J. Cirami, GCG, Inc., attached as **Exhibit 5** to Stranch Decl.¹⁰⁰ The Administrator will oversee the Notice program and will evaluate all claims received to determine whether they are reasonable, valid and payable from the Settlement Fund. The Administrator will have the authority to contact the claimant as necessary to confirm information provided in the Claim Form or to seek additional information as required. The Administrator has administered countless antitrust settlements similar to this one, and under the supervision of class counsel, will ensure that notice is issued to the class as directed by the Court, the claims are administered fairly and accurately, the website is created and contains relevant materials and contact information, and questions from class members are answered promptly.

¹⁰⁰ Additional information may be found on GCG’s website, <http://www.http://www.gardencitygroup.com/>

Plaintiffs shall work with GCG to formulate settlement notice to the class and, no later than the deadline established by the Preliminary Approval Order, Plaintiffs shall file with the Court a Motion for Preliminary Approval of the Allocation Agreement and Notice Plan, along with any supporting declarations, exhibits, and other documentation etc., which shall request entry of an order approving, in relevant part: (1) long- and short-form notices to the members of the Settlement Class; and (2) a plan to give notice of the Settlement, the terms of the Settlement Agreement, and the Allocation Agreement to members of the Settlement Class.¹⁰¹

Plaintiffs also request that the Court approve Pinnacle Financial Partners (“Pinnacle Bank, Nashville Branch”), as the Escrow Agent for the Settlement Fund, from which any taxes, court-awarded counsel fees, expenses, and payments to the class representatives will be deducted, with the remaining amount constituting the Net Settlement Fund for distribution to the class. The Administrator has experience managing similar accounts resulting from class action settlements and was selected by Class Counsel with Astellas’s consent.

VII. THE COURT SHOULD APPROVE THE PROPOSED FINAL SETTLEMENT SCHEDULE, INCLUDING SETTING A DATE FOR THE FAIRNESS HEARING

Plaintiffs propose the following schedule for completing the approval process:

Plaintiffs shall file with the Court a Motion for Preliminary Approval of the Allocation Agreement and Notice Plan, along with any supporting declarations, exhibits, and other documentation etc.	Within 30 days of the entry of the Order preliminarily approving the Settlement
Dissemination of Notices to the Class in the form and manner proposed	Within 20 days of entry of the Order preliminarily approving the Allocation Agreement and Notice Plan

¹⁰¹ See Stranch Exh. 2 at ¶5.

Filing of Plaintiffs' motion for final approval of the Settlement, the Allocation Agreement and Plan of Allocation	30 days before the date set for the Fairness Hearing
Submission of Class Counsel's application for Attorneys' Fees and Expenses, and Application for Incentive Awards to the Class Representatives	30 days before the date set for the Fairness Hearing, but no later than 9 months after entry of the Order preliminarily approving the Allocation Agreement and Notice Plan.
Deadline for Class Members to object to the Settlement and Fee Application	14 days before the date set for the Fairness Hearing
Fairness Hearing	To Be Determined By the Court ¹⁰²

Any Class member who objects to the settlement may be heard at the fairness hearing.

VIII. CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant preliminary approval of the Settlement. A proposed order granting these requests accompanies the motion for preliminary approval as **Ex. 1**.

DATED: February 4, 2016

Respectfully Submitted,

/s/ J. Gerard Stranch, IV

J. Gerard Stranch, IV

¹⁰² Due to the need to give notice to the Class of the terms of the Settlement, and their rights with respect to the Settlement, Class Counsel respectfully suggest that the Fairness Hearing be scheduled at least 120 days after preliminary approval.

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Co-Lead Indirect Purchaser Class Counsel

CERTIFICATE OF SERVICE

I hereby certify that on February 4, 2016, a true and correct copy of the foregoing
was served upon counsel of record by electronic mail.

/s/ J. Gerard Stranch, IV
J. Gerard Stranch, IV