Case No. 15-1290

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

In re: PROGRAF ANTITRUST LITIGATION

LOUISIANA HEALTH SERVICE INDEMNITY COMPANY, individually and all others similarly situated, d/b/a Blue Cross Blue Shield of Louisiana; JANET M. PAONE, on behalf of herself and all others similarly situated,
Plaintiffs - Appellees,

BURLINGTON DRUG COMPANY INC.; JUDITH CARRASQUILLO, on her behalf and on behalf of all others similarly situated; KING DRUG COMPANY OF FLORENCE INC.; NEW MEXICO UFCW UNION'S AND EMPLOYER'S HEALTH AND WELFARE TRUST FUND; PLUMBERS AND PIPEFITTERS LOCAL 572 HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; STEPHEN L. LAFRANCE HOLDINGS, INC., a/k/a SAJ DISTRIBUTORS; STEPHEN L. LAFRANCE PHARMACY, INC., a/k/a SAJ DISTRIBUTORS; UNIONDALE CHEMISTS, INC.; LOUISIANA WHOLESALE DRUG COMPANY, INC.
Plaintiffs,

v.

ASTELLAS PHARMA US, INC.,
Defendant - Appellant.

Appeal from the United States District Court for the District of Massachusetts
MDL No. 2242, Master File No. 1:11-md-02242-RWZ

BRIEF OF APPELLANT ASTELLAS PHARMA US, INC.

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June 8, 2015

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1, Appellant Astellas Pharma US, Inc. ("Astellas") states that it is an indirect wholly-owned subsidiary of Astellas Pharma Inc. (ALPMF), a publicly-traded company on the Tokyo Stock Exchange. No other publicly-held company has a 10% or greater ownership stake in Astellas.

By: _____
Counsel for Appellant
Astellas Pharma US, Inc.

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

This appeal should be set for oral argument because it raises important questions about the use of "issue classes," addressing what the district court called a "disagreement among the federal courts of appeals regarding the use of Rule 23(c)(4)." Addendum ("Adden.") at 5. Acceptance of the district court's interpretation would undermine decades of jurisprudence on the certification of class actions, not only in antitrust cases but in other areas. As this Court recognized when it granted permission to appeal on March 4, 2015, "the case presents 'special circumstances' warranting interlocutory review."

JURISDICTIONAL STATEMENT

The district court had jurisdiction under 28 U.S.C. § 1332(d) because the complaint was filed as a class action, it alleges that the amount in controversy exceeds $5,000,000 (exclusive of interest and costs), and four of the originally-named plaintiffs are citizens of states different from the defendant. Appendix ("App'x") at 90-91, ¶ 14. Defendant Astellas is a Delaware corporation with its principal place of business in Illinois. *Id.* at 90, ¶ 13. The citizenships of the original plaintiffs are as follows (*id.* at 88-90, ¶¶ 8-12):

- Janet Paone ("Paone") – Minnesota.
- Judith Carrasquillo ("Carrasquillo") – Illinois.
- Louisiana Health Service Indemnity Company d/b/a Bluecross/Blueshield of Louisiana ("BCBS LA") – Louisiana.
- New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund ("NM Fund") – New Mexico.
- Plumbers and Pipefitters Local 572 Health and Welfare Fund ("Plumbers") – Tennessee.

On June 10, 2014, the district court entered an order certifying a class. Adden. at 2-10. Astellas filed a timely petition for permission to appeal pursuant to Rule 23(f), Fed. R. Civ. P., on June 24, 2014. This Court granted the petition on March 4, 2015.

STATEMENT OF THE ISSUES PRESENTED FOR REVIEW

1. May a district court certify a class if it finds that a "significant number of class members did not suffer any injury" and that determining which class members were injured would require "myriad individual adjudications [that] would render the case unmanageable"?

2. May a district court grant "certification on the issue of antitrust violation" after finding that common questions do not predominate over individual questions for the class members' claims?

STATEMENT OF THE CASE

A. Procedural History

Several actions were brought against Astellas by direct and indirect purchasers of its drug Prograf®, alleging that Astellas violated the antitrust laws by presenting a "sham" citizen petition to the Food and Drug Administration for the sole purpose of delaying the FDA's approval of a generic version of Prograf. The claims brought by direct purchasers are not at issue. Several indirect purchasers brought suit and moved for certification of a class of indirect purchasers. On December 17, 2013, the district court denied certification. Adden. at 73. Plaintiffs then sought "certification of a class only as to the issue of Astellas's alleged antitrust conduct" under Rule 23(c)(4). *Id.* at 2. The court granted "class certification on the issue of antitrust violation." *Id.* at 9-10.

B. The Facts

Prograf is an immunosuppressant drug made by Astellas that reduces the risk of organ rejection in transplant patients. Its active ingredient is tacrolimus. About seven months before the substance patent on the drug expired, Astellas filed a citizen petition at the FDA to raise concerns, shared by the transplant community, about whether different formulations of certain immunosuppressants, including tacrolimus, are fully and safely substitutable for each other in transplant patients and whether doctors should be notified when a pharmacy switches formulations. Dkt. 361 at 1 & Ex. 46.[1] The FDA took nearly two years to consider Astellas's petition, partially granting it and partially denying it on August 10, 2009. Adden. at 32. On the same day, the FDA approved a generic tacrolimus product (a "Generic") made by Sandoz. *Id.*

Several lawsuits were brought alleging that Astellas's FDA petition was "baseless" and a "sham" not protected from antitrust challenge by the First Amendment. Plaintiffs contend that Astellas's petition delayed the FDA's approval of Sandoz's Generic by 11 months. *Id*. at 25.

Astellas sells Prograf to wholesalers, who resell the drug to pharmacies for resale to consumers. Typically, the cost of prescriptions is shared by consumers

[1] All "Dkt." citations are to the docket in the consolidated multidistrict proceeding, MDL No. 2242, Master File No. 1:11-md-02242-RWZ.

and their third-party payors ("TPPs," *e.g.*, health insurers, health benefit plans, and self-insured employers) in accordance with the specific benefit design features in their health plans. *Id*. at 56-57. In general, the consumer pays the pharmacy a copayment and the TPP pays the balance to the pharmacy. *Id*. at 57. Under the federal antitrust laws, only direct purchasers – in this case, wholesalers – can sue for overcharge damages. *See Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977). Astellas stipulated to the certification of a direct purchaser class, and subsequently settled with that class. Adden. at 33 n.5; Dkt. 678.

This appeal grows out of actions originally filed by five indirect purchasers – two consumers and three TPPs ("Plaintiffs") – who sued under state antitrust, consumer protection, and unjust enrichment laws that may permit recoveries by indirect purchasers. Adden. at 33-34. The cases were consolidated, Dkt. 69, and a motion was filed to certify a class of indirect purchasers.

A central question was whether Plaintiffs, and the members of the class they seek to represent, were injured by the alleged 11-month delay in Generic entry. Early in the proceedings, one Plaintiff (Plumbers) conceded that it did not have a valid claim. Dkt. 173 at 2. Following discovery, summary judgment was entered against two other Plaintiffs (Carrasquillo and NM Fund) because the evidence established that they were not injured. Adden. at 2 n.2, 28; Dkt. 450; Dkt. 438.

The record as to Plaintiff Carrasquillo illustrates the nature of the evidence. Subpoenas of three pharmacies were necessary to obtain her Prograf prescriptions. *See* Dkt. 325 (under seal). They revealed that for three years after Generic entry, "her prescriptions included a notation from her physician directing pharmacists not to substitute generics for Prograf," thus demonstrating that she "would not have switched from Prograf to generic tacrolimus during the damages period even if generics had been available." Adden. at 25. A subpoena of her husband's health insurer was necessary to determine the copayment structure applicable to those prescriptions. That evidence, coupled with the fact that when her husband was out of work she "received Prograf free of charge from Astellas through its Patient Assistance Program," proved that "the cost of Prograf to Carrasquillo was the same in the actual world as it would have been in the but-for world with earlier generic market entry." *Id.* at 25-26.

More broadly, the evidence demonstrated that a large percentage of the consumers in the proposed class were not injured by the alleged 11-month delay in Generic entry. Most Prograf users continued to buy Prograf even after the Generic became available. *Id*. at 59. The district court cited evidence that among these "brand loyal" consumers, 12% continued to pay the same amount in copayments

for Prograf after Generic entry, and thus were not injured.[2] *Id.* at 60. Another 45% of brand-loyal consumers actually benefited from any delay in Generic entry because their TPPs raised their co-pays for branded drugs when generics were introduced in order "to incentivize patients to switch to generics." *Id.* As for the consumers who switched to the Generic, the district court cited evidence that 29% of them were not harmed and actually would have benefited from delay "because their average tacrolimus expenditures increased following generic entry." *Id.* at 61.

The evidence also showed that many TPPs benefited from any delay because it cost them more for a Generic prescription than for a Prograf prescription. Although Prograf was priced a little higher than the Generic on average, many TPPs more than made up the difference by imposing a higher copayment for Prograf than for the Generic. Thus, "some TPPs actually paid more for tacrolimus after generic entry than they did before." *Id.* at 59. Plaintiff NM Fund was one such uninjured TPP, and summary judgment was entered against it. *Id.* at 2 n.2; Dkt. 437; Dkt. 438.

[2] The percentages cited in this paragraph are based on an analysis of "longitudinal pharmacy claims data" (*i.e.*, data that tracks the prescriptions over time of individual consumers, identified by number, not name), which "covers 35 to 40 percent of all tacrolimus prescriptions filled through retail and mail order pharmacies in the United States." Adden. at 58 & n.30.

Plaintiffs submitted expert declarations in support of their motion to certify, but their expert did not attempt to show injury to *each* class member from the alleged delay in Generic entry. "Dr. Rosenthal's analysis, while it purports to demonstrate harm to the class as a whole, does 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." Adden. at 64.

On December 17, 2013, the district court denied class certification. *Id.* at 73. It found that "plaintiffs' impact methodology provides no way of confirming, upon common proof, that every member of the class is connected to at least one higher-priced prescription, let alone whether each class member actually paid any overcharge and was therefore injured." *Id.* at 70-71. The court thus found that Plaintiffs failed to satisfy the predominance requirement of Rule 23(b)(3):

> I agree with Astellas that there is a substantial likelihood that significant numbers of class members did not suffer any injury given the wide variability of prescription prices, purchasing behavior, and insurance plans across the class. Plaintiffs have not shown that their methodology demonstrates widespread harm to class members in spite of these distinctions, or that such a determination can be made upon common proof. . . . I find that plaintiffs have failed to establish that common questions will predominate over individual ones on the issue of antitrust impact.

Id. at 71-72. The court also found that Plaintiffs failed to satisfy the superiority requirement of Rule 23(b)(3):

> [P]roof of plaintiffs' antitrust injury and damages in this action will depend on individual issues rather than common ones. In such circumstances, myriad individual questions would render the case unmanageable. . . . I therefore find that that class action is not the superior form of litigation to resolve plaintiffs' claims.

Id. at 72-73.

Plaintiffs then moved for "certification of a class only as to the issue of Astellas's alleged antitrust conduct," citing Rule 23(c)(4). *Id.* at 2. In its opinion of June 10, 2014, the district court cited a "disagreement among the federal courts of appeals regarding the use of Rule 23(c)(4)," and observed that the First Circuit has "yet to take a clear position in the debate." *Id.* at 5-6. The court rejected the line of authority that requires "a showing of predominance as to the cause of action as a whole." *Id.* Instead, it sided with cases holding that "when plaintiffs seek to certify an issue-specific class, they need only show that common questions predominate as to that particular issue." *Id.*

The court found that the "issue-specific class" satisfied the predominance requirements of Rule 23(b)(3):

> [G]iven my determination above that common questions predominate as to the issue of antitrust violation and that partial certification would materially advance the litigation for all parties, I find that IPPs [Indirect Purchaser Plaintiffs] need not demonstrate predominance for the entire action in order to certify an issue-specific class in this case.

Id. at 6.

In its discussion of Rule 23(b)(3)'s superiority requirement, the court did not explain why an *issue-specific* class was superior whereas the original proposed class was not. Previously, the court found that "proof of plaintiffs' antitrust injury and damages *in this action*" would require "myriad individual adjudications [that] would render the case unmanageable." *Id.* at 73 (emphasis added). Evidently the court's reason for finding an issue-specific class superior is that the myriad individual adjudications would be handled in other forums. Under the district court's procedure, if Plaintiffs prevail at the class trial and any absentee class members wish to recover, they will have to file separate lawsuits. The proposed class notice advises class members: "You will be solely responsible for pursuing any such lawsuit, at your own expense and with the assistance of a lawyer of your own choosing." Dkt. 478-2 at 2.

The court subsequently provided more details about how the matter will proceed if the class certification order stands:

> If the indirect purchaser cases proceed to trial, . . . the only issue will be whether Astellas engaged in conduct that violates the relevant state antitrust and consumer protection laws. Antitrust injury and damages will not be tried for either the named plaintiffs or the class at large. If the IPP class prevails on that single issue, its members – including the named plaintiffs – may proceed with their claims individually in trials on other elements of their claims, such as impact and damages.

Adden. at 74.

The two remaining named Plaintiffs advised the district court that if an antitrust violation is established at the class trial, they will request "a timetable for submitting supplemental expert opinions pertaining to impact and damages." Dkt. 532 at 2. The court has not stated whether it will permit the submission of additional expert reports long after the deadline. *See* Dkt. 269 (setting deadline of July 19, 2013, for expert reports).

SUMMARY OF THE ARGUMENT

A straightforward application of *In re Nexium Antitrust Litigation*, 777 F.3d 9 (1st Cir. 2015), requires reversal. *Nexium* permits certification of a class with uninjured members if they are "de minimis" in number and there is a "mechanism" for "distinguishing the injured from the uninjured class members" that is "administratively feasible" and implemented "prior to judgment." *Id.* at 14, 19.

In this case, the number of uninjured class members is far more than de minimis. As the district court pointed out, "Plaintiffs have not shown that their methodology demonstrates widespread harm to class members." Adden. at 71-72. In fact, a large number of class members *benefited* from any alleged delay in entry of the Generic. Therefore, the class lacks the "cohesiveness" necessary for class certification. *See Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 (1997).

Furthermore, there is no mechanism for separating the injured from the uninjured class members "prior to judgment," as *Nexium* requires. The district

court improperly left that issue to be decided in future lawsuits filed by class members. More fundamentally, regardless of the forum, there is no "administratively feasible" way to determine who was injured. Injury is a complicated issue. Extensive discovery (much of it from non-parties) was needed to test the allegations of injury asserted by the four named Plaintiffs who moved for class certification. Summary judgment was entered against two of them because the evidence proved they were not injured. The other two say they need additional expert reports in order to show injury. As the district court rightly found when it originally denied certification, "myriad individual adjudications would render the case unmanageable" if it proceeded as a class action. Adden. at 73.

This Court should also reverse because certification of a class on the issue of antitrust violation is contrary to Rule 23(b)(3). That provision permits class certification only if "the questions of law or fact common to class members predominate over *any* questions affecting only individual members" (emphasis added). The most natural reading of this language is that it requires the trial judge to consider *all* of the questions presented by the class members' claims when deciding whether the common questions predominate. That is how the Supreme Court and this Court have always analyzed predominance, focusing on whether individualized questions will overwhelm common questions.

Rule 23(c)(4) is a housekeeping rule that allows common issues to be bifurcated. It does not change the substantive standards for class certification, which is governed by Rules 23(a) and (b). Rather, like all the other subdivisions of Rule 23(c), (c)(4) addresses procedural issues for cases that already have been found to satisfy the requirements of 23(a) and (b).

The district court's interpretation should be rejected because any case satisfying the "commonality" requirement of Rule 23(a)(2) would automatically satisfy the district court's test for predominance. To satisfy (a)(2), a movant must show that "an issue . . . central to the validity" of each class member's claim can be resolved "in one stroke" for all class members. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2551 (2011). That requirement is exactly the same as the district court's test for finding predominance with an issue class. But equating those tests is improper. "Even if Rule 23(a)'s commonality requirement may be satisfied . . . , the predominance criterion is far more demanding." *Amchem*, 521 U.S. at 623-24. This Court should not adopt an interpretation that would make the predominance requirement of Rule 23(b)(3) redundant of the commonality requirement of Rule 23(a)(2) when (c)(4) is invoked. Doing so would undermine decades of jurisprudence on the appropriateness of class certification in many kinds of cases.

ARGUMENT

The decision below should be reversed for two independent reasons. First, the district court did not apply the standards set forth by this Court in *Nexium* for certifying classes with uninjured members. The district court's findings of fact make clear that a class cannot be certified under the *Nexium* standards.

Second, the district court applied the incorrect standard for certifying an issue class. A class cannot be certified under Rule 23(b)(3) unless the court concludes, after weighing all of the issues presented by the class members' claims and the defenses thereto, that common questions "predominate" over individual questions. Rule 23(c)(4) does not change this requirement; it simply authorizes the court to bifurcate common questions for trial in cases where common questions predominate.

I. The Class Was Improperly Certified Because a Large Number of Class Members Were Not Injured and No Manageable Method Exists to Determine Which Class Members Were Injured.

The district court certified a class prior to this Court's decision in *Nexium*, and did not apply the legal test adopted there for determining whether a class with uninjured members may be certified. Review of the district court's legal test is de novo. *See Tardiff v. Knox County*, 365 F.3d 1, 4 (1st Cir. 2004) (review of legal issues underlying class certification is de novo); *Smilow v. Southwestern Bell*

Mobile Systems, Inc., 323 F.3d 32, 37 (1st Cir. 2003) (abuse of discretion "occurs if the court adopts an incorrect legal rule" in certifying a class).

A. A Class May Not Be Certified Because a Substantial Number of Its Members Did Not Suffer Any Injury and Actually Benefited from the Challenged Conduct.

The class fails to satisfy the Supreme Court's "cohesiveness" requirement because it contains a large number of uninjured class members. "The Rule 23(b)(3) predominance inquiry tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *Amchem*, 521 U.S. at 623. A class is not cohesive when a substantial number of its members were unaffected by the alleged misconduct. *See Kohen v. Pacific Inv. Mgmt. Co. LLC*, 571 F.3d 672, 677 (7th Cir. 2009) ("a class should not be certified if it is apparent it contains a great many persons who have suffered no injury at the hands of the defendant"). As the Supreme Court observed:

> The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only. In order to justify a departure from that rule, a class representative must be part of the class and possess the same interest and suffer the same injury as the class members.

Wal-Mart, 131 S. Ct. at 2550 (internal quotations and citations omitted).

The district court's findings are clear: "Plaintiffs have not shown that their methodology demonstrates widespread harm to class members." Adden. at 71-72. "I agree with Astellas that there is a substantial likelihood that significant numbers

of class members did not suffer any injury." *Id.* at 71. Remarkably, the uninjured class members include at least three of the five Plaintiffs who sued Astellas. Although *Nexium* permits certification "if the class includes a de minimis number of uninjured parties," 777 F.3d at 14, that is certainly not the situation here. The facts are vastly different from those in *Nexium*, where the plaintiffs' expert "showed that *nearly all class members* suffered an antitrust injury as a result of defendants' conduct." *Id.* at 26 (emphasis added).

Furthermore, this is not merely a class with *uninjured* class members. A large fraction of its members *benefited* from any delay in Generic entry caused by the challenged conduct – a fact that utterly destroys any claim of class cohesiveness. According to the unrebutted evidence described by the district court:

- 45% of the consumers who stayed with Prograf were better off as the result of any delay in Generic entry because their copayments for Prograf rose when the Generic appeared. Adden. at 60.
- 29% of the consumers who switched to the Generic were better off as the result of any delay "because their average tacrolimus expenditures increased following generic entry." *Id.* at 61.
- "[S]ome TPPs actually paid more for tacrolimus after generic entry than they did before." *Id.* at 59. In particular, Plaintiff NM Fund conceded

that it "had not suffered injury during the proposed damages period." *Id.* at 2 n.2.

B. The District Court's Procedure Improperly Fails to Require a Pre-Judgment Determination of Which Class Members Were Injured.

An independent reason for reversing the decision below is that the district court's procedure does not provide for a determination prior to judgment of which class members were injured. Both the *Nexium* majority and the dissent agreed on that point. "At the class certification stage, the court must be satisfied that, *prior to judgment*, it will be possible to establish a mechanism for distinguishing the injured from the uninjured class members." 777 F.3d at 19 (emphasis added). "I agree entirely with the key principle that serves as the predicate for the majority's opinion – that certification of a class that includes uninjured members is possible if the district court identifies a feasible method for culling those members *prior to entry of judgment* in a way that protects defendants' rights." *Id.* at 36-37 (Kayatta, J., dissenting) (emphasis added). This requirement follows not only from Rule 23 but also from the Rules Enabling Act, 28 U.S.C. § 2072(b) (rules "shall not abridge, enlarge or modify any substantive right"). As the *Nexium* majority pointed out, the Rules Enabling Act permits a class with uninjured members only if there is a "requirement at the class certification stage . . . ensuring that a

methodology can be developed that is capable of excluding uninjured members." 777 F.3d at 32 n.28.

Under the procedure established by the district court, no "distinguishing" or "culling" will occur prior to judgment in this action. The court simply "kicked the can" down the road to future lawsuits that absent class members must bring if the class trial finds an antitrust violation and the class members wish to recover. That procedure is not permitted by *Nexium*, Rule 23, or the Rules Enabling Act.

C. A Class May Not Be Certified Because No Administratively Feasible Mechanism Exists for Distinguishing Injured from Uninjured Class Members.

Nexium further holds that a class with uninjured members cannot be certified unless the mechanism for separating injured from uninjured class members is "manageable." 777 F.3d at 14. "The court may proceed with certification so long as this mechanism will be 'administratively feasible,' *see Carrera* [*v. Bayer Corp.*, 727 F.3d 300, 307 (3d Cir. 2013)], and protective of defendants' Seventh Amendment and due process rights." 777 F.3d at 19. "[S]eparating the injured from the uninjured must be possible using a common test rather than an individual ad hoc approach." *Id.* at 24 n. 20 (citing *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 522 F.3d 6, 28 (1st Cir. 2008)). In *Carrera*, the court stated that a mechanism is administratively feasible if it "'does not require much, if any, individual factual inquiry'"; on the other hand, a mechanism is *not* feasible if

"individualized fact-finding or mini-trials will be required." 727 F.3d at 307-08 (citing William B. Rubenstein & Alba Conte, *Newberg on Class Actions* § 3:3 (5th ed. 2011)).

The findings below demonstrate that no administratively feasible mechanism exists. As the district court pointed out, "[d]iscerning the existence of such impact is impossible without the use of individualized data," and would necessitate "myriad individual adjudications [that] would render the case unmanageable." Adden. at 71, 73. The court listed at least three factors – "prescription prices, purchasing behavior, and insurance plans," with "wide variability . . . across the class" – that must be examined in order to decide whether a particular class member was injured by a delay in Generic entry. *Id.* at 71-72. The court below cited evidence of "numerous subsets of class members, both consumers and TPPs, that presumably would not have been harmed by increased prices due to plan-specific variables, including co-payment and co-insurance policies, formulary structures, and patient expenditure limits." *Id.* at 67-68. These factors are more than enough to defeat administrative feasibility. *See In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 569, 572 (E.D. Tenn. 2014) (finding that the administrative feasibility requirement was not met in a generic delay case because assessing injury would require "consideration of the individual contractual relationships underlying each transaction").

The experience with the named Plaintiffs shows how hard it is to determine injury. The consumer Plaintiffs did not possess the records needed to determine whether they were harmed by any delay in Generic entry. Like most people, they did not have records showing whether they switched to the Generic after it became available in 2009, or records showing the copayment structure under their health plans back then. Extensive (and expensive) discovery – much of it from non-parties such as pharmacies and insurance companies – was needed to obtain this information. The evidence proved that Carrasquillo was not injured, Adden. at 24-28, and Astellas presented evidence that Paone "paid more on average for tacrolimus after generics entered the market," indicating that she too was not injured, *id.* at 61. As yet, neither she nor the other remaining Plaintiff (BCBS LA) has offered any proof of injury. They told the court that they will need to submit additional expert reports. If they are able to do so, a trial will be necessary.

A mechanism is not administratively feasible if third-party discovery, an individual expert report, and a trial are needed to determine whether a particular class member was injured. Under a straightforward application of *Nexium*, this Court should reverse the certification order and direct the district court to deny class certification.

II. The District Court Improperly Certified an "Issue" Class Despite Finding That Common Questions Did Not Predominate Over Individual Questions for the Class Members' Claims.

If this Court agrees that *Nexium* requires reversal, there is no need to reach the second issue on appeal: Whether the district court, after having found that common questions do not predominate over individual questions for the class members' claims, properly granted "class certification on the issue of antitrust violation." Adden. at 9-10. This is a matter of law, and review is de novo. *See Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 295 (1st Cir. 2000); *Tardiff*, 365 F.3d at 4.

The district court granted certification under Rule 23(b)(3) because it determined "that common questions predominate *as to the issue of antitrust violation*." Adden. at 6 (emphasis added). That ruling was premised on its view that the (b)(3) predominance test should be applied differently when a plaintiff invokes Rule 23(c)(4) for certification of an issue-specific class. *Id.* Citing decisions from the Second and Ninth Circuits, the district court concluded that Plaintiffs were not required to make "a showing of predominance as to the cause of action as a whole"; rather, "when plaintiffs seek to certify an issue-specific class, they need only show that common questions predominate as to that particular issue." *Id.* at 5. As explained below in Section II.D, the district court misread the law in those Circuits.

This Court should join with the Fifth Circuit in holding that "a cause of action, as a whole, must satisfy the predominance requirement of (b)(3)." *Castano v. Am. Tobacco Co.*, 84 F.3d 734, 745 n.21 (5th Cir. 1996). Under that interpretation, Rule 23(c)(4) does not alter the predominance requirement. Rather, in cases that satisfy the substantive requirements of Rule 23(a) and (b), subdivision (c)(4) provides authority to bifurcate the trial of class questions from the determination of individual questions. This interpretation is most faithful to the language of the Rule, the intent of its framers, recent Supreme Court decisions, this Court's own precedents, and decades of jurisprudence about when class certification is appropriate for many types of cases.

A. The Text and Structure of Rule 23 Require That All Classes Satisfy the Substantive Standards of Rule 23(a) and (b).

The starting point in construing Rule 23 is its text. As the Supreme Court emphasized when discussing Rule 23:

> [O]f overriding importance, courts must be mindful that the Rule as now composed sets the requirements they are bound to enforce. Federal Rules take effect after an extensive deliberative process involving many reviewers: a Rules Advisory Committee, public commenters, the Judicial Conference, this Court, the Congress. See 28 U.S.C. §§ 2073, 2074. The text of a rule thus proposed and reviewed limits judicial inventiveness.

Amchem, 521 U.S. at 620. In case after case, the Supreme Court has reversed the use of judicial inventiveness to certify classes that could not be justified by the text of the Rule.[3]

The substantive requirements for class certification are found in Rule 23(a) and (b). Subdivision (a) is captioned "**Prerequisites**," and allows a representative to sue "on behalf of all members only" when the four requirements of 23(a) are satisfied. Subdivision (b) is captioned "**Types of Class Actions**," and it refers to three types: "A class action may be maintained if Rule 23(a) is satisfied and if" (b)(1), (2), or (3) is also satisfied. Thus, a class "must satisfy at least one of the three requirements listed in Rule 23(b)." *Wal-Mart*, 131 S. Ct. at 2548.

There is no other route to certification besides Rule 23(a) and (b). In *Amchem*, the Supreme Court rejected the argument that Rule 23(e) independently authorizes the certification of settlement classes. 521 U.S. at 621. The Court held that even if a class is proposed solely for purposes of settlement, the "safeguards provided by the Rule 23(a) and (b) class-qualifying criteria" must be met. *Id.* Rule 23(e) "was designed to function as an additional requirement, not a superseding

[3] *E.g.*, *Ortiz v. Fibreboard Corp.*, 527 U.S. 815, 834-37, 842-47 (1999) (rejecting use of 23(b)(1)(B) to certify a class bringing monetary claims); *Wal-Mart*, 131 S. Ct. at 2557 (rejecting use of 23(b)(2) to certify a class bringing monetary claims not incidental to injunctive relief); *Amchem*, 521 U.S. at 628-29 (rejecting use of 23(e) to certify a settlement class that failed to satisfy 23(a) and 23(b)(3)); *Eisen v. Carlisle & Jacquelin*, 417 U.S. 156, 176-77 (1974) (rejecting certification premised on dispensing with individual notice to class members).

direction, for the 'class action' to which Rule 23(e) refers is one qualified for certification under Rule 23(a) and (b)." *Id.*

Rule 23(c) likewise does not provide a "superseding direction." There are no substantive standards for class certification in any of its provisions. Rather, 23(c) governs a variety of procedural issues in cases that already have been found to satisfy the requirements of 23(a) and (b). Subdivision (c)(1) deals with the timing and content of the certification order, (c)(2) prescribes the procedure for notice, (c)(3) specifies the form of judgment, and (c)(5) authorizes subclasses. Rule 23(c)(4) is of the same ilk. It states: "When appropriate, an action may be brought or maintained as a class action with respect to particular issues." Surely, the rulemakers, after having carefully prescribed the requirements for a class action in 23(a) and (b), did not mean to give judges unfettered discretion to certify classes under Rule 23(c)(4) merely because they thought that procedure "appropriate."

Rule 23(c)(5) contains the same discretionary standard: "When appropriate, a class may be divided into subclasses that are each treated as a class under this rule." The courts agree that a subclass under 23(c)(5) must satisfy the same requirements of 23(a) and (b) that apply to any other class.[4] An issue class under

[4] *E.g.*, *Twelve John Does v. District of Columbia*, 117 F.3d 571, 575 (D.C. Cir. 1997) ("any subclass must independently meet the standards for class certification"); *Retired Chicago Police Ass'n v. City of Chicago*, 7 F.3d 584, 599 (7th Cir. 1993); *Betts v. Reliable Collection Agency, Ltd.*, 659 F.2d 1000, 1005 (9th Cir. 1981).

Rule 23(c)(4) must likewise satisfy the same requirements of 23(a) and (b). As Professor Laura Hines explained:

> [T]he provisions in subdivision (c) reflect the laundry list of steps a court may take after properly certifying a subdivision (b) class action. None of the other subdivision (c) provisions alter the terms under which a (b) class may be certified, or provide independent authority to certify another type of class action.

Laura J. Hines, *Challenging the Issue Class Action End-Run*, 52 Emory L. J. 709, 719 (2003).

Any notion that Rule 23(c)(4) authorizes an additional type of class action was eliminated by the 2003 amendment to Rule 23. The amended notice rule, 23(c)(2), provides as follows:

> (A) *For (b)(1) or (b)(2) Classes.* For any class certified under Rule 23(b)(1) or (b)(2), the court may direct appropriate notice to the class.
>
> (B) *For (b)(3) Classes*. For any class certified under Rule 23(b)(3), the court must direct to class members the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort.

In short, Rule 23(c)(4) does not provide an *independent* path to class certification. "Even advocates of an expansive reading of Rule 23(c)(4) concede that it must be understood to comply with Rule 23(a)'s class prerequisites and one of Rule 23(b)'s class provisions." Laura J. Hines, *The Unruly Class Action*, 82 Geo. Wash. L. Rev. 718, 727 (2014).

B. Rule 23(b)(3) Requires Consideration of *All* Questions Presented by the Class Members' Claims When Deciding Whether Common Questions Predominate.

1. The most natural reading of "predominate" in Rule 23(b)(3) is that it refers to the questions presented by the class members' claims.

A class can be certified under Rule 23(b)(3) only if "the questions of law or fact common to class members predominate over any questions affecting only individual members." But *which* questions should the trial judge consider when conducting the predominance analysis? The court below reasoned that "when plaintiffs seek to certify an issue-specific class, they need only show that common questions predominate *as to that particular issue*." Adden. at 5 (emphasis added).

But that is not what the provision says. Rule 23(b)(3) states that the common questions must predominate over "*any* questions affecting only individual members" (emphasis added). In this case, injury and damages are both individualized questions. Adden. at 73. Based on the plain language of the rule, a class cannot be certified unless the common question – whether Astellas violated the law – predominates over the individualized questions of injury and damages. The district court expressly found that this standard was not met. *Id*. at 69-72.

Both the Supreme Court and this Court have consistently interpreted the predominance test of 23(b)(3) as referring to *all* the questions presented by the class members' claims. "Considering whether 'questions of law or fact common to

class members predominate' begins, of course, with the elements of the underlying cause of action." *Erica P. John Fund, Inc. v. Halliburton Co.*, 131 S. Ct. 2179, 2184 (2011) ("*Halliburton I*"). And the analysis does not end there: "we regard the law as settled that affirmative defenses should be considered in making class certification decisions." *Waste Mgmt. Holdings*, 208 F.3d at 295.

This Court's approach to predominance is illustrated by *Tardiff*. The opinion began by asking, "What here are the issues?" 365 F.3d at 4. Then, after identifying the issues, the Court examined each one to assess the likelihood that it could be decided on a common basis with class-wide evidence. *Id.* at 4-6. The Court specifically included damages in the analysis, noting that "the presence of [individualized] damage claims does weigh against class status." *Id.* at 6. The Court concluded by weighing the common questions against the individual ones to see which predominated. *Id.* at 6-7.

Similarly, in *Nexium*, this Court expressly recognized that injury and damages must be considered when determining predominance in antitrust cases:

> To meet the predominance requirement, the party seeking certification must show that "the fact of antitrust impact can[ ] be established through common proof" and that "any resulting damages would likewise be established by *sufficiently* common proof."

777 F.3d at 18 (quoting *New Motor Vehicles*, 522 F.3d at 20; this Court's emphasis and brackets).

In this Circuit, therefore, the law is settled that the Rule 23(b)(3) predominance inquiry must take into account individual questions of injury, damages, and affirmative defenses. These holdings preclude the district court's approach of ignoring those issues in its predominance analysis.

Furthermore, both the Supreme Court and this Court have held that the (b)(3) predominance test is not satisfied when individual questions "overwhelm" the common questions. *E.g.*, *Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1433 (2013) ("[R]espondents cannot show Rule 23(b)(3) predominance: Questions of individual damage calculations will inevitably *overwhelm* questions common to the class.") (emphasis added); *Basic Inc. v. Levinson*, 485 U.S. 224, 242 (1988) ("Requiring proof of individualized reliance from each member of the proposed plaintiff class effectively would have prevented respondents from proceeding with a class action, since individual issues then would have *overwhelmed* the common ones.") (emphasis added); *In re Xcelera.com Sec. Litig.*, 430 F.3d 503, 507 (1st Cir. 2005) (securities fraud class cannot be certified if "[i]ndividual issues of reliance would . . . *overwhelm* the common ones") (emphasis added). As this Court explained in *Nexium*, "the question is whether there is 'reason to think that [individualized] questions will *overwhelm* common ones and render class certification inappropriate.'" 777 F.3d at 21 (quoting *Halliburton Co. v. Erica P.*

John Fund, Inc., 134 S. Ct. 2398, 2412 (2014) ("*Halliburton II*"); this Court's emphasis and brackets).

In short, this Court should reject the interpretation below and hold that the trial judge must weigh *all* the questions presented by the class members' claims when deciding whether the common questions predominate. After all, Rule 23(b)(3) "is a joinder device for consolidating separate but similar *claims*." *Tardiff*, 365 F.3d at 4 (emphasis added). Thus, the most natural reading of (b)(3) is that it requires predominantly common questions for the *claims* that are to be joined.

2. In antitrust cases, common questions do not predominate unless injury can be established with common proof.

Not only has this Court explained how the predominance requirement works in general, it has told district judges how that requirement applies to antitrust cases in particular. In *New Motor Vehicles*, the Court held that the Rule 23(b)(3) test is not satisfied just because the existence of a violation can be tried on a class-wide basis: "In antitrust class actions, common issues do not predominate if the fact of antitrust violation *and the fact of antitrust impact* cannot be established through common proof." 522 F.3d at 20 (emphasis added). Indeed, the Court went further in *Nexium* and stated that "[t]o meet the predominance requirement, the party seeking certification must show that . . . 'any resulting damages would likewise be

established by *sufficiently* common proof.'" 777 F.3d at 18 (quoting *New Motor Vehicles*, 522 F.3d at 20; this Court's emphasis).

Had this Court interpreted Rule 23 as the opinion below did, it would have ruled in *New Motor Vehicles* that certification was proper if limited to the violation issue. Instead, this Court vacated the class certification order and remanded so that the district court could "test the viability of plaintiffs' novel theory for proving common impact." 522 F.3d at 29. On remand, the district court granted summary judgment to the defendants because plaintiffs failed to present class-wide proof of injury. *In re New Motor Vehicles Canadian Export Antitrust Litig.*, 632 F. Supp. 2d 42, 45 (D. Me. 2009).

The opinion below predicted that this Court would permit certification in the present case because *Tardiff* "endorsed the certification of liability-only classes despite individualized damage issues." Adden. at 6. But the court below did not certify a "liability-only" class. It recognized that "a favorable judgment for plaintiffs on antitrust conduct would not, without more, establish Astellas's liability." *Id.* at 4. The law is clear: "Establishing [antitrust] liability . . . requires showing that class members were injured." *New Motor Vehicles*, 522 F.3d at 28. That is why common issues do not predominate in an antitrust case where, as here, the proof of injury is individualized.

3. Rule 23(c)(4) is a tool for managing class litigation that satisfies Rule 23(a) and (b).

Rule 23(c)(4) is most properly read as "a housekeeping rule that allows courts to sever the common issues for a class trial." *Castano*, 84 F.3d at 745 n.21. It makes clear that a class action can include *both* class-wide determinations and individualized determinations.

The history of Rule 23(c)(4) is revealing,[5] and was examined thoroughly in two articles by Professor Hines. *See* 82 Geo. Wash. L. Rev. at 746-49 *and* 52 Emory L. J. at 752-61. Before Rule 23(c)(4) was adopted in 1966, there was a circuit split on whether a class could be certified if individualized damage determinations were needed.[6] The framers of Rule 23(c)(4) – *i.e.*, the Advisory Committee on Rules of Civil Procedure – intended this provision to resolve the split. *See* Hines, 52 Emory L. J. at 756-57. The Reporter to the Committee was Professor Benjamin Kaplan, whom the Supreme Court has often cited as an

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[5] "To resolve any ambiguities [in Rule 23], we may also consider the rule's drafting history." *In re Pharm. Indus. Average Wholesale Price Litig.*, 588 F.3d 24, 39 (1st Cir. 2009).

[6] *Compare Union Carbide & Carbon Corp. v. Nisley*, 300 F.2d 561, 588-89 (10th Cir. 1961) (affirming class certification even though damages had to be proven individually by applying a class-wide formula), *with Farmers Co-op. Oil Co. v. Socony-Vacuum Oil Co.*, 133 F.2d 101, 105 (8th Cir. 1942) (finding class treatment improper, even though the antitrust claims brought by members of a purchasing cooperative raised "common questions of law and fact," because the "damages sought [by each member] . . . are different"). *See also* 7A Charles Alan Wright *et al.*, *Federal Practice & Procedure* § 1752 (3d ed. 2005) (describing pre-1966 split about certifying classes requiring individualized damage determinations).

authority on the intended meaning of Rule 23.[7] Professor Kaplan explained that this provision was meant to authorize the procedure used in the *Union Carbide* case. *See id.* That was an antitrust suit in which the jury found both liability and the amount of damages on a per-pound basis; the judge then directed a special master to calculate each class member's damages "in accordance with the per-pound formulae provided in the verdict." *Union Carbide & Carbon Corp. v. Nisley*, 300 F.2d 561, 588 (10th Cir. 1961). Professor Charles Alan Wright commented that a provision authorizing this procedure was unnecessary, calling it "the kind of picky detail which does not require statement in the rule." *See* Hines, 82 Geo. Wash. L. Rev. at 747 & n.184. But Professor Albert Sacks and Professor Kaplan responded that this provision, "although making obvious points, is useful for the sake of clarity and completeness." *Id*. at 747 & n.185.

The Advisory Committee Note on Rule 23(c)(4) is quite short, befitting its modest purpose:

> **Subdivision (c)(4).** This provision recognizes that an action may be maintained as a class action as to particular issues only. For example, in a fraud or similar case the action may retain its "class" character only through the adjudication of liability to the class; the members of the class may thereafter be required to come in individually and prove the amounts of their respective claims.

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[7] *E.g.*, *Ortiz*, 527 U.S. at 833-34, 842-43; *Amchem*, 521 U.S. at 613-17; *Phillips Petroleum Co. v. Shutts*, 472 U.S. 797, 813 n.4 (1985); *Oppenheimer Fund, Inc. v. Sanders*, 437 U.S. 340, 354 n.21 (1978).

Fed. R. Civ. P. 23(c)(4) (1966 Adv. Comm. Note). This Note should be read in tandem with the companion Note on Rule 23(b)(3), which also discussed fraud claims:

> [A] fraud perpetrated on numerous persons by the use of similar misrepresentations may be an appealing situation for a class action, and it may remain so despite the need, if liability is found, for separate determinations of the damages suffered by individuals within the class. On the other hand, although having some common core, a fraud case may be unsuited for treatment as a class action if there was material variation in the representations made or in the kinds or degrees of reliance by the persons to whom they were addressed.

Fed. R. Civ. P. 23(b)(3) (1966 Adv. Comm. Note). "Read side by side, these Notes suggest that (c)(4)(A) functions as a complement to (b)(3), explicitly authorizing a court's power to bifurcate common from individual issues." Hines, 52 Emory L. J. at 755.

There is no evidence that the drafters intended Rule 23(c)(4) to transform class action practice by modifying the requirements of (b)(3). *Id.* at 759. As noted above, they thought it a "picky detail," "making obvious points." They certainly did not contemplate Rule 23(c)(4) as authority for the procedure adopted by the court below in which the elements of the class members' cause of action would be split between *different lawsuits*. The "suggestion of partially certifying certain claim elements in one trial and allowing the other elements and defenses to proceed in separate trials expands beyond the class actions recognized by the framers of the Rules of Civil Procedure." Mark A. Perry, *Issue Certification*

Under Rule 23(c)(4): A Reappraisal, 62 DePaul L. Rev. 733, 743 (2013). This is just the sort of "judicial inventiveness" that the Supreme Court has repeatedly condemned. *See Amchem*, 521 U.S. at 620.

4. The district court's interpretation should be rejected because any case satisfying the commonality requirement of Rule 23(a)(2) would automatically satisfy the predominance requirement of Rule 23(b)(3).

The district court's test for 23(b)(3) predominance should be rejected because it is *identical* to the 23(a)(2) test for commonality. That interpretation is precluded by the Supreme Court's admonition that the predominance requirement is "far more demanding" than commonality. *Amchem*, 521 U.S. at 624.

Rule 23(a)(2) requires that there be "questions of law or fact common to the class." Only one common question is needed. But, in order to satisfy (a)(2), the question must be "an issue that is central to the validity" of each class member's claim. *Wal-Mart*, 131 S. Ct. at 2551. And, in order for that question to be "common," it must be "capable of classwide resolution – which means that determination of its truth or falsity will resolve" the issue for each class member "in one stroke."[8] *Id.*

[8] In *Wal-Mart*, the Supreme Court set tougher standards for satisfying the 23(a)(2) commonality prerequisite than some lower courts had required. *Cf. New Motor Vehicles*, 522 F.3d at 19 ("Rule 23(a)'s requirement of commonality is a low bar, and courts have generally given it a 'permissive application'").

The district court used exactly the same test to determine predominance for an issue-specific class. In its view, the (b)(3) requirement can be satisfied whenever a case has a *single* common issue: "when plaintiffs seek to certify an issue-specific class, they need only show that common questions predominate as to that particular issue." Adden. at 5. Moreover, the court described its predominance test using the same language that the Supreme Court used to describe the commonality test: The district court found that "certifying an issue-specific class here would allow the parties to resolve the question of antitrust violation in one efficient and economical stroke." *Id.* at 4. In other words, if a plaintiff can satisfy the (a)(2) commonality requirement – *i.e.*, if a "central" issue can be resolved "in one stroke" for all class members – the plaintiff will necessarily also satisfy the test adopted by the court below for finding that "common questions predominate as to that particular issue."

But the (b)(3) predominance test is clearly not the same as the (a)(2) commonality test. The Supreme Court held that "the predominance criterion is far more demanding." *Amchem*, 521 U.S. at 623-24. If a class could be certified based only on commonality, then the "vital prescription" of predominance, which was meant to "assure the class cohesion that legitimizes representative action in the first place," would be "stripped of any meaning." *Id.* at 623. This Court has likewise pointed out that the predominance requirement, "although reminiscent of

the commonality requirement of Rule 23(a), is far more demanding because it tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation." *In re Polymedica Corp. Sec. Litig.*, 432 F.3d 1, 3 n.5 (1st Cir. 2005) (internal quotations omitted). *Accord Xcelera.com*, 430 F.3d at 506 n.5; *New Motor Vehicles*, 522 F.3d at 20.

In the final analysis, the district court's interpretation is circular. "If an issue class action consists only of common issues, then by definition those common issues must predominate over individual issues because the action contains no individual issues at all." Laura J. Hines, *The Dangerous Allure of the Issue Class Action*, 79 Ind. L.J. 567, 584 (2004). In every case with a single common question, the predominance requirement would be satisfied. As the Fifth Circuit pointed out, "'[r]eading rule 23(c)(4) as allowing a court to sever issues until the remaining common issue predominates over the remaining individual issues would eviscerate the predominance requirement of rule 23(b)(3); the result would be automatic certification in every case where there is a common issue, a result that could not have been intended.'" *Allison v. Citgo Petroleum Corp.*, 151 F.3d 402, 422 (5th Cir. 1998) (quoting *Castano*, 84 F.3d at 745 n.21; Fifth Circuit's brackets). "If courts are able to artificially manufacture predominance for Rule 23(b)(3) purposes via Rule 23(c)(4), it is difficult to conceive of an instance in which certification as to at least one issue common to the class would not be achieved." Alex Parkinson,

Comcast Corp v Behrend and Chaos on the Ground, 81 U. Chi. L. Rev. 1213, 1235 (2014).

In short, "if a class is not certifiable under Rule 23(b)(3), but the common issues that did not predominate can be pulled out and certified as an 'issue class' under Rule 23(c)(4), the latter rule appears to have . . . rendered the predominance requirement a nullity." William B. Rubenstein, *Newberg on Class Actions* § 4:91 (5th ed. 2011). This Court should reject an interpretation that would make the predominance test of (b)(3) redundant of (a)(2). *See U.S. v. Cornier-Ortiz*, 361 F.3d 29, 36 (1st Cir. 2004) (stating that a statute should be construed "in order to avoid redundancy"); *see also Young v. United Parcel Service, Inc.*, 135 S. Ct. 1338, 1352 (2015) ("We have long held that a statute ought, upon the whole, . . . be so construed that, if it can be prevented, no clause is rendered superfluous, void, or insignificant.") (internal quotations omitted).

5. The district court's interpretation was rejected by the framers of the Rules.

Some commentators believe that class certification should be granted whenever an important issue for all class members can be resolved in a single trial.[9] But under this interpretation, predominance would no longer be a

[9] *E.g.*, 7AA Charles Alan Wright *et al.*, *Federal Practice & Procedure* § 1778 (3d ed. 2005) ("When common questions represent a significant aspect of the case and they can be resolved for all members of the class in a single adjudication, there is a

requirement. That, indeed, is exactly what the proponents of this view sought in a proposal considered by the Advisory Committee in 1995. The 1995 proposal would have eliminated the predominance requirement in order to "take full advantage of issue classes." *See* Jon Romberg, *Half a Loaf Is Predominant and Superior to None: Class Certification of Particular Issues Under Rule 23(c)(4)(A)*, 2002 Utah L. Rev. 249, 278. But that proposal, which had been offered to permit a "greater opportunity for use of class actions," was rejected. *See* Edward H. Cooper, *Rule 23: Challenges to the Rulemaking Process*, 71 N.Y.U. L. Rev. 13, 53, 56, 58 (1996).

Predominance therefore remains a requirement for certification under Rule 23(b)(3). It is separate from Rule 23(b)(3)'s additional requirement "that a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Thus, under the express language of the Rule, a class cannot be certified just because it is thought to be the superior method for resolving the common questions.

C. The District Court's Interpretation Would Undermine Decades of Jurisprudence on Rule 23(b)(3) Certification.

For the reasons explained above, this Court should reject the district court's interpretation of Rule 23 based on the usual principles of interpretation – the text

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clear justification for handling the dispute on a representative rather than on an individual basis.").

of the Rule, its history, and the canons of construction. But even if the Court were not constrained by these principles, it should still reject that approach.

1. The district court's interpretation would permit classes in cases where the Supreme Court reversed class certification.

Adoption of the district court's interpretation would radically transform class action practice. It would permit classes in cases where certification was denied. The breathtaking scope of this change can be seen by considering three decisions in which the Supreme Court *reversed* class certification orders because the plaintiffs failed to satisfy the predominance requirement of Rule 23(b)(3).

One example is *Comcast*, an antitrust case in which the Court held that a "class action was improperly certified under Rule 23(b)(3)" because of deficiencies in the plaintiffs' damage model:

> Without presenting another methodology, respondents cannot show Rule 23(b)(3) predominance: Questions of individual damage calculations will inevitably overwhelm questions common to the class.

133 S. Ct. at 1432-33. Yet, under the approach of the opinion below, the *Comcast* plaintiffs could have obtained class certification by asking for an issue class on whether Comcast's conduct violated the antitrust laws.

The second example is *Halliburton*, a securities fraud case in which the parties litigated for six years, and went to the Supreme Court twice, to determine whether reliance was a common or an individualized question, and thus whether

common questions predominated.[10] Yet, under the approach of the opinion below, the plaintiff could have obtained certification at the outset by the simple expedient of asking for an issue class on the indisputably common questions of material falsity and scienter. *Cf. Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 133 S. Ct. 1184, 1191 (2013) ("The alleged misrepresentations and omissions, whether material or immaterial, would be so equally for all investors comprising the class.").

Third, in *Amchem* the Supreme Court reversed the certification of a settlement class that was intended to achieve a global resolution of asbestos claims. The Court found that even if those claims presented an "overarching dispute about the health consequences of asbestos exposure," common issues did not predominate. 521 U.S. at 623-24. Yet once again, under the interpretation of the court below, the *Amchem* plaintiffs could have obtained certification under Rule 23(c)(4) on the common issue that the Court regarded as "overarching."

This Court should not adopt an interpretation that is being advocated for the avowed purpose of evading recent Supreme Court decisions. *See, e.g.*, Joseph A.

[10] In *Halliburton I*, the Court held that the plaintiffs did not have to prove loss causation at the class certification stage to invoke the fraud-on-the-market presumption of reliance. 131 S. Ct. at 2187. In the second case, *Halliburton II*, the Court held that the defendants could defeat this presumption at the class certification stage with evidence that the alleged misrepresentations did not actually affect the market price of the stock. 134 S. Ct. at 2417. Because the defendants had not been afforded an opportunity to present such evidence, the certification order was reversed and remanded. *Id.*

Seiner, *The Issue Class*, 56 B.C. L. Rev. 121, 131 (2015) ("issue class certification is [one] way to help circumvent the *Wal-Mart* decision"); Parkinson, 81 U. Chi. L. Rev. at 1233 ("liberal use of Rule 23(c)(4)" is a "means of bypassing *Comcast*"); Perry, 62 DePaul L. Rev. at 738 (noting that "Professor Coffee has proposed 'partial certification' as one 'path out of the wilderness' that avoids the 'roadblock' of *Dukes*").

2. The district court's interpretation is incompatible with the appellate guideposts for certifying classes in many areas of the law.

During the half-century since Rule 23(b)(3) was adopted, the appellate courts have set guideposts for many types of cases, explaining when common issues predominate or, alternatively, when the individualized issues are too weighty for a class action. These guideposts emerged gradually, as courts gained experience in using class actions for particular kinds of cases and learned when the class procedures worked or, conversely, when common questions were overwhelmed by individualized questions.

Antitrust. To justify a class in antitrust cases, most appellate courts now require common proof of each person's injury – not just common proof of an antitrust violation.[11] Many courts go further. Even though individualized damages

[11] *E.g.*, *New Motor Vehicles*, 522 F.3d at 28; *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311-12 (3d Cir. 2008); *Windham v. Am. Brands, Inc.*, 565

do not defeat predominance in many other areas, the emerging rule in the antitrust arena (where damage issues can be highly complex) is that to establish predominance, plaintiffs must show that class members' damages can be established by a method that is relatively easy to administer, such as a formula or model.[12]

Securities fraud. To justify a class in securities fraud cases, the appellate courts now require common proof of each person's reliance – not just common proof of a fraudulent statement and scienter.[13]

RICO. To justify a class in RICO cases alleging fraudulent practices, the appellate courts now require common proof of each class member's reliance – not just common proof of RICO's racketeering elements.[14]

F.2d 59, 65-66 (4th Cir. 1977) (en banc); *Alabama v. Blue Bird Body Co., Inc.*, 573 F.2d 309, 317-18 (5th Cir. 1978); *Bell Atl. Corp. v. AT&T Corp.*, 339 F.3d 294, 302 (5th Cir. 2003); *Messner v. Northshore Univ. Healthsystem*, 669 F.3d 802, 816, 818 (7th Cir. 2012); *Blades v. Monsanto Co.*, 400 F.3d 562, 566, 574-75 (8th Cir. 2005); *In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d 244, 252 (D.C. Cir. 2013).

[12] As the D.C. Circuit succinctly put it: "No damages model, no predominance, no class certification." *Rail Freight Fuel Surcharge*, 725 F.3d at 253. *Accord Comcast*, 133 S. Ct. at 1430, 1433 (noting that district court required plaintiffs to show that damages were measurable on a class-wide basis through use of a common methodology, and reversing due to deficiencies in plaintiffs' methodology); *Nexium*, 777 F.3d at 19; *Windham*, 565 F.2d at 65-66.

[13] *E.g.*, *Basic*, 485 U.S. at 242; *Halliburton II*, 134 S. Ct. at 2412; *Polymedica*, 432 F.3d at 17.

[14] *Compare In re U.S. Foodservice Inc. Pricing Litig.*, 729 F.3d 108, 119 (2d Cir. 2013) (certifying RICO class based on a classwide inference of reliance), *and CGC*

Mass tort. To justify class certification in mass tort cases, the appellate courts now generally require more than common proof about the defendant and its actions or products; they require common proof about the class members' connection to the tort, *e.g.*, causation.[15]

Adoption of the district court's interpretation would unmoor class action practice from these guideposts. On this point, scholars on both sides of the debate agree. This interpretation "can fundamentally revamp the nature of class actions. . . . [F]or mass torts, commercial fraud, and civil rights cases, issue certification is the tail that wags the class action dog." Romberg, 2002 Utah L. Rev. at 263, 271. "The answer may well be crucial to the future of mass tort class actions." Hines, 52 Emory L.J. at 711.

Over the years, the predominance test has produced a degree of predictability in class action practice, telling trial judges what questions to focus on in various types of cases. The insight underlying the predominance test – that a

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Holding Co. LLC v. Broad & Cassel, 773 F.3d 1076, 1089-92 (10th Cir. 2014) (same), *with Poulos v. Caesars World, Inc.*, 379 F.3d 654, 664-67 (9th Cir. 2004) (denying certification because individualized issues of reliance would predominate), *and Sandwich Chef of Tex., Inc. v. Reliance Nat'l Indem. Ins. Co.*, 319 F.3d 205, 219 (5th Cir. 2003) (same).

[15] *E.g.*, *McLaughlin v. Am. Tobacco Co.*, 522 F.3d 215, 234 (2d Cir. 2008); *Castano*, 84 F.3d at 744-45; *In re Am. Med. Sys., Inc.*, 75 F.3d 1069, 1084-85 (6th Cir. 1996); *In re N. Dist. of Cal., Dalkon Shield IUD Prod. Liab. Litig.*, 693 F.2d 847, 856 (9th Cir. 1982); *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1234 (9th Cir. 1996).

class should not be certified if common questions would be "overwhelmed" by individual ones[16] – makes eminently good sense and follows directly from the text of the Rule. Thus, the Court should hold that when deciding whether common questions predominate under Rule 23(b)(3), the trial judge must consider all of the questions raised by the class members' claims.

D. The District Court's Interpretation of Rule 23(c)(4) Is Not Supported by the Appellate Precedents.

As support for its interpretation, the district court cited opinions from the Ninth, Second, and Third Circuits. Adden. at 5-6. In addition, some commentators find support for this interpretation in decisions from the Fourth and Seventh Circuits.[17] But a careful reading shows that those Circuits do not embrace the sweeping view of Rule 23(c)(4) adopted by the district court. That is why the guideposts described above are so widely accepted and why few plaintiffs have succeeded with the ploy used below – after suffering a denial of class certification, moving for certification of an issue class.

Ninth Circuit. The district court cited *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227 (9th Cir. 1996), as holding "that when plaintiffs seek to certify an issue-specific class, they need only show that common questions predominate as to that

[16] *Basic*, 485 U.S. at 242; *Amgen*, 133 S. Ct at 1196; *Comcast*, 133 S. Ct. at 1433; *Halliburton II*, 134 S. Ct. at 2412; *Nexium*, 777 F.3d at 21.

[17] *See, e.g.*, Patricia Bronte *et al.*, *"Carving at the Joint": The Precise Function of Rule 23(c)(4)*, 62 DePaul L. Rev. 745, 745 & n.5 (2013).

particular issue." Adden. at 5. Actually, the Ninth Circuit *reversed* the certification of an issue class, holding that the trial court "abused its discretion by not adequately considering the predominance requirement before certifying the class." 97 F.3d at 1234. On remand, the plaintiffs abandoned their attempt to certify an issue class and negotiated a settlement of their own claims. *See In re Felbatol Prod. Liab. Litig.*, MDL No. 1048, No. C-94-2867, 1997 U.S. Dist. LEXIS 7619 (N.D. Cal. May 27, 1997).

Second Circuit. The opinion in *In re Nassau County Strip Search Cases*, 461 F.3d 219, 230 (2d Cir. 2006), does indeed state that a district court may "certify a class on a designated issue regardless of whether the claim as a whole satisfies the predominance test." But that statement does not reflect the actual practice in the Second Circuit. Just two years later, in *McLaughlin v. American Tobacco Co.*, 522 F.3d 215 (2d Cir. 2008), the court reversed the certification of a class of smokers who alleged that they had been deceived into smoking "light" cigarettes. Despite a common issue of whether the defendants had a scheme to defraud, the court held that a class could not be certified under Rule 23(c)(4) because of individual issues of reliance, injury, and damages. *Id.* at 234. Similarly, in *Myers v. Hertz Corp.*, 624 F.3d 537 (2d Cir. 2010), the court held that *Nassau* did not justify class certification, even though all the questions presented by plaintiffs' case-in-chief were common to the class, because the affirmative

defenses were weightier: "the predominance requirement requires a district court to consider '*all* factual or legal issues' to determine whether the issues subject to generalized proof are more 'substantial' than those subject to individual inquiry." *Id.* at 550 (internal citation omitted; Second Circuit's emphasis). And in *Dungan v. Academy at Ivy Ridge*, 344 F. App'x 645, 647-48 (2d Cir. 2009), the court affirmed the denial of class certification on the issue of misrepresentation because of individualized questions of reliance, causation, and damages.

The *Nassau* analysis is further undermined by the opinion's heavy reliance on a clause of Rule 23(c)(4) that was *eliminated* a year later. Prior to the 2007 amendment, Rule 23(c)(4) read as follows:

> When appropriate (A) an action may be brought or maintained as a class action with respect to particular issues, or (B) a class may be divided into subclasses and each subclass treated as a class, *and the provisions of this rule shall then be construed and applied accordingly*.

Fed. R. Civ. P. 23(c)(4) (prior to 2007 amendment) (emphasis added). The *Nassau* court reasoned that the final clause of Rule 23(c)(4), italicized above, modified the predominance analysis required by (b)(3):

> As the rule's plain language and structure establish, a court must first identify the issues potentially appropriate for certification [under subsection (c)(4)] "and . . . then" apply the other provisions of the rule, *i.e.*, subsection (b)(3) and its predominance analysis.

461 F.3d at 226 (Second Circuit's omission). If the *Nassau* court were right – if the final clause really did have the effect of modifying (b)(3) – then the deletion of

that clause in 2007 rendered *Nassau* obsolete; the current Rule 23(c)(4) does not contain any language modifying (b)(3). But *Nassau* was mistaken. As explained above in Section II.B.3, the framers of Rule 23(c)(4) never intended that provision to modify (b)(3). Thus, when the clause was eliminated in 2007, the Advisory Committee reported that the change was "stylistic only." Fed. R. Civ. P. 23 (2007 Adv. Comm. Note).

This Court should not emulate the Second Circuit's approach, which forces district judges to choose between (A) *Nassau*'s statement that a single common question satisfies the predominance test and (B) the rulings in *McLaughlin*, *Myers*, and *Dungan* finding class certification improper because of individualized questions. As one commentator observed, "the case law surrounding the issue class is a mess. . . . [T]he same courts (and even the same judges) reach divergent results on whether or not to allow issue class certification in various situations." Jenna G. Farleigh, *Splitting the Baby: Standardizing Issue Class Certification*, 64 Vand. L. Rev. 1585, 1619, 1622 (2011).

Fourth Circuit. *Nassau* cited *Gunnells v. Healthplan Services, Inc.*, 348 F.3d 417 (4th Cir. 2003), as support for its interpretation. But in *Gunnells*, the Fourth Circuit applied the same test that that is advocated in this Brief. The court affirmed certification because "common issues do predominate in Plaintiffs' cause of action, as a whole, against TCPM." *Id.* at 438. The predominance issue in that

case arose because, in addition to the class claims against defendant TCPM, the plaintiffs brought individual claims against other defendants. The members of the Fourth Circuit panel disagreed about whether the predominance analysis should encompass all of the causes of action raised in the complaint (including individual claims) or whether the court should "confin[e] its predominance inquiry to [the] cause of action" brought on behalf of the class. *Id.* The majority confined its analysis to the class members' "cause of action, as a whole." *Id.* That is exactly the test advocated here.

Third Circuit. The opinion below also cited (but did not follow) the "discretionary test adopted by the Third Circuit." Adden. at 6. In *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 272 (3d Cir. 2011), the Third Circuit acknowledged the split "over the extent to which the ability to certify issue classes alters the predominance requirement." But, instead of examining the language of Rule 23 to decide this point, and "[r]ather than joining either camp in the circuit disagreement," the court adopted a different approach to certifying issue classes in cases where "common issues do not predominate." *Id.* at 272-73. In its view, trial judges should base their certification decisions on an evaluation of nine factors distilled from the American Law Institute's *Principles of the Law of Aggregate Litigation* §§ 2.02-05 (2010). But this approach has no support in the text of the

Rule. The substantive standards for certifying a class are set forth in Rule 23(a) and (b), not in the recommendations of the ALI.

Seventh Circuit. Some commentators have mistakenly attributed to the Seventh Circuit the view that Rule 23(c)(4) provides an independent basis for certifying classes when common issues do not predominate. *See, e.g.*, Seiner, 56 B.C. L. Rev. at 134. But the Seventh Circuit has never so held. Even when issue classes were utilized in (b)(3) cases,[18] the Seventh Circuit has weighed all questions in deciding whether common questions predominated, and has recognized "that the requirement of predominance is not satisfied if 'individual questions . . . overwhelm questions common to the class.'" *Butler v. Sears, Roebuck & Co.*, 727 F.3d 796, 801 (7th Cir 2013) (quoting *Amchem*, 521 U.S. at 623; Seventh Circuit's omission).[19]

[18] Some of the Seventh Circuit's cases discussing Rule 23(c)(4) were brought under Rule 23(b)(2), which does not have a predominance requirement. *See McReynolds v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 672 F.3d 482, 491-92 (7th Cir. 2012); *In re Allstate Ins. Co*, 400 F.3d 505, 508 (7th Cir. 2005).

[19] It is fair to say that the Seventh Circuit is more inclined to find predominance than many other courts, particularly in cases that present individual issues of causation. *See* Andrey Spektor, *The Death Knell of Issue Certification and Why That Matters After Wal-Mart v. Dukes*, 26 St. Thomas L. Rev. 165, 188 (2014) ("This article focuses on Judge Posner's decisions because they provide particularly stark contrasts with those recently issued by the Supreme Court."). The Seventh Circuit's approach is illustrated by contrasting two water contamination cases. In *Mejdrech v. Met-Coil Systems Corp.*, 319 F.3d 910, 911 (7th Cir. 2003), the court upheld certification limited to the question of whether defendant's activities violated the law, leaving injury and damages to be determined later if plaintiffs prevailed. But in *Parko v. Shell Oil Co.*, 739 F.3d

First Circuit. This Court has correctly treated Rule 23(c)(4) as a bifurcation procedure. The use of this provision arose in *Smilow*, where the district court denied class certification primarily because the issue of damages appeared to be individualized. In reversing, this Court explained that "even if individualized determinations were necessary to calculate damages, Rule 23(c)(4)(A) would still allow the court to maintain the class action with respect to other issues." 323 F.3d at 41. In *Smilow*, as in *Tardiff*, this Court expressly considered damages in deciding whether common issues predominated. *Id.* at 40-41. Then, after finding that common questions of liability did predominate, it noted that Rule 23(c)(4) would permit a class trial on those common questions, followed by a separate procedure for resolving individual questions of damages. *Id.*

This Court's precedents provide the proper guidance. The substantive standards for class certification are found in Rule 23(a) and (b). Rule 23(b)(3) requires a predominance of common questions, and in deciding whether that requirement is satisfied, the trial judge must weigh all of the questions presented by the class members' claims, including injury, damages, and affirmative defenses. If common questions do predominate, then Rule 23(c)(4) authorizes a class trial limited to the common questions, with the individualized questions to be decided

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1083, 1086 (7th Cir. 2014), the court reversed class certification because the district judge never "investigated the realism of the plaintiffs' injury and damage model."

separately. But a class should not be certified if, as the district court expressly found here, common questions do not predominate for the class members' "cause of action, as a whole," Adden. at 5, and "myriad individual adjudications would render the case unmanageable," *id.* at 73.

CONCLUSION

The Court should reverse the order granting certification of a class of indirect purchasers and direct the district court to deny class certification.

Respectfully submitted,

June 8, 2015 By: _____

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CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 11,984 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

I also certify that this brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6) because it uses 14 point Times New Roman font.

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CERTIFICATE OF SERVICE

I certify that on June 8, 2015, I caused the foregoing brief and following addendum to be electronically filed using the ECF system, which will send notice to all counsel of record.

June 8, 2015

By: _____
Counsel for Appellant
Astellas Pharma US, Inc.

Case No. 15-1290

UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT

In re: PROGRAF ANTITRUST LITIGATION

LOUISIANA HEALTH SERVICE INDEMNITY COMPANY, individually and all others similarly situated, d/b/a Blue Cross Blue Shield of Louisiana; JANET M. PAONE, on behalf of herself and all others similarly situated,
Plaintiffs - Appellees,

BURLINGTON DRUG COMPANY INC.; JUDITH CARRASQUILLO, on her behalf and on behalf of all others similarly situated; KING DRUG COMPANY OF FLORENCE INC.; NEW MEXICO UFCW UNION'S AND EMPLOYER'S HEALTH AND WELFARE TRUST FUND; PLUMBERS AND PIPEFITTERS LOCAL 572 HEALTH AND WELFARE FUND, individually and on behalf of all others similarly situated; STEPHEN L. LAFRANCE HOLDINGS, INC., a/k/a SAJ DISTRIBUTORS; STEPHEN L. LAFRANCE PHARMACY, INC., a/k/a SAJ DISTRIBUTORS; UNIONDALE CHEMISTS, INC.; LOUISIANA WHOLESALE DRUG COMPANY, INC.
Plaintiffs,

v.

ASTELLAS PHARMA US, INC.,
Defendant - Appellant.

Appeal from the United States District Court for the District of Massachusetts
MDL No. 2242, Master File No. 1:11-md-02242-RWZ

ADDENDUM TO BRIEF OF APPELLANT ASTELLAS PHARMA US, INC.

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ADDENDUM TABLE OF CONTENTS

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NO. 1:11-md-02242-RWZ

IN RE: PROGRAF ANTITRUST LITIGATION

SEALED

ORDER

June 10, 2014

ZOBEL, D.J.

Defendant Astellas Pharma US, Inc. ("Astellas"), maker of the branded tacrolimus drug Prograf, filed a citizen petition with the Food and Drug Administration ("FDA") in 2007 challenging the approval process for generic tacrolimus, a prescription immunosuppressant used in organ transplant patients. Plaintiffs, direct and indirect purchasers of tacrolimus, assert that the petition was objectively baseless and motivated by a scheme by Astellas to unlawfully extend its monopoly in the market for tacrolimus products.[1]

Currently before the court are several motions that are ripe for decision: (1) Indirect Purchaser Plaintiffs' Motion for Reconsideration of Class Certification (Docket # 371); (2) Consolidated Plaintiffs' Motion to Strike Astellas's Designations of Non-Reporting Experts (Docket ## 330 and 332); (3) Astellas's Motion for Summary Judgment on All Claims Against It (Docket # 358); (4) Astellas's Motion for Summary Judgment as to All Claims Made by Plaintiff Judith Carrasquillo (Docket # 308); and (5) Astellas's Motion to Unseal Memorandum of Decision Regarding Class Certification

[1] More detailed background information can be found in the court's prior opinions in the case.

(Docket # 426). I address the pending motions seriatim below.

1. Indirect Purchaser Plaintiffs' Motion for Reconsideration of Class Certification (Docket # 371)

On December 17, 2013, I denied indirect purchaser plaintiffs' ("IPPs") motion for class certification.[2] See Docket # 350. Although the proposed class met the requirements of Fed. R. Civ. P. 23(a), IPPs failed to demonstrate predominance and superiority under Rule 23(b)(3) on the issue of antitrust impact because their methodology could not show widespread injury to class members without the use of individualized data. In their motion for reconsideration, IPPs do not seek to challenge the court's holdings with respect to antitrust impact; rather, they request partial certification of a class only as to the issue of Astellas's alleged antitrust conduct.[3]

Rule 23(c)(4) provides that "[w]hen appropriate, an action may be brought or maintained as a class action with respect to particular issues." The provision enables courts to isolate certain issues for class certification even where other uncommon or unmanageable issues may preclude certification with respect to the case as a whole. See 7AA CHARLES ALAN WRIGHT, ET AL., FEDERAL PRACTICE & PROCEDURE, § 1790 (3d ed. 2005) ("[T]he theory of Rule 23(c)(4)(A) is that the advantages and economies of

[2] IPPs are Louisiana Health Service Indemnity Company d/b/a BlueCross BlueShield of Louisiana ("BCBSLA"), New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund ("NMUFCW"), Plumbers and Pipefitters Local Union Number 572 Health and Welfare Fund, Janet M. Paone, and Judith Carrasquillo. Summary judgment against NMUFCW was allowed on April 3, 2014, following IPPs' concession that NMUFCW had not suffered injury during the proposed damages period. See Docket ## 437 and 438.

[3] IPPs have not previously sought partial certification of a class in this case. Thus, their motion for "reconsideration" is more accurately viewed as a request that the court exercise its ability to alter or amend the order denying class certification pursuant to Fed. R. Civ. P. 23(c)(1)(C).

adjudicating issues that are common to the entire class on a representative basis may be secured even though other issues in the case may need to be litigated separately by each class member."). Thus, courts can certify classes as to liability only, leaving damages for later individualized determinations. In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 28 (1st Cir. 2008); Tardiff v. Knox County, 365 F.3d 1, 7 (1st Cir. 2004). Certification can also be of more limited scope, covering specific common issues short of completely resolving liability. See, e.g., Payton v. Abbott Labs, 83 F.R.D. 382, 386-87 (D. Mass. 1979) ("If the plaintiffs win favorable determinations on the class issues, they will not have proved the defendants' liability to class members, but they will have established legal and factual prerequisites to it. Answers to common questions need not guarantee a determination of liability."), vacated on other grounds, 100 F.R.D. 336 (D. Mass. 1983); Fleischman v. Albany Medical Center, No. 1:06-cv-765, 2008 WL 2945993, at *4-7 (N.D.N.Y. July 28, 2008) (granting partial certification as to violation of antitrust law, but not as to injury-in-fact or damages); McQuiklen v. A&R Development Corp., 576 F. Supp. 1023, 1031 (E.D. Pa. 1983) (listing cases holding class certification to be appropriate "where common issues important to the litigation can be resolved on a classwide basis even though the common issues may not be dispositive").

IPPs assert that partial certification is appropriate here because common issues clearly predominate with respect to the first element of an antitrust claim, violation of antitrust law. As noted in the decision denying certification, "[t]he showing necessary to prove a violation in this case – the possession of monopoly power in the relevant

market and the willful maintenance of that power through anti-competitive or exclusionary means – focuses entirely on Astellas's alleged conduct rather than that of individual class members and can be proven through evidence common to the class." Docket # 350 at 21. Thus, all IPP class members, as well as the certified class of direct purchaser plaintiffs, present the same allegations and proof of misconduct by Astellas.

Partial certification offers several legal and practical advantages in this case. Many individual indirect purchaser plaintiffs are unlikely to have the resources or incentive to litigate an entire antitrust case against Astellas on their own; proving antitrust conduct by Astellas, as evidenced by the parties' efforts to date, is a complex and costly endeavor. Even if such separate legal actions are pursued, they are likely to require duplicative discovery and redundant litigation, and may result in inconsistent adjudications regarding Astellas's conduct. In contrast, certifying an issue-specific class here would allow the parties to resolve the question of antitrust violation in one efficient and economical stroke. While a favorable judgment for plaintiffs on antitrust conduct would not, without more, establish Astellas's liability, it would significantly advance each class member's claims; with a violation of antitrust law already determined, class members could then choose to proceed with their claims individually to prove impact and damages. Conversely, a judgment in Astellas's favor would be binding on all class members and foreclose any liability on their claims.[4] See Payton,

[4] Neither party has addressed whether issue preclusion would apply if an issue class is not certified and the question of antitrust violation were adjudicated only as to the named indirect purchaser plaintiffs. While it appears that subsequent plaintiffs could possibly use a verdict against Astellas to prevent relitigation of the issue in future cases, the same would not be true for Astellas in the event it prevails here. See Gunnells v. Healthplan Services, Inc., 348 F.3d 417, 427 (4th Cir. 2003) ("[P]roceeding with individual claims makes the defendant vulnerable to the asymmetry of collateral

83 F.R.D. at 387 ("Victory for the defendants in this action will guarantee them freedom from harassing or repetitive litigation asserting theories and claims that have been disposed of. Victory for the plaintiffs will go far towards bringing them recovery.").

Astellas argues, however, that certification of Rule 23(c)(4) issue is not available because there has not been a showing of predominance as to the cause of action as a whole. As I previously acknowledged in another case, In re Bank of America Home Affordable Modification Program (HAMP) Contract Litigation, M.D.L. No. 10-2193-RWZ, 2013 WL 4759649, at *9 (D. Mass. Sept. 4, 2013), there is disagreement among the federal courts of appeals regarding the use of Rule 23(c)(4). The Fifth Circuit requires that "a cause of action, as a whole, must satisfy the predominance requirement" in order for a class to be certified on any issue. Castano v. Am. Tobacco Co., 84 F.3d 734, 745 n. 21 (5th Cir. 1996). The Second and Ninth Circuits, on the other hand, have held that when plaintiffs seek to certify an issue-specific class, they need only show that common questions predominate as to that particular issue. See In re Nassau Cnty. Strip Search Cases, 461 F.3d 219, 226-27 (2d Cir. 2006) (analyzing the language of subsection (c)(4) and rejecting Castano's interpretation as rendering the provision "virtually null"); Valentino v. Carter-Wallace, Inc., 97 F.3d 1227, 1234 (9th Cir. 1996).

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estoppel: If [defendant] lost on a claim to an individual plaintiff, subsequent plaintiffs could use offensive collateral estoppel to prevent [defendant] from litigating the issue. A victory by [defendant] in an action by an individual plaintiff, however, would have no binding effect on future plaintiffs because the plaintiffs would not have been party to the original suit.") (internal citations omitted); Allen v. McCurry, 449 U.S. 90, 95 (1980) ("[T]he concept of collateral estoppel cannot apply when the party against whom the earlier decision is asserted did not have a 'full and fair opportunity' to litigate that issue in the earlier case.") (citation omitted).

"Collateral estoppel thus is a double-edged sword for a defendant." Coffin v. Bowater Inc., 228 F.R.D. 397 n.13 (D. Me. 2005). Class certification, in contrast, would provide Astellas with "the benefit of finality and repose," Gunnells, 348 F.3d at 427, that issue preclusion cannot, since a victory in this action would apply consistently to all class members' claims grounded in antitrust conduct.

The Third Circuit, in Gates v. Rohm and Haas Co., 655 F.3d 255, 273 (3d Cir. 2011), declined to join either camp and instead followed guidance set forth in the Final Draft of the American Law Institute's Principles of Aggregate Litigation, which recommends that the court consider a number of factors, including, inter alia, the type of claims and issues in question, the complexity of the case, "the efficiencies to be gained by granting certification in light of realistic procedural alternatives," the substantive law of the underlying claims, the impact of partial certification on the rights of the parties, the potential preclusive effect or lack thereof that resolution of the proposed issue class will have, the repercussions of partial certification on the resolution of remaining issues, the impact of individual proceedings upon each other, and the evidence to be presented on the certified issue.

The First Circuit – though yet to take a clear position in the debate – has endorsed the certification of liability-only classes despite individualized damage issues, see Tardiff, 365 F.3d at 6, which suggests it may agree with the more flexible view espoused by the Second and Ninth Circuits or, at the very least, the discretionary test adopted by the Third Circuit. Therefore, and given my determination above that common questions predominate as to the issue of antitrust violation and that partial certification would materially advance the litigation for all parties, I find that IPPs need not demonstrate predominance for the entire action in order to certify an issue-specific class in this case.

Astellas raises additional objections to partial certification: that the proposed class includes members who lack Article III standing, and that bifurcation of IPPs'

claims on antitrust conduct and antitrust impact/damages would violate the Seventh Amendment's Reexamination Clause.

Astellas contends, citing Denney v. Deutsche Bank, 443 F.3d 253, 264 (2d Cir. 2006), that the proposed class cannot be certified here because it includes many members who suffered no injury and therefore lack Article III standing. IPPs counter that courts do not require proof of absent class members' standing in order to certify a class. In support, IPPs point to the Fifth Circuit's recent analysis in In re Deepwater Horizon, 739 F. 3d 790, 800-807 (5th Cir. 2014), of the two primary approaches taken by courts in evaluating standing for the purposes of class certification. The first approach "hinges exclusively on the Article III standing of the 'named plaintiffs' or 'class representatives' . . . [and] requires courts to ignore absent class members entirely." Id. at 800. See also 1 WILLIAM B. RUBENSTEIN, NEWBERG ON CLASS ACTIONS § 2:3 (5th Ed. 2011) ("[P]assive members need not make any individual showing of standing because the standing issue focuses on whether the named plaintiff is properly before the court, not whether represented parties or absent class members are properly before the court."). Under the second approach, demonstrated in Denney, "courts must ensure that absent class members possess Article III standing by examining the class definition," although without "scrutinizing or weighing any evidence of absent class members' standing or lack of standing during the Rule 23 stage." Id. at 801.

Under either approach, I find that IPPs have sufficiently demonstrated standing to proceed at this stage of the litigation. "[T]he presence of one party with standing is sufficient to satisfy Article III's case-or-controversy requirement," Rumsfeld v. Forum for

Academic and Institutional Rights, Inc., 547 U.S. 47, 52 n.2 (2006), and Astellas does not challenge the standing of at least one named IPP plaintiff, BCBSLA. See also 1 RUBENSTEIN, supra at § 2:8 ("So long as at least one class representative has standing, the case may proceed with that party acting as the class's representative."). As for the absent class members, Denney does "not require that each member of a class submit evidence of personal standing," but rather asks whether the class "is defined in such a way that anyone within it would have standing." 443 F.3d at 264. Taking IPPs' allegations as true, all the class members purchased, paid for, or reimbursed for prescription tacrolimus at supracompetitive prices as a result of Astellas' antitrust conduct. Even if closer investigation of any individual class member's claim may ultimately reveal a lack of injury-in-fact,[5] the class as defined does not include obviously uninjured members or members "who concede that they lack any causally related injury." In re Deepwater Horizon, 739 F.3d at 804 (internal quotations omitted). Astellas conflates the showing required for standing with the higher evidentiary showing necessary to actually prevail on claims of injury. "[S]o long as every class member contemplated by the class definition can *allege* standing," the Denney test is satisfied. Id. (internal quotation omitted).

With respect to Seventh Amendment concerns, I find none here. The Seventh Amendment provides that "no fact tried by a jury, shall be otherwise reexamined in any

[5] Indeed, in previously denying class certification, I found that variability in important factors suggested that significant numbers of class members may not have been harmed, and that IPPs had failed to show that their impact methodology could demonstrate widespread harm to the class despite such distinctions. See Docket # 350 at 42-43. This does not mean, however, that the class definition is deficient for standing purposes.

Court of the United States, than according to the rules of the common law." U.S. CONST. amend. VII. Therefore, a court "must not divide issues between separate trials in such a way that the same issue is reexamined by different juries." Matter of Rhone-Poulenc Rorer, Inc., 51 F.3d 1293, 1303 (7th Cir. 1995). Astellas claims that the antitrust violation issue is so intertwined with issues of antitrust impact that splitting them among separate juries would violate the Seventh Amendment. However, as already discussed, litigation on antitrust violation would focus entirely on Astellas's conduct and the state of the tacrolimus market, whereas, assuming such violation, a trial of antitrust impact and damages issues would involve fact-finding regarding whether a particular plaintiff made a tacrolimus purchase at a supracompetitive price and the amount of any overcharges incurred. Such issues are "so distinct and separable" that they can be cleanly divided amongst separate trials "without injustice," Franchi Const. Co., Inc. v. Combined Ins. Co. of America, 580 F.2d 1, 7 (1st Cir. 1978) (quoting Gasoline Products Co. v. Champlin Refining Co., 283 U.S. 494, 500 (1931)); a jury examining the latter can do so without revisiting findings previously made about the former.[6]

Accordingly, IPPs' motion seeking partial class certification on the issue of

[6] Astellas argues that, to prevail on the issue of antitrust violation, IPPs must prove only that Astellas caused *some* delay in the market entry of generic tacrolimus, but the issue of an individual class member's injury would turn in part on a *precise* "but-for" market entry date for generic tacrolimus. Thus, Astellas claims that both juries (one in the trial on antitrust violation, another in the trial on antitrust impact and damages) would need to assess how Astellas's conduct may have impacted generic entry. But this "overlap" can be easily resolved by instructing the first jury to make a specific determination about when generic tacrolimus would have entered the market but for the antitrust conduct. The second jury could then, using that finding, evaluate a plaintiff's injury without having to reexamine Astellas's conduct and its effect on generic market entry.

antitrust violation is ALLOWED.

2. Consolidated Plaintiffs' Motion to Strike Astellas's Designations of Non-Reporting Experts (Docket ## 330 and 332)

Astellas identified nine witnesses as experts for trial, and provided expert reports for four. The remaining five have been designated as "non-reporting" experts under Fed. R. Civ. P. 26(a)(2)(C). Plaintiffs seek to strike the expert designations of four of these non-reporting experts – all transplant physicians – as improper.

Under Rule 26(a)(2)(A), a party must disclose the identity of any witness it may use at trial to present expert testimony or evidence. The rule divides expert witnesses into two categories: (1) if the expert witness is "one retained or specifically employed to provide expert testimony in the case or one whose duties as the party's employee regularly involve giving expert testimony," a detailed written report must accompany the disclosure, Fed. R. Civ. P. 26(a)(2)(B); (2) if no written report is required, then the disclosure must only state the subject matter of the witness's testimony and a summary of the facts and opinions to which the witness is expected to testify, Fed. R. Civ. P. 26(a)(2)(C).

To serve as a non-reporting expert, a witness must have been personally involved in or witnessed the events giving rise to the litigation and his or her expert testimony must be incidental to such involvement. The First Circuit, in interpreting the phrase "retained or specially employed," acknowledged "the difference between a percipient witness who happens to be an expert and an expert who without prior knowledge of the facts giving rise to the litigation is recruited to provide expert opinion

testimony." Downey v. Bob's Discount Furniture Holdings, 633 F.3d 1, 6 (1st Cir. 2011). The plaintiffs in Downey sued a furniture retailer for damages from a bedbug infestation alleged to have arisen from furniture purchased from the defendant. The First Circuit held that an exterminator who had inspected the plaintiffs' home for bedbugs following furniture delivery could testify as an expert witness on the issue of causation without providing a report:

> Like a treating physician – and unlike a prototypical expert witness – [the exterminator] was not retained or specially employed for the purpose of offering expert testimony. Rather, he was 'an actor with regard to the occurrences from which the tapestry of the lawsuit was woven.' Put another way, his opinion testimony arises not from his enlistment as an expert but, rather, from his ground-level involvement in the events giving rise to the litigation.

Id. at 6 (internal citations omitted).

Astellas insists, and plaintiffs strongly dispute, that the four experts at issue are percipient witnesses whose expert opinions arise from personal involvement in the underlying events of this case. Drs. David C. Cronin II, Goran B. Klintmalm, Michael Abecassis, and Benedict Cosimi are all experienced transplant surgeons who, according to Astellas, will offer expert opinions based on their clinical and medical experience – including explanations about the use of narrow therapeutic index drugs in the treatment of transplant patients, various concerns related to switching patients from one formulation of an immunosuppressant to another, and the validity and reasonableness of requests made in Astellas's citizen petition. Drs. Cronin and Klintmalm are also slated to offer opinions as to FDA guidelines and requirements for bioequivalence testing. Plaintiffs contend that none of these proposed experts played

any role in Astellas's decision to draft and file the citizen petition, the actual preparation of the petition, or in the FDA's review of the petition, and thus their opinions are not premised on personal participation in the events giving rise to the litigation.[7] Astellas counters that the objective merit of its petition is at the heart of this case and that the witnesses have personal knowledge, based on their experience as transplant physicians and members of the "transplant community," about the factual underpinnings of that assessment.

Plaintiffs have the better of the argument. Unlike the exterminator in Downey, Astellas's proposed experts were not, for the most part, percipient witnesses to the relevant events in this case; their opinions were not formed during the course of their personal involvement in the citizen petition, but as a result of their "external" experience as transplant physicians. Ground-level involvement with patients or the transplant community is not the same thing as ground-level involvement in the facts and events surrounding the filing of Astellas's citizen petition. Indeed, under Astellas's view, any transplant physician with opinions about immunosuppressants, FDA guidelines, or the petition's validity could conceivably qualify as a percipient non-reporting expert in this case. Such a result is untenable.

Two minor exceptions exist here, however. Drs. Cronin and Klintmalm did have *some* involvement in the citizen petition process. Dr. Cronin submitted a letter to the

[7] Plaintiffs also point out that Astellas previously subpoenaed and deposed Drs. Cronin, Klintmalm, and Abecassis as fact witnesses, and that plaintiffs therefore examined them as such under significant time restraints and without the disclosure of expected testimony. Moreover, at a March 14, 2013 hearing, in the context of a dispute between the parties on reimbursing fact witnesses, Astellas represented that Dr. Cronin is "being deposed as a fact witness." See Docket # 330, Ex. A at 44.

FDA in support of the citizen petition in 2008. Likewise, in 2007, Dr. Klintmalm, as president of American Society of Transplant Surgeons ("ASTS"), signed a letter to the FDA reiterating the requests in Astellas's petition. As such, Drs. Cronin and Klintmalm may testify as fact witnesses regarding their respective letters; to the extent they formed relevant expert opinions during the course of preparing and submitting such letters, they are permitted to offer them. However, they may not testify as to other matters outside that limited scope.

Plaintiffs' motion to strike Astellas's designations of non-reporting experts is ALLOWED IN PART and DENIED IN PART as described above.

3. Astellas's Motion for Summary Judgment on All Claims Against It (Docket # 358)

Summary judgment is appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). The court must view the record in the light most favorable to the nonmovant and draw all justifiable inferences in that party's favor. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 255 (1986). Astellas seeks summary judgment on all claims brought against it, asserting that plaintiffs cannot prove causation-in-fact or show that the citizen petition was a sham. Plaintiffs argue that important material facts on both issues remain in dispute.

Astellas's citizen petition asked the FDA to: (1) require generic manufacturers of narrow therapeutic index ("NTI") drugs, including tacrolimus, to establish that their formulations are bioequivalent to the brand drug not only in healthy people, but also in

transplant patients (the "Bioequivalence Testing Request"); (2) require certain labeling changes to ensure that doctors and patients are notified when a pharmacy switches a transplant patient from one brand or generic version of an NTI drug to another (the "Notification Request"); (3) require that different versions of such drugs have different appearances so that patients, physicians, and pharmacists can easily distinguish them from one another (the "Source Differentiation Request"); and (4) require that different dosage strengths of such drugs have different appearances (e.g., capsule color) to reduce medication errors (the "Dosage Differentiation Request"). Nearly two years later, the FDA rejected the first three requests but granted the Dosage Differentiation Request. That same day, the FDA approved an Abbreviated New Drug Application ("ANDA") filed by Sandoz, Inc., a generic pharmaceutical manufacturer, for the sale of generic tacrolimus. Plaintiffs accuse Astellas of filing a baseless "sham" citizen petition to foreclose market entry by generic competitors and improperly extend its monopoly on tacrolimus; as a result, generic approval was delayed and, in the interim, plaintiffs paid or reimbursed for tacrolimus purchases at supracompetitive prices.

A. Causation

To prevail on an antitrust claim, a plaintiff "must show that [defendant's antitrust] violation was a 'material cause' of its injury." Addamax Corp. v. Open Software Foundation, Inc., 949 F. Supp. 549, 554 (D. Mass. 1997). "[A] fair degree of certainty is . . . essential to show the causative relation of defendants' misconduct and plaintiff's injury." Id. (quoting Momand v. Universal Film Exchanges, Inc., 172 F.2d 37, 43 (1st Cir. 1948), cert. denied, 336 U.S. 967 (1949)).

Astellas asserts that plaintiffs cannot show that any delay in the FDA's approval of generic tacrolimus was attributable to the unsuccessful citizen petition requests as opposed to the successful (and thus, objectively reasonable) Dosage Differentiation Request. It emphasizes that plaintiffs' causation expert, Martha Bennett, testified that she did not have an opinion as to which of Astellas's four requests may have delayed the FDA's approval of Sandoz's generic tacrolimus. Ms. Bennett gave similar testimony in another pharmaceutical antitrust case, In re Wellbutrin XL Antitrust Litig., Nos. 08-2431, 08-2433, 2012 WL 1657734, at *34 (E.D. Pa. May 11, 2012); when asked if she could state "to any professional certainty" that the citizen petition would have taken less time to resolve had it been limited only to successful requests, the expert responded that she did not know. The court in Wellbutrin granted summary judgment to the defendants due to the plaintiffs' failure to show causation, a result that Astellas insists is likewise required here.

However, in Wellbutrin, the plaintiffs had "not pointed to any other evidence in the record from which a jury could reasonably conclude that the FDA would have approved the ANDAs earlier if the Citizen Petition had been limited to the successful, non-sham requests." Id. In contrast, plaintiffs in this case cite relevant evidence beyond Ms. Bennett's testimony suggesting that at least some, if not all, of the delay was attributable to Astellas' unsuccessful requests. As a preliminary matter, it is evident that the petition itself did indeed delay the FDA's approval of Sandoz's ANDA. See, e.g., Direct Purchaser Plaintiffs' Statement of Facts ("DPPs' SOF") at ¶¶ 197, 201, 218. Plaintiffs argue that the Dose Differentiation Request, though nominally granted,

could not have contributed significantly to that delay because it was an uncontroversial issue with no impact on existing FDA practice or policy. According to plaintiffs, because different strengths of drugs are routinely required to be differentiated, there was no real dispute between the FDA, Astellas, or Sandoz over the practice – certainly not enough to occupy the FDA for two years.[8] Tellingly, the FDA's "approval" of the Dosage Differentiation Request amounts to two sentences expressing agreement with the position, in contrast to the paragraphs and pages devoted to addressing Astellas's other requests. See Docket # 362 at Ex. 9.

Plaintiffs also point to statements made by the FDA indicating that the unsuccessful portions of the citizen petition caused delay. After its petition was largely denied, Astellas brought a lawsuit in the United States District Court for the District of Columbia seeking a temporary restraining order and preliminary injunction requiring the FDA to revoke its approval of generic tacrolimus until the agency reversed its decisions regarding bioequivalence testing, warnings and notifications to physicians and patients, and source differentiation. See DPPs' SOF ¶ 216; Docket # 390, Ex. 215. In opposition, the FDA stated that its delay in approving Sandoz's ANDA was, in part, "directly attributable to the need to evaluate and respond to a citizen petition submitted by Astellas, *raising the same objections* to the approval standards for generic tacrolimus *it has asserted in this lawsuit*." DPPs' SOF ¶ 218; Docket # 390, Ex. 216 at 2

[8] Plaintiffs add that dosage differentiation was particularly a non-issue in the case of tacrolimus. Because Prograf was already dose-differentiated, Sandoz's generic tacrolimus was always intended to be dose-differentiated as well, since FDA regulations required that labels for both brand and generic products be the same.

(emphasis added).

Such evidence is sufficient to raise a genuine issue of material fact as to whether Astellas's allegedly sham requests caused any delay in generic approval beyond the successful request. Summary judgment on the basis of causation is not warranted.

B. Sham Petition

"Those who petition government for redress are generally immune from antitrust liability." Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49, 56 (1993) ("PRE"). The Noerr-Pennington doctrine "which derives from the First Amendment's guarantee of 'the right . . . to petition the government for redress of grievances,' U.S. Const. amend. I, shields from antitrust liability entities who join together to influence government action – even if they seek to restrain competition or to damage competitors." Davric Maine Corp. v. Rancourt, 216 F.3d 143, 147 (1st Cir. 2000) (citations omitted). Noerr-Pennington immunity is similarly applicable to acts of advocacy before agencies and courts. California Motor Transport Co. v. Trucking Unlimited, 404 U.S. 508, 510 (1972). The doctrine does not apply, however, where a defendant's effort "ostensibly directed toward influencing governmental action, is a mere sham to cover what is actually nothing more than an attempt to interfere directly with the business relationships of a competitor." Eastern R. R. Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961). The Supreme Court has established a two-pronged inquiry for determining whether the petitioning complained of is a "sham": a plaintiff must show that defendant's petitioning activity is, first,

"objectively baseless," and second, subjectively a concealed attempt calculated to stifle competition. PRE, 508 U.S. at 61.

At issue here is the first prong of the test. Astellas contends that plaintiffs cannot prove that the citizen petition was a sham because its requests to the FDA were not objectively baseless as a matter of law.[9] Under PRE, "objectively baseless" signifies that "no reasonable litigant [or, in this case, petitioner] could realistically expect success on the merits." Id. "If an objective litigant could conclude that the suit [or petition] is reasonably calculated to elicit a favorable outcome, the suit is immunized under Noerr." Id.

Astellas first argues that the petition was not objectively baseless because its requests mirrored longstanding recommendations and concerns of medical experts in the transplantation field. Astellas points to white papers addressing generic substitution of NTI immunosuppressant drugs published by the National Kidney Foundation ("NKF") and the American Society of Transplantation ("AST") in 1999 and 2003, respectively. Both papers recommended bioequivalence testing of generic NTI drugs in patients and noted the importance of informing doctors about switching between different formulations. AST and another prominent American transplantation

[9] The parties offer differing views on the standard of proof on this issue. Astellas, citing CVD, Inc. v. Raytheon Co., 769 F.2d 842, 849-51 (1st Cir. 1985), claims that plaintiffs must prove that the citizen petition was objectively baseless by clear and convincing evidence. Plaintiffs retort that the CVD case is grounded in the unique standards of patent law, and that here, as in most civil litigation, the standard of proof is by a preponderance of the evidence. The Federal Circuit has not yet made explicit the standard of proof for showing objective baselessness under the sham exception to Noerr-Pennington. See, e.g., Wellbutrin, 2012 WL 1657734 at *4-5 (discussing lack of clarity regarding standard). Nonetheless, it is unnecessary to resolve the question here, since I find plaintiffs' evidence sufficient to survive summary judgment under either standard.

society, the American Society of Transplant Surgeons ("ASTS"), along with transplant surgeon Dr. David Cronin, also submitted letters to the FDA echoing the requests made in Astellas's citizen petition. Moreover, Astellas notes that other regulatory agencies have enacted policies and measures that echo those requested in its citizen petition; in 2006, Canada narrowed the acceptable bioequivalence range for NTI drugs and suggested that studies in patients may be necessary, and in 2000, the North Carolina Board of Pharmacy prohibited pharmacists from switching between different formulations of cyclosporine (another NTI drug widely used in transplant patients) without physician notification and patient consent, and required the same for tacrolimus in 2009 after reviewing Astellas's citizen petition.

Plaintiffs, however, raise questions about the reliability and credibility of these recommendations. They allege, citing expert testimony, that the NKF and AST white papers contained no scientific or medical data, but were instead premised on theoretical and unsupported physician concerns. Plaintiffs also present evidence that AST, ASTS, and Dr. Cronin all had significant financial ties to Astellas and that their letters, which plaintiffs argue lacked meaningful scientific data, were prompted – if not entirely ghostwritten – by the company. Similarly, plaintiffs discount the weight of other agency decisions, asserting that Canada's narrowing of bioequivalence ranges for NTI drugs is immaterial since Astellas's petition did not request such changes by the FDA, and the substitution restrictions enacted in North Carolina were not based in data, were insufficient to meet the FDA's statutory standard, and followed intense lobbying and marketing by Astellas.

Astellas also maintains that its requests were reasonable because they addressed unsettled issues of agency policy on which the FDA had specifically requested public comment. See, e.g., Bath Petroleum Storage, Inc. v. Market Hub Partners, L.P., 129 F. Supp.2d 578, 594 (W.D.N.Y. 2000) (in evaluating objective baselessness, noting that defendant "did not initiate the proceeding before [the agency], but rather . . . responded to a public notice issued by [the agency], which invited any person desiring to be heard to file comments or protests."). On May 31, 2007, the FDA announced draft guidance recommending bioequivalence testing of tacrolimus products in healthy people (as opposed to patients) and invited public comment by September 28, 2007. Astellas claims that this invitation – in the context of prior agency statements signaling that, for some drugs, the FDA would be open to requiring bioequivalence testing in patients – indicated that the FDA's draft guidance on tacrolimus was not settled policy, and it therefore responded by filing its citizen petition on September 21, 2007, and written comments on the draft guidance a week later. Given such circumstances, Astellas asserts that a reasonable petitioner could realistically conclude that the FDA was open to modifying its policies on bioequivalence testing for tacrolimus, as requested by the petition.

But here, too, plaintiffs identify disputed questions of fact. They insist that the FDA's bioequivalence testing standards were not unsettled, and that the 2007 guidance on tacrolimus actually reinforced the agency's decades-old standards for testing in healthy subjects. According to plaintiffs, inviting public comment was not an indication by the FDA that it was reconsidering its policies, but simply a mandatory measure

under the Administrative Procedures Act, 5 U.S.C. §§ 551-559. Plaintiffs also cite agency statements and policies showing that the FDA would alter its bioequivalence testing standards only based upon ”well-documented evidence,” which plaintiffs claim Astellas lacked.

As for the scientific merit of the requests themselves, the parties advance starkly different assessments. Astellas argues that the petition sought relief that was well within the ambit of governing FDA regulations and its requests were supported by appropriate materials, including policy concerns and clinical studies about the “switchability” of different formulations of cyclosporine. Plaintiffs counter with expert testimony challenging the studies as scientifically deficient, poorly designed, and inconclusive; in their estimation, the studies clearly fell short of the type of evidence required for the FDA to change its standards. Plaintiffs also accuse Astellas of intentionally concealing a report by the American Medical Association evaluating, among many others, the cyclosporine studies and concluding that “[w]hile concerns still persist among some physicians about the therapeutic equivalence of generic NTI drugs to their brand name innovator products, scientific evidence to support these concerns either does not exist or is very weak.” DPPs’ SOF ¶ 33.

Finally, Astellas claims that the FDA’s responses to its citizen petition, as well as various developments following its filing, confirm that the petition had merit. On March 11, 2008, the FDA sent Astellas an “Interim Response” stating that the petition “raises complex issues requiring extensive review and analysis.” Astellas’s Statement of Undisputed Facts (“Astellas’s SUF”) at ¶ 79-80. A few months later, an FDA official

allegedly was "very complimentary" of the petition to Astellas employees, characterizing it as "excellent." Id. at ¶ 81-82. Astellas also notes the FDA's final response to the petition gave extended consideration to its requests, suggesting that the petition was far from frivolous or baseless but rather raised legitimate issues requiring serious examination. Furthermore, following the denial of the citizen petition, two new clinical studies allegedly demonstrated that switching transplant patients between different tacrolimus formulations may be problematic without follow-up blood monitoring, while another study indicated that a generic form of tacrolimus was not bioequivalent to Prograf in transplant patients. In April 2010, the FDA's Advisory Committee voted that the FDA's current bioequivalence standards were not adequate for NTI drugs, and the agency subsequently revised its draft guidance for tacrolimus to recognize it as an NTI drug and require more rigorous bioequivalence testing. While Astellas admits that the testing changes do not precisely match its requests, it argues they nonetheless show that Astellas's petition was not objectively baseless in asserting that standard bioequivalence testing was not adequate for tacrolimus. More recently, in 2012, the FDA announced that it was funding bioequivalence tests of tacrolimus in patients "to help address the public concerns regarding the quality of generic tacrolimus and improve review practices of generic tacrolimus if necessary." Astellas's SUF ¶¶ 122, 124. Astellas also notes that transplant societies continue to advocate for policies that mirror requests made in the citizen petition and that regulatory authorities around the world have taken action to address concerns that generic NTI immunosuppressant drugs may not be fully substitutable in patients.

In response, plaintiffs argue persuasively that the FDA's responses and post-petition developments do not definitively show that the petition was not a sham.[10] They assert that FDA's interim response was a tentative one issued before full review, the final response explicitly indicated the petition's lack of sufficient scientific or clinical support, and the alleged statements by the FDA official cannot be attributed to the agency. Plaintiffs also point out that the bioequivalence testing changes later adopted by the FDA were not requested in Astellas's petition and therefore are of little relevance to its merit. Plaintiffs' expert, in reviewing the newer clinical studies, concludes that none demonstrate the need for bioequivalence testing in transplant patients. DPPs' SOF, Ex. 225 at ¶¶ 45-54. As for the FDA's 2012 decision to sponsor studies comparing generic and branded tacrolimus, plaintiffs dismiss the move as intended to assuage unsupported public concerns, not driven by scientific ones. Whether or not that is indeed the case, and any resulting significance it may carry with respect to the citizen petition's merit, are questions for the jury.

Based on all the above, I find that material predicate facts remain in dispute about the objective basis for Astellas's requests to the FDA, including the credibility

[10] Plaintiffs generally object to Astellas's use of post-petition evidence to support its motion, arguing that only facts that existed at the time of the petition's filing are relevant. See Filmtec Corp. V. Hydranautics, 67 F.3d 931, 938 (Fed. Cir. 1996) (objective baselessness analysis "requires an inquiry into the reasonableness of the antitrust defendant's litigation when filed."). Astellas, however, notes that courts evaluating objective baselessness have considered scientific and regulatory events occurring after a filing that are consistent with the petition's requests. See, e.g., Louisiana Wholesale Drug Co. v. Sanofi-Aventis, No. 07 Civ. 7343 (HB), 2008 WL 169362, at *5 (S.D.N.Y. Jan. 18, 2008) (subsequent FDA action consistent with petition's request supported jury finding that the petition was not objectively baseless); In re Warfarin Sodium Antirust Litig., No. MDL 98-1232-SLR, 1998 WL 883469, *7 (D. Del. Dec. 7, 1998) (petition not objectively baseless where "FDA later proposed to adopt the very bioequivalency standards recommended by defendant"), rev'd on other grounds, 214 F.3d 395 (3rd Cir. 2000). I will consider post-petition events to the limited extent that they may shed light on the objective reasonableness of Astellas's petition at the time it was filed.

and scientific merit of supporting materials. Accordingly, Astellas's motion for summary judgment as to all claims against it is DENIED.

4. Astellas's Motion for Summary Judgment as to All Claims Made by Plaintiff Judith Carrasquillo (Docket # 308)

Astellas moves separately for summary judgment against indirect purchaser plaintiff Judith Carrasquillo ("Carrasquillo"). It presents two arguments: the first based on the availability of unjust enrichment as a remedy for indirect purchasers under Illinois law, and the second on the merits of Carrasquillo's claim. Because I agree with Astellas on the latter, I need not resolve the former.[11]

To prevail on her claims for unjust enrichment under Illinois law, Carrasquillo must establish that Astellas "has unjustly retained a benefit to [her] detriment." HPI Health Care Servs., Inc. v. Mt. Vernon Hosp., Inc., 545 N.E.2d 672, 679 (Ill. 1989). Carrasquillo also must show Article III standing, that she "has suffered a concrete and

[11] Illinois has adopted, by statute, the Illinois Brick bar to antitrust class action claims by indirect purchasers. See 740 Ill. Comp. Stat. 10/7(2) (2010); Illinois Brick Co. v. Illinois, 431 U.S. 720, 735 (1977). Astellas asserts that Illinois law also precludes an indirect purchaser plaintiff from making an end-run around Illinois Brick and the statute by raising antitrust claims under a theory of unjust enrichment. See, e.g., In re Digital Music Antitrust Litig., 812 F. Supp. 2d 390, 413 (S.D.N.Y. 2011) (dismissing indirect purchaser unjust enrichment claims brought under Illinois law); In re Flonase Antirust Litig., 692 F. Supp. 2d 524, 543 (E.D. Pa. 2010) ("Illinois has adopted the logic of *Illinois Brick*, and therefore Plaintiffs may not assert a claim for unjust enrichment under Illinois law."). Astellas further argues that Illinois law does not allow claims for unjust enrichment to be brought without an independently viable underlying claim. See Martis v. Grinnell Mut. Reinsurance Co., 905 N.E.2d 920, 928 (Ill. App. Ct. 2009).

Carrasquillo strongly disagrees. She contends that Illinois statutory law only prohibits antitrust class actions and does not preclude her from bringing an unjust enrichment claim as a class action. She also disputes that her unjust enrichment claim can simply be dismissed as an end-run around Illinois Brick. See In re G-Fees Antitrust Litig., 584 F. Supp. 2d 26, 46 (D.D.C. 2008) ("No reason or logic supports a conclusion that a state's adherence to the rule of *Illinois Brick* dispossesses a person not only of a statutory legal remedy for an antitrust violation, but also dispossesses the same person of his right to pursue a common law equitable remedy."). Finally, Carrasquillo asserts that Illinois law does provide a stand-alone claim for unjust enrichment and that the Illinois Supreme Court has repeatedly sustained unjust enrichment claims not founded on separate underlying claims. See Raintree Homes, Inc. v. Vill. of Long Grove, 807 N.E.2d 439, 445 (Ill. 2004); Indep. Voters v. Ill. Commerce Comm'n, 510 N.E.2d 850, 856-58 (Ill. 1987); Cleary v. Philip Morris Inc., 656 F.3d 511, 516 (7th Cir. 2011) ("The Illinois Supreme Court appears to recognize unjust enrichment as an independent cause of action.").

particularized injury that is fairly traceable to the challenged conduct, and is likely to be redressed by a favorable judicial decision." Hollingsworth v. Perry, 133 S. Ct. 2652, 2661 (2013).

Carrasquillo claims that she overpaid for Prograf due to Astellas's alleged misconduct in delaying the market entry of generic tacrolimus. Yet Astellas maintains that Carrasquillo cannot prove that she would have paid less for tacrolimus had generic versions been available in September 2008, the date on which she claims Sandoz should have entered the market, rather than in August 2009, the actual date of generic entry. According to IPPs' economist, Dr. Meredith Rosenthal, there were no damages resulting from overcharges after 2009. The inquiry thus focuses on whether Carrasquillo overpaid for her tacrolimus prescriptions during the period between September 2008 and December 2009.

The record shows that Carrasquillo would not have switched from Prograf to generic tacrolimus during the damages period even if generics had been available. Carrasquillo used Prograf continuously from 2000 until July 2012, well after generic entry; indeed, prior to her switch to generic tacrolimus in 2012, her prescriptions included a notation from her physician directing pharmacists not to substitute generics for Prograf. The evidence also indicates that Carrasquillo would not have paid less for her Prograf had generic tacrolimus been available in September 2008. From September 2008 to October 2009, Carrasquillo was insured by Blue Cross Blue Shield of Illinois ("BCBSIL") through her husband's employer and paid a $30 flat co-pay for Prograf, which was classified as a "Tier 2" drug on the plan's formulary both before and

after generic entry. From November 2009 to November 2010, Carrasquillo lost her insurance when her husband lost his job, but received Prograf free of charge from Astellas through its Patient Assistance Program ("PAP"). From November 2010 until her switch to generic tacrolimus in July 2012, Carrasquillo once again was insured by BCBSIL after her husband's re-employment; Prograf was still a Tier 2 drug at that time, though BCBSIL had raised its copay for Tier 2 to $40. Therefore, throughout the damages period, the cost of Prograf to Carrasquillo was the same in the actual world as it would have been in the but-for world with earlier generic market entry.

During briefing for class certification, however, IPPs identified one unique instance in which Carrasquillo purportedly overpaid for Prograf. On October 11, 2009, between the time she lost her insurance and when she began receiving free Prograf via PAP, Carrasquillo allegedly made a single Prograf purchase pursuant to the Medicare Part B program, which required her to pay coinsurance in the amount of 20% of the drug's cost. But the analysis conducted by Dr. Rosenthal indicates that the prescription price of Prograf during the fourth quarter of 2009 in the actual world was $567.79, while its price in the but-for world of earlier generic entry was $585.71 – meaning that Carrasquillo's 20% coinsurance payment would have been *higher* with earlier generic entry than it actually was.

Faced with these unhelpful numbers, Carrasquillo presents yet another theory of harm. She concedes that she was not overcharged for her October 11, 2009 Prograf purchase due to its retail price, but now claims she did suffer an overcharge due to "lost coverage" by PAP. Carrasquillo enrolled in PAP following her October 11, 2009

purchase after being referred to the program by a patient advocate at her hospital. Carrasquillo argues that in the but-for world, she would have benefitted from PAP much earlier, making it likely that she would not have paid anything for her October 11, 2009 purchase. To wit, she alleges that Astellas expanded and promoted PAP as a countermeasure to generic entry and, had generic entry occurred earlier, Astellas would have begun its PAP campaign earlier, leading her to enroll in PAP at least a month sooner.

Carrasquillo's new arguments are highly speculative. Even if Astellas had indeed expanded and promoted PAP in response to generic entry, and would have done so earlier in the but-for world, there is a scant evidence that this would have had any impact on when Carrasquillo enrolled in PAP. Carrasquillo contends that she was "exactly the type of patient Astellas targeted" for PAP and that her enrollment in PAP resulted mainly from the efforts of Astellas and the patient advocate, such that an earlier increased marketing campaign would have led to earlier awareness in the medical community and, consequently, earlier coverage for her.[12] Yet, the record reveals that the impetus for Carrasquillo's enrollment in PAP was her husband's job loss in October 2009 and her resulting loss of insurance; at that point, having paid for her October 11, 2009 prescription via Medicare, Carrasquillo then contacted a hospital social worker, who referred her to the patient advocate. See Docket # 356, Declaration

[12] There is no suggestion that Carrasquillo would not have been eligible for PAP prior to the expansion of its income eligibility criteria. In any event, since the eligibility expansion occurred in the summer of 2009, the changes would already have been in place by October 2009 had she sought to enroll then.

of Ben Keith, Ex. A. There is no indication Carrasquillo would have somehow contacted the social worker for assistance sooner in the but-for world, or that the social worker or patient advocate were previously unaware of PAP prior to the alleged marketing push by Astellas. Likewise, Carrasquillo points to no evidence that she herself would have become personally aware of and applied for enrollment in PAP prior to October 11, 2009 in the but-for world; in fact, at her deposition – occurring years after Astellas's heightened PAP campaign – she testified that she had never heard of the program. Id.

Carrasquillo simply fails to present sufficient evidence that her participation in PAP would have been accelerated by earlier generic entry. As such Astellas's motion for summary judgment as to Carrasquillo is ALLOWED.

5. Astellas's Motion to Unseal Memorandum of Decision Regarding Class Certification (Docket # 426)

The court's December 17, 2013, memorandum of decision denying certification of a class of indirect purchasers (Docket # 350) was issued under seal. Astellas now requests that the memorandum be unsealed and placed on the public docket, asserting that it does not divulge non-public sensitive information or pose a sufficient threat to any party's interests. After reviewing the memorandum, I agree. The motion to unseal is ALLOWED.

CONCLUSION

(1) Indirect Purchaser Plaintiffs' Motion for Reconsideration of Class Certification (Docket # 371) is ALLOWED, and on reconsideration, partial class certification

is ALLOWED on the issue of antitrust violation.

(2) Consolidated Plaintiffs' Motion to Strike Astellas's Designations of Non-Reporting Experts (Docket ## 330 and 332) is ALLOWED IN PART and DENIED IN PART. Drs. Cronin and Klintmalm shall be permitted to testify only as to their involvement in preparing and submitting letters to the FDA in support of Astellas's citizen petition, including any expert opinions incidental to such involvement. The remaining expert designations shall be stricken.

Consolidated Plaintiffs' Motion for Leave to File Reply to Astellas's Memorandum in Opposition (Docket # 338) is ALLOWED.

(3) Astellas's Motion for Summary Judgment on All Claims Against It (Docket # 358) is DENIED. Astellas's assented-to Motion for Leave to File Excess Pages (Docket # 359) is ALLOWED.

(4) Astellas's Motion for Summary Judgment as to All Claims Made by Plaintiff Judith Carrasquillo (Docket # 308) is ALLOWED. Judgment may be entered for Astellas.

(5) Astellas's Motion to Unseal Memorandum of Decision Regarding Class Certification (Docket # 426) is ALLOWED. Astellas's assented-to Motion for Leave to File Reply in Support (Docket # 439) is ALLOWED.

June 10, 2014
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NO. 1:11-md-02242-RWZ

IN RE: PROGRAF ANTITRUST LITIGATION

MEMORANDUM OF DECISION

December 17, 2013

S E A L E D

ZOBEL, D.J.

Plaintiffs in this consolidated antitrust action are indirect purchasers of Prograf, a branded prescription immunosuppressant used in organ transplant patients. They are suing Astellas Pharma US, Inc. ("Astellas"), a pharmaceutical manufacturer and maker of Prograf, for filing an allegedly baseless citizen petition with the Food and Drug Administration ("FDA") with the sole intent of foreclosing market entry by generic competitors and improperly extending its monopoly. Plaintiffs seek to certify a class of consumers and third-party payors ("TPPs")[1] under antitrust, consumer protection, and unjust enrichment laws of numerous states.

After a hearing and careful consideration of the parties' voluminous submissions, I find that plaintiffs have not satisfied the requirements of Fed. R. Civ. P. 23(b)(3). Accordingly, their motion for class certification (Docket # 153) is DENIED.

[1] Third-party payors include health benefit plans, health insurers, and self-insured employers.

I. Background[2]

A. Astellas and Prograf

Astellas manufactures, markets, and sells Prograf, a brand name prescription immunosuppressant used to prevent organ rejection by patients who have had liver, kidney, or heart transplants. The main active ingredient in Prograf is tacrolimus. The FDA approved Prograf 1 mg and 5 mg capsules and injections in 1994, and 0.5 mg capsules in 1998. Astellas's patent for Prograf expired on April 8, 2008.

B. Drug Approval Process

Under the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301–392, manufacturers who wish to market a new drug product must obtain FDA approval by filing a New Drug Application ("NDA"). An NDA must contain specific data concerning the safety and effectiveness of the drug. In 1984, Congress passed the Hatch-Waxman Amendments that modified the FDCA by creating a streamlined process for bringing generic drugs to market without the need to file lengthy and costly NDAs with the FDA. Manufacturers of generic drugs may submit an Abbreviated New Drug Application ("ANDA"), which incorporates and relies on the scientific findings of safety and effectiveness established by the brand name drug's original NDA. To receive FDA approval, a prospective generic manufacturer must demonstrate that the generic drug it seeks to market is "bioequivalent" to the brand name drug, meaning that the generic drug has essentially the same active ingredient, dosage form, route of administration, and strength as its branded counterpart.

[2] The following descriptions and allegations are drawn from plaintiffs' amended complaint.

Federal regulations allow individuals or entities to express concerns to the FDA about safety, scientific, or legal issues regarding a product anytime before or after its market entry by means of a citizen petition. Such a petition may request that the FDA take, or refrain from taking, any administrative action. 21 CFR § 10.30. The FDA commissioner must respond to, but not necessarily resolve, each citizen petition within 180 days of receipt. Plaintiffs assert that, because reviewing and responding to a citizen petition is a resource-intensive and time-consuming task, the FDA typically takes much longer than 180 days to issue a final response.

C. Sandoz and Astellas's Citizen Petition

On December 28, 2006, Sandoz, Inc. ("Sandoz"), a generic pharmaceutical manufacturer, filed an ANDA to market and sell tacrolimus capsules in 0.5 mg, 1 mg, and 5 mg dosages. On September 21, 2007, while Sandoz's application was still pending, Astellas filed a citizen petition requesting, among other things, changes in bioequivalence testing requirements for tacrolimus products. Plaintiffs allege that the FDA maintained a well-known practice at that time of withholding ANDA approval until after its consideration of and response to relevant citizen petitions was complete.[3]

Nearly two years later, on August 10, 2009, the FDA denied nearly all the relief requested in Astellas's citizen petition and approved Sandoz's ANDA for generic tacrolimus. Sandoz brought its generic tacrolimus products to market the following

[3] On September 28, 2007, less than a week after Astellas filed its petition, the FDA Amendments Act of 2007, 21 U.S.C. § 355(q), went into effect. The amendments, which apply only to citizen petitions filed on or after September 27, 2009, require the FDA to not delay approval of a pending ANDA because of a citizen petition unless such a delay is necessary to protect the public health. The amendments also permit the FDA to summarily dismiss citizen petitions whose primary purpose is to delay generic competition.

day.[4]

D. Procedural History

Plaintiffs New Mexico United Food and Commercial Workers Union's and Employers' Health and Welfare Trust Fund ("NMUFCW"), Louisiana Health Service Indemnity Company d/b/a Bluecross/Blueshield of Louisiana ("BCBSLA"), Janet M. Paone ("Paone"), and Judith Carrasquillo ("Carrasquillo") (collectively, "plaintiffs"), each initiated suits against Astellas in late 2011, and following consolidation, filed an amended class action complaint on March 27, 2012. They allege that Astellas, by filing a baseless "sham" citizen petition with the FDA, sought to improperly delay market entry by generic competitors and extend its monopoly on tacrolimus drugs. Plaintiffs claim that absent Astellas's exclusionary conduct, generic tacrolimus would have entered the market in April 2008 (at patent expiration) instead of in August 2009. The complaint alleges that, as a result, consumers and TPPs were prevented from purchasing or reimbursing for less-expensive generic tacrolimus and were forced to pay supra-competitive prices for branded Prograf.[5]

Plaintiffs bring state law claims for the violation of antitrust and/or consumer protection statutes of 27 jurisdictions and common law unjust enrichment under the laws of 32 jurisdictions. They move to certify an indirect purchaser class of:

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[4] Astellas unsuccessfully sought a temporary restraining order against the FDA to stay the approval of Sandoz's generic. The FDA subsequently approved ANDAs for several other generic versions of tacrolimus in 2010.

[5] A related antitrust lawsuit against Astellas, alleging the same misconduct, has been filed by direct purchasers of Prograf under § 2 of the Sherman Act. Upon Astellas's stipulation, I allowed the direct purchaser plaintiffs' motion for class certification on April 23, 2013 (Docket # 216).

All persons or entities in the United States and its territories who purchased, paid for, and/or reimbursed for some or all of the purchase price for branded Prograf capsules in 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, 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 following persons or entities are excluded from the proposed Class:

a. Defendant and its officers, directors, management, employees, subsidiaries, and affiliates;

b. all governmental entities (except for government funded employee benefit plans);

c. all persons or entities who purchased Prograf for purposes of resale or directly from Defendant or its affiliates;

d. fully insured health plans—*i.e.*, plans that purchased insurance from another third-party payor covering 100% of the plan's reimbursement obligations to its members;

e. any "flat co-pay" consumers whose purchases were paid in part by a third-party payor and whose co-payment share of the purchase price did not vary between brand-name and generic drug purchases;

f. individual consumers whose only purchases of Prograf were subsidized through the Astellas Prograf Assistance Program (PAP) and/or the Astellas Prograf Value Card Program;[6]

g. the judges in this case and any members of their immediate families.

[6] Under PAP, Astellas paid the entire prescription cost for uninsured or underinsured consumers who qualified. Similarly, under the Value Card ("VC") Program, Astellas paid the consumer's copayment or coinsurance costs such that consumers paid little or no copay.

Plaintiffs' Proposed Order (Docket # 153, Ex. 1). Astellas opposes certification. A hearing on plaintiffs' motion for class certification was held on August 6, 2013.

II. Legal Standard

Federal Rule of Civil Procedure 23 governs class certification. The district court may only certify a class after a "rigorous analysis of the prerequisites established by Rule 23." Smilow v. Sw. Bell Mobile Tel. Sys., 323 F.3d 32, 38 (1st Cir. 2003); see also Comcast Corp. v. Behrend, 133 S. Ct. 1426, 1432 (2013). Under Rule 23(a), a party seeking class certification must show that:

> (1) the class is so numerous that joinder of all members is impracticable;
>
> (2) there are questions of law or fact common to the class;
>
> (3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and
>
> (4) the representative parties will fairly and adequately protect the interests of the class.

Fed. R. Civ. P. 23(a). These four requirements are known as numerosity, commonality, typicality, and adequacy. See Smilow, 323 F.3d at 38.

In addition, the party seeking certification must show that one of the requirements of Rule 23(b) is met. Plaintiffs seek to proceed under Rule 23(b)(3), which allows a class action 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." Fed. R. Civ. P. 23(b)(3).

III. Discussion

A. Ascertainability

As a preliminary matter, the proposed class must satisfy an implicit requirement in Rule 23 of ascertainability, i.e., that "determining whether a particular individual is a member of the class is administratively feasible." Shanley v. Cadle, 277 F.R.D. 63, 67 (D. Mass. 2011); see also 7A Charles Alan Wright et al., Federal Practice & Procedure (Civil) § 1760 (3d ed. 2013). All class members need not be identified at the outset; rather, the class is ascertainable if it can be determined by "stable and objective factors." Kent v. SunAmerica Life Ins. Co., 190 F.R.D. 271, 278 (D. Mass. 2000).

Astellas claims plaintiffs' proposed class is not ascertainable because individualized investigation would be required to identify potential members. It takes issue not so much with the class definition per se, but with its exclusions – namely, the exclusion of fully-insured health plans, "flat co-pay" consumers, and consumers whose only purchases of Prograf were subsidized through Astellas's assistance programs. Astellas argues that these indirect purchasers would be impossible to identify (and therefore exclude from the class) without extensive inquiry into individual pharmacy and benefits records.[7]

Astellas does not dispute, however, that the criteria for membership in the proposed class are objective, based upon whether an indirect purchaser paid or reimbursed for Prograf during a specified time period in the delineated jurisdictions.

[7] Astellas also asserts an inability to differentiate uninjured indirect purchasers from possibly injured ones from *within* the class as defined. Such arguments pertain more to whether plaintiffs can adequately demonstrate class-wide injury (a predominance inquiry) than to ascertainability of the class.

"The presence of such an objective criterion overcomes the claim that the class is unascertainable." Matamoros v. Starbucks Corp., 699 F.3d 129, 139 (1st Cir. 2012). As for the exclusions cited by Astellas, they, too, are based on objective criteria: either a consumer had only flat co-pays between branded and generic drugs, or she did not; either a patient's only Prograf purchases were subsidized by Astellas, or they were not; either a health plan ultimately bore the costs of Prograf purchases, or it did not. Consumer class members can sign affidavits under penalty of perjury certifying that they paid for at least one Prograf prescription that was not subject to a flat co-pay or subsidy, and TPPs presumably would know, or would have records showing, whether they ever paid for a Prograf purchase. See Donovan v. Philip Morris USA, Inc., 268 F.R.D. 1, 9 (D. Mass. 2010) (rejecting ascertainability concerns where factors at issue – smoking history and a diagnosis of lung cancer – were objective criteria and could be certified through affidavits or doctors' letters).

Astellas's complaints really amount to concerns about the administrative burden of determining class members, which – while valid – are issues of manageability, not ascertainability. The proposed class is ascertainable.

B. Rule 23(a) Requirements[8]

1. Numerosity

Under Rule 23(a)(1), the numerosity requirement is met if "the class is so numerous that joinder of all members is impracticable." Here, plaintiffs estimate that

[8] Astellas does not dispute that the numerosity, commonality, and typicality requirements have been met.

class members from numerous states will number in the tens of thousands. Numerosity is easily satisfied.

2. Commonality

Commonality asks whether there are "questions of law or fact common to the class." Fed. R. 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.

Plaintiffs advance a number of common questions, the answers to which are "apt to drive the resolution of the litigation." Id. at 2551 (quoting Richard A. Nagareda, Class Certification in the Age of Aggregate Proof, 84 N.Y.U. L. Rev. 97, 132 (2009)). These include: "(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."

Plaintiffs' Brief ("Pl. Br.") (Docket # 155) at 16. Plaintiffs have met the commonality requirement.

3. Typicality

The typicality requirement is satisfied if "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). The representative plaintiffs are sufficiently typical if their claims "arise from the same course of conduct and are based on the same legal theory as the class claims." Evergreen Ultra Short Opportunities Fund Securities Litigation, 275 F.R.D. 382, 389 (D. Mass. 2011). Here, 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. Accordingly, I find the typicality requirement satisfied.

4. Adequacy of Representation

Adequacy of representation requires that "the representative parties will fairly and adequately protect the interests of the class." Fed. R. Civ. P. 23(a)(4). This entails a two-part showing: "(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." Andrews v. Bechtel Power Corp., 780 F.2d 124, 130 (1st Cir. 1985). Astellas does not challenge the qualifications of

proposed class counsel. Indeed, plaintiffs' lead counsel have extensive experience in pharmaceutical class action lawsuits and have vigorously and capably represented the putative class throughout the course of this litigation.

Astellas does raise objections to three of the named plaintiffs which I will treat as adequacy arguments. Astellas charges that NMUFCW and the two consumer plaintiffs, Paone and Carrasquillo, were not injured and therefore cannot properly serve as class representatives. It bases that conclusion on an analysis of plaintiffs' Prograf and generic tacrolimus purchases. Plaintiffs, however, counter with their own analysis and evidence which purport to show that NMUFCW, Paone, and Carrasquillo were harmed.

If in fact the named plaintiffs suffered no injury, it could create an internal conflict within the class. But Astellas's arguments, which depend on premises and assumptions that plaintiffs dispute, do not convince me, at least at this stage, that plaintiffs have interests so antagonistic to the other class members that they could not adequately represent the class. See Matamoros, 699 F.3d at 138 ("To forestall class certification the intra-class conflict must be so substantial as to overbalance the common interests of the class members as a whole."); George v. National Water Main Cleaning Co., 286 F.R.D. 168, 177 (D. Mass. 2012) (defendants' argument that named plaintiffs may have benefitted from the alleged illegal conduct "makes assumptions about the merits that are not now before the Court"). The named plaintiffs are part of the putative class, allege the same injury as the class members, and thus far have shown that their interests align with those of the absent class members. I am satisfied that the adequacy requirement has been met.

C. Rule 23(b) Requirements

Having fulfilled the prerequisites of Rule 23(a), plaintiffs must also overcome the hurdles of Rule 23(b)(3), which authorizes a class action where "the questions of law or fact common to class members predominate over any questions affecting only individual members, and . . . a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Certifying a class under Rule 23(b)(3) requires "a close look at the case before it is accepted as a class action." In re New Motor Vehicles Canadian Export Antitrust Litig., 522 F.3d 6, 18 (1st Cir. 2008) (quoting Amchem Prods. v. Windsor, 521 U.S. 591, 615 (1997)).

Astellas argues that plaintiffs cannot satisfy Rule 23(b)(3) for two primary reasons: demonstrating antitrust impact to class members will require individualized inquiries as opposed to common evidence, and the diversity of state laws at issue in this case precludes certification. I address these contentions in reverse order.

1. Variation in State Laws[9]

Plaintiffs bring common law unjust enrichment claims under the laws of 32 different jurisdictions, as well as statutory antitrust and consumer protection claims under the laws of 27 of those jurisdictions.[10] Plaintiffs insist that the relevant state laws

[9] The parties agree that under Massachusetts choice-of-law rules, the court must apply the law of the state where each consumer purchased tacrolimus. See In re Relafen Antitrust Litigation, 221 F.R.D. 260 at 277-78 (D. Mass. 2004).

[10] Plaintiffs' consumer protection claims are closely linked to their antitrust claims and are premised on three main theories of liability: (1) the state consumer protection statute "borrows" violations of other antitrust statutes as the basis for a claim; (2) Astellas's monopolistic conduct amounts to "unfair methods of competition" or "unfair" or "unconscionable" acts or practices prohibited by the consumer protection law; and (3) Astellas engaged in "deceptive" conduct aimed at the FDA or the federal courts in violation of the consumer protection statute. See Plaintiffs' Reply Brief ("Pl. Rep. Br.") (Docket # 272) at 21-22 .

are substantially similar and can be applied together. Astellas, in turn, argues that there are significant differences among the state laws that make class treatment impracticable and unmanageable. The parties' arguments involve overlapping concerns about predominance and superiority.

Certification of a multi-state class action presents numerous, but not insurmountable, substantive and practical challenges. The key inquiry here is "not whether the laws of multiple states are identical, but whether the Court can manage the differences." Overka v. American Airlines, Inc., 265 F.R.D. 14, 20 (D. Mass. 2010). While uniformity of state laws is not required under Rule 23(b)(3), "variations in state law may swamp any common issues and defeat predominance." In re Pharmaceutical Industry Average Wholesale Price Litigation, 230 F.R.D. 61, 82 (D. Mass. 2005) (quoting Klay v. Humana, Inc., 382 F.3d 1241, 1261 (11th Cir. 2004)). Manageability concerns have also prompted courts in some cases to find that a "class action is not a superior method for adjudicating" claims under the laws of multiple jurisdictions. In re Celexa and Lexapro Marketing and Sales Practices Litigation, 291 F.R.D. 13, 19 (D. Mass. 2013). "Courts should look at how issues are likely to play out in the context of the case to see what individual issues are likely to arise, and what state law differences are irrelevant and may be ignored." In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 84.

Plaintiffs provided the court with a detailed state-by-state review of the antitrust and consumer protection laws at issue.[11] They claim that each statute prohibits monopolization, provides a cause of action for indirect purchasers, and requires the same general elements for liability. Moreover, plaintiffs note that most of the relevant states have harmonization provisions or judicial precedent requiring that the state statutes be interpreted in accordance with applicable federal law.

Astellas responds with its own analysis highlighting various differences among the state antitrust and consumer protection statutes. Such differences include whether businesses can bring claims as plaintiffs; whether proof of reliance is required;

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[11] **Arizona**: Arizona Uniform State Antitrust Act, Ariz. Rev. Stat. § 44- 1401, *et seq*. and the Constitution of the State of Arizona, Article 14, § 15; **California:** California Unfair Competition Act, Cal. Bus. & Prof. Code § 17200, *et seq*.; **Delaware:** 6 Delaware Code Ann. § 2511, *et seq*.; **District of Columbia:** District of Columbia Antitrust Act, D.C. Code § 28-4501, *et seq*. and District of Columbia's Consumer Protection Procedures Act, D.C. Code Ann. § 28-3901, *et seq*.; **Florida:** Florida Deceptive and Unfair Trade Practices Act, Fla. Stat. Ann. § 501.201, *et seq*.; **Iowa:** Iowa Competition Law, Iowa Code §§ 553.4, 553.5; **Maine:** Maine Monopolies and Profiteering Statute, Me. Rev. Stat. Ann. tit. 10, § 1101, *et seq*. and Maine's Unfair Trade Practices Act, Me. Rev. Stat. Ann., tit. 5, § 207, *et seq*.; **Massachusetts:** Massachusetts Consumer Protection Act, Mass. Gen. Laws ch. 93A, § 11; **Michigan:** Michigan Antitrust Reform Act, Mich. Comp. Laws § 445.771, *et seq*.; **Minnesota:** Minnesota Antitrust Law of 1971, Minn. Stat. § 325D.49, *et seq*. and Minnesota Consumer Fraud Act, Minn. Stat § 325F.67, *et seq*.; **Mississippi:** Miss. Code Ann. § 75-21-1, *et seq*.; **Missouri:** Missouri Merchandising Practices Act, Mo. Rev. Stat. § 407.025; **Nebraska:** Ne. Rev. Stat. § 59-801, *et seq*. and Nebraska's Consumer Protection Act, Neb. Rev.
Stat. § 59-1601 *et seq*.; **Nevada:** Nevada Unfair Trade Practices Act, Nev. Rev. Stat. § 598A.010, *et seq*. and Nevada Deceptive Trade Practices Act, Nev. Rev. Stat. § 598.0903, *et seq*.; **New Hampshire:** New Hampshire state consumer protection laws, N.H. Rev. Stat. § 358-A, *et seq*.; **New Mexico:** New Mexico Antitrust Act, N.M. Stat. Ann. § 57-1-1, *et seq*. and New Mexico Unfair Practices Act, N.M. Stat. Ann. § 57-12-1, *et seq*.; **North Carolina:** North Carolina's antitrust and unfair competition law, N.C. Gen. Stat. § 75-1, *et seq*.; **North Dakota:** North Dakota Antitrust Act, N.D. Cent. Code § 51- 08.1-01, *et seq*.; **Oregon:** Oregon's antitrust laws, Or. Rev. Stat. §§ 646.780, *et seq*.; **Pennsylvania:** Pennsylvania Unfair Trade Practices and Consumer Protection Law, 73 Pa. Stat. Ann. § 201-1, *et. seq*.; **Puerto Rico:** Puerto Rico Antitrust Act, Puerto Rico Code 10 LPRA § 257, *et seq*.; **Rhode Island:** Rhode Island's eceptive Trade Practices Act, R.I. Gen. Laws § 6-13.1.1, *et. seq*.; **South Dakota:** South Dakota's antitrust law, S.D. Codified Laws § 37-1- 3, *et seq*.; **Tennessee:** Tennessee Trade Practices Act, Tenn. Code Ann. § 47-25-101, *et seq*.; **Vermont:** Vermont Consumer Fraud Act, Vt. Stat. Ann. tit. 9, § 2451, *et seq*.; **West Virginia:** West Virginia Antitrust Act, W. Va. Code § 47-18-1; **Wisconsin:** Wisconsin Antitrust Act, Wis. Stat. § 133.01, *et seq*.

variability regarding the nature and level of scienter and intent to deceive; variability regarding the nature of fraud or deception required; demand or notice provisions; requirements that the actionable misconduct occur within the state; whether a Hanover Shoe[12] "pass-on defense" is permitted; and the availability of different types of damages. Astellas also contends that unilateral monopolization is not actionable in Tennessee, and that in some jurisdictions that follow Illinois Brick[13] indirect purchasers may not pursue antitrust claims under the state's consumer protection act.

Such differences in the applicable antitrust and consumer protection laws are not so significant as to preclude a finding of predominance. Nearly all the state antitrust laws track the language and scope of the Sherman Act, while harmonization provisions instruct that consumer protection statutes be construed in accordance with federal interpretations of the Federal Trade Commission Act, which declares unlawful "unfair methods of competition in or affecting commerce, and unfair or deceptive acts or practices in or affecting commerce," 15 U.S.C. § 45. Plaintiffs correctly point out that many of the alleged variations identified by Astellas are not relevant to the claims brought in this case. Reliance and scienter, required by some consumer protection statutes, are unlikely to be material or require individualized inquiry where the basis for

[12] In Hanover Shoe v. United Shoe Machine, 392 U.S. 481 (1968), the Supreme Court held that a defendant in an antitrust action may not assert, as a defense, that the plaintiff was not injured by the antitrust violation because it "passed on" the overcharges it suffered to its customers.

[13] In Illinois Brick Co. v. Illinois, 431 U.S. 720 (1977), the Supreme Court held that indirect purchasers lack standing to sue for antitrust violations under federal law. In the wake of that decision, some states enacted so-called "Illinois Brick repealer statutes" permitting state law antitrust damage actions by or on behalf of indirect purchasers. Other states allow indirect purchasers to pursue similar claims under their consumer protection acts.

plaintiffs' claims is not fraudulent conduct or misrepresentations directed at them, but rather Astellas's unlawful monopolistic practices and its deceptive conduct directed at the FDA , which will depend on evidence common to all class members. The Hanover Shoe pass-on defense, typically invoked against direct purchasers, is also of little relevance here, where class members are "final" purchasers who did not resell Prograf. Discrete issues of law, such as standing and the effect of Illinois Brick in specific jurisdictions, can be resolved by the court in summary judgment proceedings.[14] To the extent that some jurisdictions may require distinctive elements to establish liability, special questions can be submitted to the jury on whether such elements were satisfied. Finally, plaintiffs propose to manage variations in the damages available under each state's laws through a detailed trial plan in which special jury findings will be used to establish aggregate damages for each jurisdiction. I find that plaintiffs have demonstrated sufficient commonality among the relevant antitrust and consumer protection laws.[15] See In re Terazosin Hydrochloride Litig., 220 F.R.D. 672, 695 (S.D. Fla. 2004) (finding predominance under antitrust laws of 17 jurisdictions because "the

[14] The question of whether unilateral monopolization claims may be brought under Tennessee law can also be addressed via summary judgment practice. I note that while the language of the Tennessee Trade Practices Act does not by its terms include unilateral conduct, the Tennessee Court of Appeals, without addressing the issue, allowed a claim of monopolization by a single firm to go forward in Sherwood v. Microsoft Corp., No. M2000-01850-COA-R9-CV, 2003 WL 21780975 (Tenn. Ct. App. July 31, 2003).

[15] Notwithstanding this finding, two topics merit special comment. First, plaintiffs have not alleged compliance with any relevant notice provisions under the state statutes. Second, it appears that there is no right to bring a class action under Mississippi law. Am. Bankers Ins. Co. of Fla. v. Booth, 830 So. 2d 1205, 1214 (Miss. 2002) ("[t]he rule is that Mississippi does not permit class actions"). Both issues may warrant excluding potential class members in those jurisdictions. See In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 84-85 (excluding consumers in states where class actions are not permitted and plaintiffs did not show compliance with notice provisions).

essential elements of Indirect Purchaser Plaintiffs' antitrust claims do not vary significantly from state-to-state, and they are susceptible to proof using common evidence."); In re Pharm. Indus. Average Wholesale Price Litig., 230 F.R.D. at 85 (finding that common legal and factual issues predominated under the consumer protection laws of all but 9 states).

The parties raise similar arguments with respect to unjust enrichment laws. Plaintiffs argue that common law claims for unjust enrichment are substantially identical across all the relevant jurisdictions.[16] They assert that all of their unjust enrichment claims share the same essential elements: (1) enrichment of the defendant at the expense of the plaintiff; (2) that the defendant retained the benefit; and (3) that retention of the benefit without payment would create an injustice. See Plaintiffs' State by State Unjust Enrichment Laws (Docket # 155, Ex. 2) (listing elements of unjust enrichment claims in each jurisdiction). Astellas does not dispute these core elements, but claims that such "surface similarities" mask material variations in the laws of different states. Chief among them are different standards for privity between plaintiffs and defendants;[17] varying requirements about the nature of the conduct[18] and the intent

[16] 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.

[17] Florida and Massachusetts require a direct relationship between plaintiff and defendant, see American Safety Ins. Serv., Inc. v. Griggs, 959 So. 2d 322, 331 (Fla. Dist. Ct. App. 2007), and Blake v. Prof'l Coin Grading Serv., 898 F. Supp. 2d 365, 390 (D. Mass. 2012), while other states require no privity or are inconsistent/silent on the issue.

[18] For example: Arizona requires an "absence of justification" for the benefit conferred. Community Guardian Bank v. Hamlin, 898 P.2d 1005, 1008 (Ariz. Ct. App. 1995). North Carolina requires that the benefit not be "conferred gratuitously or by an interference in the affairs of another

or scienter required[19]; and whether adequate remedies at law (such as antitrust claims) preclude recovery.[20] Astellas also notes differences in the effect of Illinois Brick on indirect purchasers' ability to pursue unjust enrichment claims, the number of elements that make up a claim, and the basis and measure of recovery. In response, plaintiffs argue that many of the cited variations are minor and that material additional elements can be presented to the jury through a special verdict form.

There are numerous examples from the case law in support of both parties' positions. Compare, e.g., Overka, 265 F.R.D. at 20-21 (ruling that the unjust enrichment laws of 34 jurisdictions are "substantially common and the differences between them are manageable"), In re Relafen, 221 F.R.D. at 278-80 (certifying a multi-state settlement class for unjust enrichment claims in five states), and In re Terazosin Hydrochloride, 220 F.R.D. at 701 (rejecting argument that multi-state class was unmanageable because of substantial variations in unjust enrichment laws) with Faherty v. CVS Pharmacy, No. 09-CV-12102, 2011 WL 810178, at *5 (D. Mass. Mar. 9, 2011) (declining to certify class on unjust enrichment claims in 44 jurisdictions due to "the intricate nature of the task and the potential for juror confusion"), Spencer v. Hartford Financial Services Group, Inc., 256 F.R.D. 284, 305 (D. Conn. 2009) (finding that legal variations in unjust enrichment claims of 50 states defeated a finding of

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party." Southeastern Shelter Corp. v. BTU, Inc., 572 S.E. 2d 200, 206 (N.C. 2002).

[19] Some jurisdictions – Florida, Kansas, Maine, Massachusetts, Missouri, New Mexico, North Carolina, Oregon, Pennsylvania, Rhode Island, and Wisconsin – require appreciation or knowledge of the benefit by the defendant.

[20] In Arizona, Iowa, Maine, Massachusetts, Minnesota, North Dakota, and Puerto Rico, unjust enrichment claims are only available where there is no adequate remedy at law.

predominance), and In re Conagra Peanut Butter Products Liability Litigation, 251 F.R.D. 689, 698 (N.D. Ga. 2008) ("The many differences among jurisdictions should prevent the Court from finding that common issues of law predominate on this [unjust enrichment] claim."). In the particular circumstances of this case, however, I am persuaded that plaintiffs have the better of the argument. "In all states, the focus of an unjust enrichment claim is whether the defendant was *unjustly* enriched." Powers v. Lycoming Engines, 245 F.R.D. 226, 231 (E.D. Pa.2007) (emphasis in original), rev'd on other grounds, 2009 WL 826842, 328 Fed. Appx. 121 (3d Cir. 2009). See also Cohen v. Chilcott, 522 F. Supp. 2d 105, 116 (D.C. Cir. 2007) ("Although Plaintiffs assert claims under the unjust enrichment laws of the fifty states, such claims may involve predominant common questions insofar as they all require a showing that Defendants were unjustly enriched at the expense of the Class Members. Moreover, the existence of minor differences in state law does not preclude the certification of nationwide classes."). I find 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.[21]

2. Predominance of Common Questions of Law or Fact

The parties' arguments over certification center largely on the question of predominance. Predominance tests "whether proposed classes are sufficiently

[21] There are questions, not raised here, as to whether plaintiffs can assert unjust enrichment claims in states where applicable antitrust and consumer protection statues do not provide for an equitable remedy. See Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC, 737 F. Supp. 2d 380, 426 (E.D. Pa. 2010). Such issues, as well as the availability of unjust enrichment claims in Illinois Brick jurisdictions, are legal questions that can be resolved through summary judgment.

cohesive to warrant adjudication by representation." Amchem, 521 U.S. at 623. Common questions may predominate despite the existence of individual differences, as long as "a sufficient constellation of common issues binds class members together." Waste Mgmt. Holdings v. Mowbray, 208 F.3d 288, 296 (1st Cir. 2000). However, the predominance standard is "far more demanding" than the commonality requirement of Rule 23(a)(2). In re New Motor Vehicles, 522 F.3d at 20 (quoting Amchem, 521 U.S. at 624). Deciding what questions predominate requires the court to "formulate some prediction as to how specific issues will play out." Waste Mgmt., 208 F.3d at 298.

Evaluating predominance "begins, of course, with the elements of the underlying cause of action." Erica P. John Fund, Inc. v. Halliburton Co., 131 S. Ct. 2179, 2184 (2012). "Under both federal and state law, the essential elements of a private antitrust action are the same: proof of a violation by the defendant, a demonstration of injury to the plaintiff, and an approximation of the plaintiff's damages."[22] In re Relafen, 221 F.R.D. at 275. See also In re Wellbutrin XL Antitrust Litigation, 282 F.R.D. 126, 139 (E.D. Pa. 2011) (elements of plaintiffs' antitrust claims are "(1) a violation of the state antitrust laws and/or state consumer protection laws, (2) individual injury, and (3) measurable damages."). Plaintiffs' burden at the class certification stage is not to prove each of these elements; "Rule 23(b)(3) requires a showing that *questions* common to the class predominate, not that those questions will be answered, on the

[22] The analysis that follows applies equally to plaintiffs' consumer protection claims, which rely on the same theory and operative evidence as their antitrust claims. Similarly, plaintiffs' claims for unjust enrichment are based upon the same facts and proof underlying their antitrust and consumer protection claims. That is, in order to prove that it would be inequitable for Astellas to retain the benefit of class members' purchases, plaintiffs must show that such "enrichment" was the result of Astellas' unlawful anti-competitive conduct.

merits, in favor of the class." Amgen Inc. v. Connecticut Retirement Plans and Trust Funds, 133 S. Ct. 1184, 1191 (2013) (emphasis in original).

Plaintiffs assert, and Astellas does not dispute, that common issues predominate with respect to the first element, violation of antitrust law. I agree. The showing necessary to prove a violation in this case – the possession of monopoly power in the relevant market and the willful maintenance of that power through anti-competitive or exclusionary means – focuses entirely on Astellas' alleged conduct rather than that of individual class members and can be proven through evidence common to the class. See In re Relafen, 221 F.R.D. at 275 ("The alleged antitrust violation relates solely to [defendant's] conduct, and, as such, constitutes a common issue subject to common proof); In re Wellbutrin XL, 282 F.R.D. at 140 ("The issues of relevant market, monopoly power, and exclusionary conduct can be proven uses common, class-wide evidence because such issues focus on the defendants' conduct rather than individual class members.").

As for the third element, measurable damages, plaintiffs need not supply precise damage figures for each class member at the class certification stage; instead, they may present proof of class damages in the aggregate. See In re Pharm. Indus. Average Wholesale Price Litig., 582 F.3d 156, 197-98 (1st Cir. 2009). Here, plaintiffs propose to calculate aggregate damages for the entire class through the use of "yardstick" methodology, examined in more detail below, and allocate those damages

later to individual class members through a separate claims process.[23] While ultimate determinations regarding the amount of each class member's recovery will invariably depend on individualized inquiry, "predominance is not defeated by individual damages questions as long as liability is still subject to common proof." In re New Motor Vehicles, 522 F.3d at 28 (citations omitted).

But whether liability in this case is in fact subject to common proof is the primary quarrel between the parties. In contrast to antitrust violation and damages, predominance on the second element, a demonstration of injury or "antitrust impact," is the subject of vigorous and complex debate. "In antitrust actions, common issues do not predominate if . . . the fact of antitrust impact cannot be established through common proof." In re New Motor Vehicles, 522 F.3d at 20. See also In re Hydrogen Peroxide Antitrust Litig., 552 F.3d 305, 311-12 (3d Cir. 2008) (plaintiffs need not prove the element of antitrust impact at the certification stage, but must demonstrate that it is "capable of proof at trial through evidence that is common to the class rather than individual to its members."). Plaintiffs' theory of impact "must include some means of determining that each member of the class was in fact injured, even if the amount of each individual injury could be determined in a separate proceeding." In re New Motor Vehicles, 522 F.3d at 28.

In an overcharge case, impact is shown through proof that (1) the defendant charged more for its product than it would have but-for its antitrust violation; and (2)

[23] Plaintiffs also calculate unjust enrichment damages by applying yardstick methodology to data on sales, profits, and costs.

class members paid for the product at the illegally inflated price. In re Terazosin Hydrochloride, 220 F.R.D. at 696. Plaintiffs assert that Astellas's alleged monopolization of the tacrolimus market resulted in two types of overcharge injuries to class members. First, they contend that consumers and TPPs were limited to purchasing or reimbursing for branded Prograf prescriptions during the class period instead of having the opportunity to pay for cheaper generic tacrolimus. Second, they claim that class members were also overcharged for branded Prograf, which was more expensive during the class period than it would have been absent Astellas's exclusionary conduct.

a. Plaintiffs' Proof of Antitrust Impact

In support of their arguments, plaintiffs submitted an expert report from Dr. Meredith Rosenthal, who was asked to "opine on whether the proposed Class would have been impacted economically by the alleged foreclosure of generic entry by [Astellas] and if so whether there is a scientifically acceptable methodology by which such impact could be measured." Rosenthal Decl. (Docket # 293), Part I.[24] Dr. Rosenthal explains that, in the pharmaceutical industry, generic entry generally leads to "much more vigorous price competition that will drive down prices for a given chemical entity." Id. at ¶ 20. Price competition is also influenced by TPPs, who adopt various cost control mechanisms – including tiered formularies, generic substitution

[24] Dr. Rosenthal is a Professor of Health Economics and Policy at the Harvard School of Public Health and an Academic Affiliate of Greylock McKinnon Associates, a consulting and litigation support firm. She holds a Ph.D in Health Policy from Harvard University and has consulted in numerous litigation matters concerning the pharmaceutical industry. Rosenthal Decl. ¶¶ 1-4.

programs, and coinsurance – and make other concerted efforts to incentivize consumers and their physicians to choose lower-cost drugs such as generics. Citing economic literature and theory, Dr. Rosenthal asserts that "when generics enter the market, a large portion of brand prescriptions are substituted by [sic] the less expensive generics resulting in significant savings relative to the pre-generic entry period." Id. at ¶ 27.

Dr. Rosenthal claims that these market principles were at work in the tacrolimus market and that delayed generic entry resulted in higher prices for class members and higher profits for Astellas. She proposes the use of "yardstick" methodology to demonstrate what would have occurred had Sandoz been able to launch its generic product on April 15, 2008 instead of in August 2009.[25] Under the yardstick approach, actual prices and quantities in the target market are compared with prices and quantities in a similar market untainted by anti-competitive activity; in this case, the comparison market is the actual market for tacrolimus *after* generic entry. Dr. Rosenthal utilized nationwide retail sales data from IMS Health, a vendor of pharmaceutical industry data, to calculate average prescription prices for both Prograf and generic tacrolimus for every quarter in the class period. She then constructed yardsticks based on what occurred in the tacrolimus market following actual generic entry and applied them to past data to simulate prices, prescriptions, market share, and other factors that would have existed in a "but-for" world. For example, observing a

[25] The "yardstick" approach is a commonly used method of economic analysis in antitrust cases. See, e.g., IIA Phillip E. Areeda, et al., Antitrust Law, at 388 (3d ed. 2007); In re Flonase Antitrust Litigation, 284 F.R.D. 207, 233 (E.D. Pa. 2012); In re Wellbutrin XL, 282 F.R.D. at 140.

12.5-percent price difference between the average retail prescription price of Prograf in the quarter just prior to actual generic entry in August 2009 and the average retail prescription price of the (cheaper) generic just after entry, Dr. Rosenthal applied a 12.5-percent reduction to the average price of Prograf around the but-for generic entry date of April 2008 to estimate a but-for price of the generic drug for that following quarter.

From this yardstick analysis, Dr. Rosenthal concludes that, absent Astellas' alleged misconduct, generic tacrolimus would have quickly captured up to 45.5 percent market share between April 2008 and December 2009, and that but-for generic prices would have been lower than the actual Prograf prices throughout that period. She likewise finds that but-for prices of Prograf would have been lower than actual Prograf prices for three of the seven quarters in the same period.

Dr. Rosenthal's report also notes that the number of PAP and VC prescriptions increased substantially after the launch of generic tacrolimus in the actual world, possibly the result of a strategic effort by Astellas to keep patients on Prograf. Dr. Rosenthal posits that had generic entry occurred earlier, these increases would likewise have occurred earlier. She therefore modeled the number of increased PAP and VC prescriptions that would have occurred in the but-for world and included their estimated value in her overcharge analysis.

Compiling various calculations, Dr. Rosenthal estimated aggregate overcharge damages for both "foreclosed generic switchers," class members who paid for Prograf in the actual world but would have purchased or reimbursed for the cheaper generic in

the but-for world, and "brand loyalists," those who paid for Prograf in both the actual and but-for worlds, but would have paid less for the brand in the but-for world.[26] Using percentages derived from national survey data about health plans, formularies, and average co-pay/co-insurance amounts, Dr. Rosenthal further allocated these overcharges among uninsured consumers (who paid for their prescriptions in full), insured consumers (who paid a co-pay or co-insurance), and TPPs.[27] She concludes that class members were injured economically by Astellas's foreclosure of generic entry through the fourth quarter of 2009, after which the overcharge damages end.[28]

b. Astellas's Objections

Astellas takes issue with numerous aspects of Dr. Rosenthal's report and counters with declarations from Dr. Pierre-Yves Cremiuex, an economist expert, and Kristin Fox-Smith, a healthcare billing and reimbursement expert.[29] According to

[26] Although Dr. Rosenthal initially referred to "brand loyalists" as "class members," she later clarified in her rebuttal declaration that the term as used in her analysis actually pertains to *prescriptions*, i.e., a "brand loyalist" is a prescription that remained branded even after generic entry. Thus, any given class member could have both "generic switcher" and "brand loyalist" prescription purchases in the but-for world.

[27] Dr. Rosenthal's calculations also include Medicare Part B copayments.

[28] Dr. Rosenthal's end date for overcharge damages conflicts with the December 2010 end date of plaintiffs' proposed class period.

[29] Dr. Cremieux is a Managing Principal of Analysis Group, Inc., an economics research consulting firm, and an Adjunct Professor in the Economics Department at the University of Québec at Montréal and the Yale School of Management. He received his Ph.D. in economics from the University of California, Berkeley, and has worked extensively on health economics, pharmacoeconomics, and antitrust issues. Cremiuex Decl. (Docket # 257, Ex. HH) ¶¶ 1-2.

Kristin Fox-Smith has worked 19 years in the pharmaceutical billing and health plan sectors of the healthcare industry, particularly with respect to transplant patients. She is currently the Reimbursement Manager at Indiana University Health and the principal of Reimbursement Solutions, LLC, in which capacity she consults with hospitals and health systems throughout the United States on healthcare billing and reimbursement issues. Fox-Smith Decl. (Docket # 257, Ex. GG) ¶¶ 1-2.

Astellas, Dr. Rosenthal's analysis fails to show that all members of the putative class were injured due to the alleged delay in generic entry, and, in fact, many were not.

To begin, both Astellas's experts contend that Dr. Rosenthal's use of average pharmacy prices and average co-payment and co-insurance terms present a skewed picture of what individual consumers and TPPs actually pay for tacrolimus. Because Prograf is priced on a per-milligram basis, the price of a prescription depends not only on the number of capsules, but also on the dosage strength. Cremieux Decl. ¶ 22. The dosage strengths prescribed to a tacrolimus patient hinge on various factors (including race, age, type of transplant, time since transplant, etc.) and may change depending on medical need. Thus, prescription prices vary significantly across patients and for individual patients over time. Id. at ¶ 23. Prescription data from 2008-2010 confirms this reality, revealing a wide distribution of per-prescription prices for both Prograf and generic tacrolimus. Pharmacy prices for both versions ranged from under $100 to over $1,500, with no tight "bell curve" around the average prices of that period. Id. at ¶¶ 24 and 110, Exs. 3.A. and 3.B. While the average Prograf prescription price is $608, 25 percent of prescriptions are priced below $242 and 25 percent are above $856; the average prescription price of generic tacrolimus is $520, but 25 percent of prescriptions are below $198 and another 25 percent are above $702. Id. Astellas claims, then, that "average" prices are inaccurate reflections of the actual range of tacrolimus prices and cannot be used to assess the fact or extent of overcharge injury.

Astellas points out similar flaws in the way Dr. Rosenthal accounts for how consumers and TPPs pay for prescriptions. While uninsured patients generally pay in

full for their prescriptions out-of-pocket, insured consumers and TPPs "share" the cost of prescriptions in accordance with the specific policies and design features of their health plans. Fox-Smith Decl. ¶ 34. Patients contribute to the cost of a prescription by paying a co-payment (a set dollar amount) or co-insurance (a percentage of the pharmacy price). Id. at ¶ 37-38. Drugs eligible for reimbursement by a particular health plan are listed on the "formulary," which is often organized into "tiers" dictating different levels of coverage. Id. at ¶ 35. Drugs in the lowest tier, where most generics are categorized, require the lowest member co-payment or co-insurance; drugs in higher tiers correspond with higher patient contributions. Id. Even for drugs on the same formulary tier, co-payment and co-insurance requirements may vary greatly under different health plans offered by the same TPP. Id. at ¶ 37-38.

Accordingly, Fox-Smith claims that the average co-payment and co-insurance terms used by Dr. Rosenthal "obscure huge variations in pharmaceutical benefit design and payment structures for Prograf during the relevant time period." Id. at ¶ 16. Transplant patients are insured by thousands of different commercial and governmental drug benefit plans, each with its own unique terms, and many patients receive financial assistance from third-party sources, maintain secondary or tertiary insurance coverage, and change prescription drug plans during the course of their treatment. Id. at ¶¶ 16-17, 32. There are also a variety of complex contractual relationships between TPPs and other entities which make it difficult to determine which entity ultimately paid for a prescription and whether or not it bore any overcharge. Id. at ¶ 17. Given this context, Fox-Smith opines that determining what a particular class member would have paid for

generic tacrolimus or Prograf at any given time during the class period would require individualized analysis of consumer prescription and payment history and the details of relevant insurance plans, including information about coverage limitations, co-payment/co-insurance terms, prescription drug formularies, and any front-end deductibles, out-of-pocket maximums, or benefit caps. Id. at ¶¶ 46-48.

Due to such variations in prescription costs, purchasing behavior, and insurance plan terms, Astellas asserts that it is not possible to determine through common proof whether a class member's per-prescription expenditures would have differed between Prograf and generic tacrolimus purchases, or between the actual world and the but-for world. Even if the average pharmacy price of Prograf in the actual world were higher than the but-for prices of Prograf and generic tacrolimus at a particular time, a consumer or TPP may not have paid any overcharge on a given prescription depending on health plan design and prescription history. Using longitudinal pharmacy claims data from Wolter-Kluwers ("WK"),[30] Dr. Cremieux illustrates such scenarios and argues that the class as defined contains large subsets of "uninjured" members.

Dr. Cremieux first highlights two important factors that distinguish this case from other generic entry situations and make injury to class members less likely. Generic drugs are typically priced significantly below their branded equivalents (on average 40 to 50 percent lower within the first year after market entry) and quickly overtake sales of the branded drug. Cremieux Decl. ¶¶ 18, 19, 21. Dr. Rosenthal also notes these

[30] The Wolters Kluwers data covers 35 to 40 percent of all tacrolimus prescriptions filled through retail and mail order pharmacies in the United States from January 2003 to September 2012.

patterns in her report, asserting that "retail price discounts for generic drugs one year after launch may be as much as 25% relative to the brand" and that "it is not uncommon for a generic drug launched today to capture 80-90% market share within 6 months to a year." Rosenthal Decl. ¶ 25. But in the case of Prograf, neither trend materialized. Cremieux Decl. ¶¶ 8, 20, 21. The average pharmacy price of the generic was only about 9 percent lower than that of Prograf for the first year after generic entry in the actual world. Id. at ¶ 21, Ex. 2. Similarly, the but-for generic prescription prices calculated by Dr. Rosenthal are only about 12 to 15 percent lower than her but-for Prograf prescription prices. See Rosenthal Decl. Att. C.3.a (Column 8) and C.3.b. (Column 8). Prograf also maintained an unusually high share of total tacrolimus prescriptions after generic entry, keeping more than half of the market one year later. Cremieux Decl. ¶ 20, Ex. 1. Dr. Cremieux explains that these idiosyncracies indicate that a large number of tacrolimus patients were "brand loyal" even after generic entry; patients who switched to generic tacrolimus ("generic switchers") did not realize the kinds of savings that patients typically realize when generic entry occurs; and the small price difference between Prograf and the generic could be captured by either the patient or the health plan according to drug coverage terms, but often not by both, meaning some TPPs actually paid more for tacrolimus after generic entry than they did before. Id. at ¶ 8. Such conclusions are significant because they suggest that many class members were not injured.

For instance, Dr. Cremieux claims that many brand loyal patients were actually harmed by or indifferent to generic entry because of their health plans' treatment of

Prograf's formulary tier status. Id. at ¶¶ 57-58. Consumers whose health plans moved Prograf to a higher tier on the drug formulary after generic entry – a common practice used to incentivize patients to switch to generics, see Fox-Smith Decl. at ¶ 39 – were thereafter subject to higher co-pays or co-insurance for their Prograf prescriptions. Cremieux Decl. ¶ 57, Ex. 8.A.1. Other brand loyal consumers saw no change in their tacrolimus costs upon generic entry because their plans kept Prograf on the same formulary co-pay tier. Id. at ¶ 57. Based on empirical analysis of the WK data, Dr. Cremieux estimates that 45 percent of brand loyalists in the data set paid more for tacrolimus and an additional 12 percent of brand loyalists experienced no change in their expenditures as a result of generic entry. Id. at ¶ 57, Ex. 5. These brand loyalists would not have paid less for their tacrolimus prescriptions had generics been available earlier and were therefore not harmed by any alleged delay.

Dr. Cremieux also maintains that large numbers of "generic switcher" consumers were uninjured by delayed generic entry. He notes that not all generic switchers switched to the generic drug immediately after it became available; many continued to purchase Prograf for a period of time before switching to the generic, and others switched back and forth between Prograf and generic tacrolimus. Id. at ¶ 60. Dr. Cremieux posits that, even assuming these patients would have made such switches earlier in a but-for world, fact of injury will depend on the timing of their Prograf and generic purchases and the specific details of their drug benefit plans. Id. at ¶¶ 59-60, 62. Like brand loyalists, generic switchers may have paid more for their Prograf prescriptions after generic entry because of formulary shifts. Id. at ¶ 62. If those higher

brand expenditures outweighed the savings occasioned by generic purchases, some of these switchers paid more, on average, for their tacrolimus prescriptions following generic entry than prior to it. Id.[31] Dr. Cremieux provides several examples of individual generic switchers (including both named consumer plaintiffs, Carrasquillo and Paone) who paid more on average for tacrolimus after generics entered the market. Id. at ¶¶ 63-68, Exs. 9.A.1-4. He finds that approximately 29 percent of all generic switchers represented by the WK data would not have been better off in the but-for world because their average tacrolimus expenditures increased following generic entry. Id. at ¶ 62.

Another subset of "unharmed" class members identified in Dr. Cremieux's analysis consists of patients whose health plans provide for capped annual expenditures. Some health plans limit patients' annual out-of-pocket prescription costs to a fixed dollar amount, beyond which their co-payment or co-insurance share would drop to zero. Id. at ¶ 69; Fox-Smith Decl. ¶ 44. Thus, patients who hit the cap will pay the same amount annually for all the drugs they purchase, regardless of whether they buy Prograf or generic tacrolimus.[32] Assessing whether these consumers were injured

[31] Moreover, although Dr. Rosenthal purports to exclude "flat co-pay" consumers from her analysis by factoring out patients enrolled in plans with a "single tier formulary design where consumers pay a fixed copay regardless of whether the drug is generic or brand," Rosenthal Decl. ¶ 52, Dr. Cremieux points out that it is possible for beneficiaries of plans with tiered cost-sharing formulas to also have the same co-pay for Prograf and generic tacrolimus. This occurs because some multi-tier plans require no patient expenditures for either brand or generic tacrolimus prescriptions and because some plans may "shift the brand to a higher tier and place the generic at the brand's old tier position on the formulary." Cremieux Decl. ¶¶ 54, 106.

[32] According to Fox-Smith, "transplant patients are more likely to reach their out-of-pocket cap than the average population because of the large number of drugs they typically take and their high drug costs." Fox-Smith Decl. ¶ 44.

would require evaluating the timing and expense of all their prescription drug purchases, of both tacrolimus and other drugs, to determine whether they would have still reached the cap had generic tacrolimus been available earlier. Cremieux Decl. ¶ 70. Dr. Cremieux estimates that approximately 3 percent of brand loyalists and 2 percent of generic switchers tracked in the WK data were uninjured by generic delay solely due to expenditure caps. Id. at ¶ 70, Ex. 5.

Dr. Cremieux also asserts that many TPPs in the proposed class were not injured by the alleged delay in generic entry. Depending on plan-specific features, a TPP's expense per prescription may actually increase when a consumer switches from Prograf to generic tacrolimus. Where a switch results in a decrease in patient expenditures (e.g., a lower co-pay) that outweighs the decrease in the pharmacy price between the brand and the generic, TPPs are left with a higher net cost. Id. at ¶¶ 81-83. In such scenarios, Prograf will be less expensive for the TPP than the generic, and the TPP is not injured by delayed generic injury. Id. Dr. Cremieux claims this is exactly what would have happened to plaintiff NMUFCW in the but-for world. Using plan and purchase data, Dr. Cremieux conducted an analysis of NMUFCW's payments with respect to the tacrolimus prescriptions of its beneficiaries. Under NMUFCW's plan, patients paid 20 percent of the cost of Prograf prescriptions, but nothing for generic prescriptions. Since the reduction in price between Prograf prescriptions and generic prescriptions was less than the reduction in the beneficiaries' share from 20 percent to zero, NMUFCW paid more on average for generic tacrolimus than it did for Prograf following generic entry. Id. at ¶¶ 85-87, Ex. 15.A-15.B.5. Given the relatively modest

price difference between Prograf and generic tacrolimus, Dr. Cremieux predicts that similar circumstances are likely for other TPPs in the class and identifies several TPPs from the WK data that also paid more for generic tacrolimus than for Prograf after generic entry. Id. at ¶¶ 92-93, Exs. 16B, 17. He notes, however, that such determinations cannot be conducted on a class-wide basis, but instead would require analysis of individualized plan-level data. Id. at ¶¶ 88, 94.

Finally, Dr. Cremieux contends that Dr. Rosenthal's impact methodology suffers from numerous flaws. Id. at ¶¶ 100-127. He argues that her analysis relies improperly on average prices per prescription and fails to account for important factors that affect what consumers and TPPs actually pay for prescriptions, including differences in the specific features and requirements of patients' pharmaceutical drug plans. Id. at ¶¶ 110, 113. He also criticizes her imposition of a damages "floor" in her calculations – counting "negative" overcharges as "zero" overcharges in instances where members of the class may have been better off as a result of generic delay – claiming that this approach overstates the aggregate harm to the class. Id. at ¶ 117. Moreover, the vast majority of Dr. Rosenthal's overcharge damages to brand loyalists (80 percent) rests on an assumption that the increase in PAP prescriptions following generic entry would have occurred earlier in the but-for world. Id. at ¶ 120. Dr. Cremieux argues that such calculations unfairly inflate the damages because the expansion of PAP eligibility in late 2009 and 2010 was not linked to generic entry, as Dr. Rosenthal assumes, but was a measure taken by Astellas in light of the high U.S. unemployment rate at that time. Id.; see also Declaration of John Liu (Docket #257, Ex. II) ¶ 10.

At bottom, Astellas and its experts insist that plaintiffs' approach fails to adequately demonstrate the fact or extent of injury to class members and misidentifies numerous uninjured class members as injured. Astellas concludes that common questions do not predominate here because class-wide impact, or lack thereof, can only be assessed through onerous individualized inquiry.

c. Analysis

I find that plaintiffs have not demonstrated predominance on the element of antitrust impact. Plaintiffs must provide the court with "enough information to evaluate preliminarily whether the proposed model will be able to establish, without the need for individual determinations. . . which consumers were impacted by the alleged antitrust violation and which were not." In re New Motor Vehicles, 522 F.3d at 28. Dr. Rosenthal's analysis, while it purports to demonstrate harm to the class as a whole, does 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.

Dr. Rosenthal's reliance on average prescription prices to model the impact of delayed generic entry is problematic. A "prescription" of tacrolimus is not a standard unit of the drug; it indicates no set number of capsules or quantity of milligrams. Indeed, prescriptions for Prograf and generic tacrolimus vary widely in dosage and price, a fact obscured by the "average" prescription prices Dr. Rosenthal used to construct her but-for world. Dr. Rosenthal's pricing yardsticks are derived from observed differences in the average prescription prices of Prograf before and after

generic entry, and between the average prescription prices of Prograf and generic tacrolimus. Yet such differences are not always indicative of any actual discrepancy in the price of tacrolimus itself; they may reflect, instead, changes in the overall quantity or dosage of the drug being prescribed.

Averaging also "glides over what may be important differences" among the class. In re Graphics Processing Units Antitrust Litigation, 253 F.R.D. 478, 494 (N.D. Cal. 2008). The American Bar Association has warned of the pitfalls of using averages to show impact:

> Sometimes the prices used by economists are averages of a number of different prices charged to different customers or for somewhat different products. Using such averages can lead to serious analytical problems. For example, *averages can hide substantial variation across individual cases, which may be key to determining whether there is common impact*. In addition, average prices may combine the prices of different package sizes of the same product or of somewhat different products. When this happens, the average price paid by a customer can change when the mix of products that the customer buys changes — even if the price of no single product changed.

ABA Section of Antitrust Law, Econometrics: Legal, Practical, and Technical Issues 220 (2005) (emphasis added). As previously described, there is substantial variance not only in the pharmacy prices and dosages of tacrolimus prescriptions, but also in how benefit plans allocate the cost of a tacrolimus prescription between patient and insurer, in the timing of drug purchases, and in the costs actually incurred by individual class members. Other courts have rejected the use of averages in econometric analyses where it masks wide variations in the class. See, e.g., Allied Orthopedic Appliances, Inc. v. Tyco Healthcare Group L.P., 247 F.R.D. 156, 167 (C.D. Cal. 2007) ("[S]ensor

prices operate according to a widely varying distribution, so the average price for any particular sensor only furnishes part of the picture. . . This gives the Court little basis to conclude that the average price of generics sets some sort of evidentiary standard by which it may be decided that all or virtually all purchasers of [brand-name] sensors were overcharged "); Reed v. Advocate Health Care, 268 F.R.D. 573 (N.D. Ill. 2009) (holding that plaintiffs' use of averages "unacceptably masks the significant variation" in the compensation of registered nurses); In re Graphics Processing, 253 F.R.D. at 493-97 ("While averaging may be tolerable in some situations, the record here shows that it has in fact masked important differences between products and purchasers").

Even if the averages accurately reflected tacrolimus prices (e.g., if prices per prescription were less varied and formed bell-shaped curves around the average), plaintiffs' model does not show that Astellas's alleged misconduct resulted in higher prices than would have occurred in the but-for world. Dr. Rosenthal asserts that "prices for Prograf were higher than generic prices would have been absent the foreclosure" and that "branded Prograf prices were higher than they would have been if generic tacrolimus had launched earlier." Rosenthal Decl. ¶ 14. But while her analysis demonstrates the former, it fails to show the latter. Dr. Rosenthal's own calculations indicate that but-for Prograf prices would have been, on average, *higher* than actual Prograf prices during four of the seven quarters in her antitrust damages period. Rosenthal Decl. Att. C.3.b. Brand loyal purchases in the actual world during those quarters, then, were priced lower rather than higher than in the but-for world, and to a degree that outweighs Dr. Rosenthal's calculated overcharges for the remaining three

quarters. Id. Similarly, data from the last two quarters of 2009 show that actual world prices of generic tacrolimus were less on average than the estimated but-for price of generics for the same time period, meaning that at least some generic purchases during those quarters were likewise not subjected to any price inflation. Id. at Att. C.3.a. More importantly, quantifying differences in average prescription prices does not, by itself, adequately demonstrate class-wide injury in this case. Assuming that average prices for prescriptions of Prograf and generic tacrolimus would have been less in the but-for world than the average prescription price of Prograf in the actual world, that would not automatically mean that all the members of the proposed class suffered an overcharge for their purchases. See Sheet Metal Workers Local 441 Health & Welfare Plans v. GlaxoSmithKline, No. 04-5898, 2010 WL 3855552, at *30 (E.D. Pa. Sept. 30, 2010) ("Just because an average price was increased or decreased by the alleged foreclosure does not mean that all members of the proposed class paid supra-competitive prices..."); Reed, 268 F.R.D. at 591 ("Measuring average base wage suppression does not indicate whether each putative class member suffered harm from the alleged conspiracy. In other words, it is not a methodology common to the class that can determine impact with respect to each class member."). Observed disparities in average prices do not necessarily translate into a corresponding picture of what a class member actually paid. This is because, as Astellas's experts explain, the cost that a consumer or TPP incurs for a tacrolimus prescription is not simply a function of the drug's pharmacy price, but is dependent on the unique requirements and features of specific drug benefit plans. Dr. Cremieux identified numerous subsets of class

members, both consumers and TPPs, that presumably would not have been harmed by increased prices due to plan-specific variables, including co-payment and co-insurance policies, formulary structures, and patient expenditure limits.

In rebuttal, Dr. Rosenthal faults Dr. Cremieux for making actual-to-actual comparisons instead of conducting a but-for analysis, thereby arriving at incorrect conclusions. Rosenthal Reb. Decl. ¶¶ 23-24. Her criticism on this point is well-taken; Dr. Cremieux's analysis compares data in the actual world before and after generic entry – he does not calculate but-for prices and compare them to actual prices prior to generic entry. Dr. Rosenthal notes that when an appropriate but-for yardstick analysis is conducted on NMUFCW claims data, it becomes clear that NMUFCW did pay more in the actual world than it would have in the but-for world on the majority of its claims and in aggregate.[33] Id. at ¶¶ 25-26, Att. C. Dr. Rosenthal also claims that Dr. Cremieux's comparison of average payments before and after generic entry for individual TPPs is flawed because he relies on incomplete sample data from WK. Id. at ¶ 24. She asserts that Dr. Cremieux's comparisons are "worthless" because he "does not know how many claims are missing from the before and after period and what prices were paid for those claims." Id. at n.23.[34]

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[33] In his surrebuttal report, Dr. Cremiuex conducts yet another analysis of NMUFCW's claims using Dr. Rosenthal's yardstick methodology, but with an "updated" but-for generic entry date of September 2008, which Astellas claims plaintiffs have adopted. Dr. Cremieux concludes that, under this adjusted analysis, NMUFCW was not harmed. Cremieux Sur-rebuttal Decl. (Docket # 278, Ex. A) ¶¶ 9, 22.

[34] The parties also fiercely debate the correct definition of antitrust impact. According to plaintiffs,"every indirect purchaser who made a purchase at a supra[-]competitive price" suffers injury, regardless of whether the same indirect purchaser benefitted from the generic delay on other purchases during the class period. Pl. Rep. Br. at 13. Plaintiffs insist that it is irrelevant whether a particular class member would have paid more, on average, for tacrolimus prescriptions in the but-for world than in the

Despite such apparent defects in Dr. Cremieux's methodology and sample analyses, the issues Astellas raises about uninjured class members and the need for individualized inquiries are nonetheless valid. "Even assuming the plaintiffs can show on a basic level that prices for both generic and branded [drug] increased as a result of [defendant]'s allegedly anti-competitive conduct, they must also demonstrate that *all* end-payor purchasers made a purchase at a supra-competitive price." Sheet Metal Workers, 2010 WL 3855552, at *26. Dr. Rosenthal's analysis simply does not make this showing.[35] It appears that not every prescription of Prograf sold during the class

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actual world, so long as there is at least one instance of actual overpayment. Thus, Dr. Rosenthal treats any "negative" damages as "zero" damages in her initial analysis. Rosenthal Reb. Decl. ¶¶ 29-30.

Astellas, in contrast, argues that assessing a class member's true but-for position includes accounting for "both the positive *and* negative injury arising from the alleged antitrust misconduct." Astellas's Sur-Reply Br. (Docket # 278) at 2. It 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. See, e.g., Kottaras v. Whole Foods Market, 281 F.R.D. 16, 25 (D.D.C. 2012) (rejecting impact analysis that aggregated losses from antitrust conduct without crediting gains and finding that "benefits must be offset against losses"); Los Angeles Memorial Coliseum Com'n v. National Footbal League, 791 F.2d 1356, 1367 (9th Cir. 1986) ("An antitrust plaintiff may recover only to the 'net' extent of its injury; if benefits accrued to it because of an antitrust violation, those benefits must be deducted from the gross damages caused by the illegal conduct."); Blair & Page, "Speculative" Antitrust Damages, 70 Wash. L. Rev. 423, 430 (1995) ("The principal of individual net harm guides the definition of the plaintiff's actual and but-for conditions. . . . When an illegal practice harms the plaintiff in one way but benefits the plaintiff in another, the two effects must be offset."); Areeda, Antitrust Violations Without Damage Recoveries, 89 Harv. L. Rev. 1127, 1136 (1976) (noting "the necessity of offsetting injuries which plaintiffs may have suffered at the hands of defendants with benefits which they may have derived from the very activities they attack."). It matters little, however, because I find that plaintiffs here have not even demonstrated that every class member did make a purchase at a supra-competitive price.

[35] Dr. Rosenthal states that she was instructed by counsel that plaintiffs "do not need to present a methodology to identify each and every Class member," Rosenthal Reb. Decl. ¶ 14, and thus her analysis demonstrates the impact of alleged misconduct only on the class as a whole, without regard to whether every class member actually suffered harm. Rosenthal Reb. Decl. ¶ 16 ("My calculations accurately capture all the transactions in question regardless of which entity is entitled to claim damages for them."); Rosenthal Dep. at 19 (conceding that her determination of aggregate injury does not identify injury as to any particular class member).

The court in In re K-Dur Antitrust Litigation, No. 01-1652 (JAG), 2008 WL 2660723 (D.N.J. Mar. 27, 2008), another antitrust suit alleging delayed generic entry, rejected a similar approach to showing antitrust impact. There, indirect purchaser plaintiffs sought to certify a nationwide class of consumers

period was more expensive (based on pharmacy price) than its but-for counterpart. See Rosenthal Decl. Att. C.3.a and C.3.b (showing higher but-for prices for Prograf and tacrolimus in some quarters). And, as even plaintiffs and Dr. Rosenthal acknowledge, not every prescription of Prograf purchased during the class period, even at higher pharmacy prices, imposed an actual overcharge on the class member(s) who paid for it. See, e.g., Rosenthal Deposition (Docket # 257, Ex. C) at 24 ("In the sense of an overcharge model, there may be class members whose overcharge was zero . . . "); Id. at 127-28 (conceding that brand loyal consumers whose health plans move Prograf to a higher tier after generic entry would pay a higher co-payment in the but-for world, leading to a "negative overcharge"); Rosenthal Reb. Decl. n.30 ("I recognize that consumers who pay fixed copayments for the brand in both the actual and but-for worlds would not have paid a lower copay in the but-for world."); Id. Att. C. (showing "negative" damages for NMUFCW on some tacrolimus purchases during the class period). Yet plaintiffs' impact methodology provides no way of confirming, upon common proof, that every member of the class is connected to at least one higher-priced prescription, let alone whether each class member actually paid any overcharge

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and TPPs who purchased or reimbursed for the brand-name drug. As with Prograf, the small difference between the price of the branded drug and its generic alternative meant that, depending on co-pay structures, some TPPs likely paid more for the generic than for the branded drug. Variable co-pays also affected whether some consumer class members had suffered any overcharge injury. In light of these difficulties, plaintiffs advanced a "joint purchase" theory of impact, claiming injury to all class members who jointly paid part of the supra-competitive retail price of the brand drug, "irrespective of whether the portion of the price paid by particular consumers or TPPs was actually higher than the portion of the price they would have paid for the generic version." Id. at *10. The court declined to find predominance on impact, finding that the joint purchaser theory lacked precedence and was at odds with class certification decisions which specifically excluded potential plaintiffs who could not demonstrate individual injury. Id. at *13.

and was therefore injured.[36] Discerning the existence of such impact is impossible without the use of individualized data. See Sheet Metal Workers, 2010 WL 3855552, at *26 ("If only some end-payors paid increased prices, this would suggest the plaintiffs will have to prove economic impact customer-by-customer."); In re Hydrogen Peroxide Antitrust Litigation, 552 F.3d 305, 314 n.12 ("Generally, when the prices for some customers are going up while the prices of other customers are not, there is reason to doubt that the different customers (class members) are experiencing a common impact.") (quoting ABA Section of Antitrust Law, Econometrics 210 (2005)).

Plaintiffs argue that "'a class will often include persons who have not been injured by the defendant's conduct,' and 'such a possibility or indeed inevitability' does not prevent certification." Pl. Rep. Br. at 17 (quoting Kohen v. Pacific Inv. Management Co., LLC., 571 F.3d 672, 677 (7th Cir. 2009)). While that may be true, "a class should not be certified if it is apparent it contains a great many persons who have suffered no injury at the hands of the defendant." Id. at 677. I agree with Astellas that there is a substantial likelihood that significant numbers of class members did not suffer any injury given the wide variability of prescription prices, purchasing behavior, and insurance plans across the class. Plaintiffs have not shown that their methodology

[36] Overcharges associated with the hypothetical expansion of Astellas's PAP and VC programs in the but-for world, while relevant for calculating aggregate damages, are unhelpful in establishing class-wide injury because the increased subsidies are applied to some brand loyalist prescriptions as opposed to all class members across the board. See Rosenthal Decl. Att. C.3.b and C.3.e (calculating number and value of prescriptions that would have been covered by both programs in the but-for world). That is, increased PAP or VC subsidies would not necessarily have had an effect on class as a whole (only some, not all, patients who made post-entry Prograf purchases would have benefitted under either program), so the inclusion of their "lost" value in the consumer overcharges does not show that every class member was harmed.

demonstrates widespread harm to class members in spite of these distinctions, or that such a determination can be made upon common proof. Cf. In re Flonase, 284 F.R.D. at 224-226 (plaintiffs' expert tested the robustness of his methodology by conducting a "sensitivity analysis" that took into account distinctions in plan provisions, and he found that, even using extreme values, diverse class members were still harmed). Accordingly, I find that plaintiffs have failed to establish that common questions will predominate over individual ones on the issue of antitrust impact. The class cannot be certified.

3. Superiority

Superiority looks to whether "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy." Fed. R. Civ. P. 23(b)(3). Pertinent factors include class members' interests in individually controlling their own litigation; the extent and nature of any existing or pending litigation concerning the controversy; the desirability of concentrating the litigation of claims in the particular forum; and the likely difficulties of managing a class action. See Fed. R. Civ. P. 23(b)(3)(A)-(D). Plaintiffs assert that class treatment here would allow for efficient prosecution of many plaintiffs' common claims without the unnecessary duplication of evidence, effort, or expense. They argue that individual class members' claims are too small, and their resources too few, to justify bringing separate complex antitrust lawsuits against a large and well-armed opponent. Without class certification, plaintiffs warn that "Astellas's conduct will go unchallenged and Class members will go uncompensated." Pl. Br. at 36.

These are meritorious arguments, since the "core purpose of Rule 23(b)(3) is to vindicate the claims of consumers and other groups of people whose individual claims would be too small to warrant litigation." Smilow, 323 F.3d at 41. However, as previously discussed, proof of plaintiffs' antitrust injury and damages in this action will depend on individual issues rather than common ones. In such circumstances, myriad individual adjudications would render the case unmanageable. See 2 Newburg on Class Actions § 4:74 (5th ed. 2013) ("[M]any courts that find common predominance lacking, also hold that the prevalence of individual issues renders the case unmanageable for superiority purposes."). I therefore find that class action is not the superior form of litigation to resolve plaintiffs' claims.

IV. Conclusion

Plaintiffs' motion for class certification (Docket # 153) is DENIED.

Plaintiffs' motion for leave to file excess pages on their memorandum in support of class certification (Docket # 152) is ALLOWED. Astellas's motions for leave to file a sur-reply and surrebuttal report in opposition to class certification (Docket ## 277 and 278) are ALLOWED.

December 17, 2013
DATE

/s/Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

NO. 1:11-md-02242-RWZ

IN RE: PROGRAF ANTITRUST LITIGATION

ORDER

December 2, 2014

ZOBEL, D.J.

In their status report filed yesterday (Docket # 636), the Indirect Purchaser Plaintiffs ("IPPs") asked the court to clarify whether the named IPPs' damages will be tried at the same time as Astellas's alleged antitrust violation, the issue for which I certified a partial class. See Docket # 450.

If the indirect purchaser cases proceed to trial, see Docket # 611 (discussing uncertainty created by pending appeal of my partial class certification order), the only issue will be whether Astellas engaged in conduct that violates the relevant state antitrust and consumer protection laws. Antitrust injury and damages will not be tried for either the named plaintiffs or the class at large. If the IPP class prevails on that single issue, its members—including the named plaintiffs—may proceed with their claims individually in trials on other elements of their claims, such as impact and damages. See Docket # 450 at 9-10.

The IPPs' status report also raises the possibility of supplemental expert reports. Docket # 636 at 2. This order should obviate the need for those reports, as well as any

other new discovery. For the avoidance of doubt though, all discovery relating to the IPP actions is hereby STAYED until the completion of the direct purchaser trial.

December 2, 2014
DATE

/s/ Rya W. Zobel
RYA W. ZOBEL
UNITED STATES DISTRICT JUDGE

Federal Rule of Civil Procedure 23

(a) **Prerequisites.** One or more members of a class may sue or be sued as representative parties on behalf of all members only if:

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

(2) there are questions of law or fact common to the class;

(3) the claims or defenses of the representative parties are typical of the claims or defenses of the class; and

(4) the representative parties will fairly and adequately protect the interests of the class.

(b) **Types of Class Actions.** A class action may be maintained if Rule 23(a) is satisfied and if:

(1) prosecuting separate actions by or against individual class members would create a risk of:

(A) inconsistent or varying adjudications with respect to individual class members that would establish incompatible standards of conduct for the party opposing the class; or

(B) adjudications with respect to individual class members that, as a practical matter, would be dispositive of the interests of the other members not parties to the individual adjudications or would substantially impair or impede their ability to protect their interests;

(2) the party opposing the class has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole; or

(3) 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.

(c) **Certification Order; Notice to Class Members; Judgment; Issues Classes; Subclasses.**

(1) ***Certification Order.***

(A) *Time to Issue.* At an early practicable time after a person sues or is sued as a class representative, the court must determine by order whether to certify the action as a class action.

(B) *Defining the Class; Appointing Class Counsel.* An order that certifies a class action must define the class and the class claims, issues, or defenses, and must appoint class counsel under Rule 23(g).

(C) *Altering or Amending the Order.* An order that grants or denies class certification may be altered or amended before final judgment.

(2) ***Notice.***

(A) *For (b)(1) or (b)(2) Classes.* For any class certified under Rule 23(b)(1) or (b)(2), the court may direct appropriate notice to the class.

(B) *For (b)(3) Classes.* For any class certified under Rule 23(b)(3), the court must direct to class members the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort. The notice must clearly and concisely state in plain, easily understood language:

(i) the nature of the action;

(ii) the definition of the class certified;

(iii) the class claims, issues, or defenses;

(iv) that a class member may enter an appearance through an attorney if the member so desires;

(v) that the court will exclude from the class any member who requests exclusion;

(vi) the time and manner for requesting exclusion; and

(vii) the binding effect of a class judgment on members under Rule 23(c)(3).

(3) ***Judgment.*** Whether or not favorable to the class, the judgment in a class action must:

(A) for any class certified under Rule 23(b)(1) or (b)(2), include and describe those whom the court finds to be class members; and

(B) for any class certified under Rule 23(b)(3), include and specify or describe those to whom the Rule 23(c)(2) notice was directed, who have not requested exclusion, and whom the court finds to be class members.

(4) ***Particular Issues.*** When appropriate, an action may be brought or maintained as a class action with respect to particular issues.

(5) ***Subclasses.*** When appropriate, a class may be divided into subclasses that are each treated as a class under this rule.

(d) **Conducting the Action.**

(1) ***In General.*** In conducting an action under this rule, the court may issue orders that:

(A) determine the course of proceedings or prescribe measures to prevent undue repetition or complication in presenting evidence or argument;

(B) require--to protect class members and fairly conduct the action--giving appropriate notice to some or all class members of:

(i) any step in the action;

(ii) the proposed extent of the judgment; or

(iii) the members' opportunity to signify whether they consider the representation fair and adequate, to intervene and present claims or defenses, or to otherwise come into the action;

(C) impose conditions on the representative parties or on intervenors;

(D) require that the pleadings be amended to eliminate allegations about representation of absent persons and that the action proceed accordingly; or

(E) deal with similar procedural matters.

(2) ***Combining and Amending Orders.*** An order under Rule 23(d)(1) may be altered or amended from time to time and may be combined with an order under Rule 16.

(e) **Settlement, Voluntary Dismissal, or Compromise.** The claims, issues, or defenses of a certified class may be settled, voluntarily dismissed, or compromised only with the court's approval. The following procedures apply to a proposed settlement, voluntary dismissal, or compromise:

(1) The court must direct notice in a reasonable manner to all class members who would be bound by the proposal.

(2) If the proposal would bind class members, the court may approve it only after a hearing and on finding that it is fair, reasonable, and adequate.

(3) The parties seeking approval must file a statement identifying any agreement made in connection with the proposal.

(4) If the class action was previously certified under Rule 23(b)(3), the court may refuse to approve a settlement unless it affords a new opportunity to request exclusion to individual class members who had an earlier opportunity to request exclusion but did not do so.

(5) Any class member may object to the proposal if it requires court approval under this subdivision (e); the objection may be withdrawn only with the court's approval.

(f) **Appeals.** A court of appeals may permit an appeal from an order granting or denying class-action certification under this rule if a petition for permission to appeal is filed with the circuit clerk within 14 days after the order is entered. An appeal does not stay proceedings in the district court unless the district judge or the court of appeals so orders.

(g) **Class Counsel.**

(1) ***Appointing Class Counsel.*** Unless a statute provides otherwise, a court that certifies a class must appoint class counsel. In appointing class counsel, the court:

(A) must consider:

(i) the work counsel has done in identifying or investigating potential claims in the action;

(ii) counsel's experience in handling class actions, other complex litigation, and the types of claims asserted in the action;

(iii) counsel's knowledge of the applicable law; and

(iv) the resources that counsel will commit to representing the class;

(B) may consider any other matter pertinent to counsel's ability to fairly and adequately represent the interests of the class;

(C) may order potential class counsel to provide information on any subject pertinent to the appointment and to propose terms for attorney's fees and nontaxable costs;

(D) may include in the appointing order provisions about the award of attorney's fees or nontaxable costs under Rule 23(h); and

(E) may make further orders in connection with the appointment.

(2) ***Standard for Appointing Class Counsel.*** When one applicant seeks appointment as class counsel, the court may appoint that applicant only if the applicant is adequate under Rule 23(g)(1) and (4). If more than one adequate applicant seeks appointment, the court must appoint the applicant best able to represent the interests of the class.

(3) ***Interim Counsel.*** The court may designate interim counsel to act on behalf of a putative class before determining whether to certify the action as a class action.

(4) ***Duty of Class Counsel.*** Class counsel must fairly and adequately represent the interests of the class.

(h) **Attorney's Fees and Nontaxable Costs.** In a certified class action, the court may award reasonable attorney's fees and nontaxable costs that are authorized by law or by the parties' agreement. The following procedures apply:

(1) A claim for an award must be made by motion under Rule 54(d)(2), subject to the provisions of this subdivision (h), at a time the court sets. Notice of the motion must be served on all parties and, for motions by class counsel, directed to class members in a reasonable manner.

(2) A class member, or a party from whom payment is sought, may object to the motion.

(3) The court may hold a hearing and must find the facts and state its legal conclusions under Rule 52(a).

(4) The court may refer issues related to the amount of the award to a special master or a magistrate judge, as provided in Rule 54(d)(2)(D).