UNITED STATES COURT of APPEALS
For the First Circuit

No. 15-1290
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 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

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CORPORATE DISCLOSURE STATEMENT

Pursuant to Federal Rules of Appellate Procedure 26.1, Appellees state that none of them has a parent corporation and that no publicly held corporation has a 10% or greater ownership interest.

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STATEMENT OF ISSUES

1. Fed. R. Civ. P. 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 plain language of the Rule 23(c)(4) permits certification of "particular issues," the decisions of eight circuit courts endorse the broad view that Rule 23(c)(4) permits issues classes, and no circuit now rejects the view that Rule 23(c)(4) issue classes can serve an important function in the efficient administration of complex cases. Should this Court nevertheless hold that a district court has no discretion under Rule 23(c)(4) to certify *some* issues in a case unless it also finds that *all* issues in the case can be certified?

2. The district court certified a class of drug end payors regarding the liability issues of (i) whether a brand drug maker violated antitrust law by pursuing a frivolous petition with the FDA to frustrate the timing of the FDA's approval of generic versions of the brand's immunosuppressant drug, and (if so) (ii) the period of that generic delay. The district court left for individual trials the issue of the economic consequences flowing from the delay to each of the health plan and consumer purchasers in the class. Did the district court abuse its discretion by certifying common issues of liability while leaving for individual treatment the impact and damages suffered by each class member?

STANDARD OF REVIEW

A district court's order certifying a class is evaluated for "abuse of discretion." *In re Nexium Antitrust Lit.*, 777 F.3d 9, 17 (1st Cir. 2015) (citing *Smilow v. Sw. Bell Mobile Sys., Inc.*, 323 F.3d 32, 37 (1st Cir. 2003)). "[B]ut this chameleon phrase is misleading. Express standards for certification are contained in Rule 23, so an appeal can pose pure issues of law reviewed *de novo* or occasionally raw findings of fact that are rarely disturbed." *Tardiff v. Knox Cnty.*, 365 F.3d 1, 4 (1st Cir. 2004). Factual determinations are reviewed for clear error. *Nexium*, 777 F.3d at 17 (citing *In re PolyMedica Corp. Sec. Litig.*, 432 F.3d 1, 4 (1st Cir. 2005)).

I. STATEMENT OF THE CASE

A. Facts

This case challenges the successful efforts of brand drug company Astellas Pharma US, Inc. ("Astellas") to frustrate the FDA's ordinary course processing of applications for approval of generic versions of Astellas's widely used immunosuppressant brand drug Prograf (generic: tacrolimus). To delay generic entry into the U.S. market, Astellas served objectively baseless demands on the FDA, insisting the FDA impose conditions for generic approvals that were unscientific, less efficient than accepted methods, or contrary to law and regulation. While the FDA predictably denied Astellas's petitions (as they were unsupported by any clinically-meaningful data, a *sine qua non* to have the FDA change scientific policy), the demands had their intended effect of delaying generic competition for about one year. The yearlong absence of more affordable, generic tacrolimus products had widespread impacts on payors (consumers and health plans) for this much-needed post-transplant maintenance drug.

1. FDA uses science-based testing standards to ensure safe, substitutable generic drugs.

Manufacturers seek generic drug approval by filing an Abbreviated New Drug Application ("ANDA"). An ANDA applicant must demonstrate that the generic product contains the same active ingredient, route of administration, dosage form, and labeling information as the corresponding brand name drug, and

is bioequivalent. 21 USC §355(j)(2)(A)(i-viii). A typical bioequivalence test is performed in a blind crossover study design using healthy adults. Testing in healthy volunteers is more accurate than testing in patients (as the condition of illness presents several confounding factors, such as additional medications or disease state, that make it more difficult to determine if there are differences between formulations of the same active ingredient). (Appellees' Sealed Supplemental Appendix "SA" 00613–14).[1] The FDA has repeatedly shown single-dose healthy volunteer testing is the scientifically accurate and reliable method to prove bioequivalence. (SA-00610–13).

2. Citizen petitions cause delay of generic equivalents.

A citizen petition is a formal demand that the FDA take, or refrain from taking, administrative action.[2] A petition must include the specific action the requester is seeking, a statement of grounds, and a certification that the petition is truthful and accurate.[3]

By the early 2000s, brand companies abused the petition process to delay FDA processing of generic applications, and in 2006 the FDA's Office of Generic

[1] End payors joined and adopted Direct Purchaser Plaintiffs concurrently filed opposition papers. (Dkt. 383 at 1383 at 1) (Unless otherwise noted, all "Dkt." citations are to the docket in the consolidated multidistrict proceeding, MDL No. 2242, Master File No. 1:11-md-02242-RWZ).

[2] *See* 21 CFR § 10.30.

[3] *Id.*

Drugs explained to Congress that the FDA wastes considerable resources addressing sham petitions because it needed to prepare for the frequent litigation that often followed petition denials. (SA-00619). Congress sought to curb this abuse in provisions contained in the Food and Drug Administration Amendments Act of 2007 ("2007 Amendment").

3. Delaying the market entry of generic drugs causes payors to be overcharged.

Entry of AB-rated generics leads to vigorous competition that drives down prices. (SA-00694). The greater the number of generics, the greater the price competition and decline in generic and brand prices. (SA-00695–96). The rate of generic substitution and price discounting has increased over the last several decades. (SA-00696).

A primary driver of this monopoly-to-commodity transformation is state substitution laws that require or permit pharmacies to substitute AB-rated generics for their equivalent brand-name drugs, unless the physician expressly forbids it. (SA-00695; *see, e.g.*, Ariz. Rev. Stat. Ann. § 32-1963.01(A); Fla. Stat. § 465.025(2)). In addition, every link in the payment chain—third-party payor ("TPP"), prescription benefit manager ("PBM"), pharmacy, and consumer—has an incentive to choose less expensive generic drugs. TPPs and PBMs encourage consumers to pick generic drugs over brand-name drugs. (SA-00695). Tiered formularies set lower co-payments for generic drugs, a proven way to influence

drug choice and spending. (SA-00694–95). TPPs and PBMs also use generic substitution programs and coinsurance, which requires the consumer to pay a percent of the retail price instead of a fixed dollar amount. (*Id*.). Pharmacies are also financially motivated to substitute generics; TPPs and PBMs often reimburse pharmacies more generously for generic drugs and reward high rates of generic substitution. (SA-00695).

4. The affordability of drugs that help prevent serious illness or death is a matter of both health and economics.

Prograf (tacrolimus) is an immunosuppressant primarily used by organ transplant recipients to prevent organ rejection. Patient compliance is "one of the most important factors impacting long-term graft survival" and access to affordable immunosuppressants is critical to health outcomes. (SA-00623–24). Because of high costs, transplant patients are often forced to ration medications. (*Id.*).

The FDA approved Astellas's marketing of Prograf in 1994. By the 2000's, Prograf dominated the immunosuppressant market, becoming a standard part of necessary post-transplant treatment and maintenance therapy. (SA-00629–30).

5. Astellas's scheme to delay entry of generic Prograf.

By 2007, Prograf accounted for more than half of Astellas's revenues. (*Id.*). Astellas knew that once generics entered the market, Astellas would lose huge

profits on its most important product. (*Id.*). [redacted]

With Prograf's patent set to expire and the prospect of generic competition nearing, in 2007 Astellas schemed to delay generic entry and minimize the loss of market share. Astellas launched a series of fear-mongering campaigns suggesting the advent of FDA-approved generic products would not yield safe and substitutable generics. (SA-00630–31). No legitimate scientific basis existed for the fears Astellas spread. [redacted]

Along with the denigration of generic substitutes, Astellas planned to frustrate the FDA's processing of generic applications. As Astellas noted [redacted]

6. Astellas's petition was objectively baseless and caused delay.

On September 21, 2007, Astellas filed a citizen petition[4] seeking to impose new FDA requirements on manufacturers of generic tacrolimus including (i) performing bioequivalence tests in transplant patients, (ii) including label provisions that would dissuade pharmacists from automatically switching a patient and, (iii) providing appearance differentiation between different dosage levels (something that FDA already requires). (Appellees' Supplemental Appendix "A" 00001–02).

In support of its bioequivalence testing demand, Astellas provided no clinically meaningful data. The five studies it did cite *actually supported* FDA's current practices, or failed to document lack of bioequivalence between immunosuppressant products. (A-00009). Internally, Astellas acknowledged that,

[redacted]

[4] Astellas rushed to file the petition before the enactment of the 2007 Amendments. (SA-01122-23). [redacted]

The petition's notification and warning language demands also lacked scientific support. (SA-00652–53). The demand was also contrary to the law and regulation; if FDA categorizes a drug as a "therapeutic equivalent," it can be freely substituted for the brand version. (A-00014). The warning Astellas proposed would suggest the contrary.[5]

[redacted]

On September 11, 2008 (a year later), Astellas filed a supplement with the FDA. (SA-00671). The supplement contained a false certification regarding its lack of knowledge of ghost written materials. (*Id.*; SA-01130, 1135).

7. Generic tacrolimus would have entered the market earlier absent Astellas's Petition and Supplement.

On April 8, 2008, Astellas's Prograf patent expired. [redacted]

[redacted]

[5] FDA did "grant" one illusory petition request—that manufacturers of generic tacrolimus differentiate dosage strengths. Existing FDA policy already requires drugs to be differentiated by strength, either through color or shape. (SA-00655–57). Astellas knew this. (*Id.*).

Absent the petition, generic maker Sandoz's generic tacrolimus would have been approved earlier than its August 10, 2009, approval date. (SA-00675–78). On September 3, 2008, the chief of FDA's Regulatory Support Branch stated that Sandoz's "ANDA is eligible for Full Approval . . . . There is a pending CP 07P-0358 which must be answered prior to issuance of an approval action." (SA-00675–76). On August 11, 2009, having stockpiled finished generic tacrolimus since 2008, Sandoz came to market with a generic tacrolimus drug product immediately upon FDA approval, and the same day that the FDA denied the petition. (SA-00678).

After the FDA denied the petition, Astellas sought a temporary restraining order. (SA-00680). The FDA's response identified Astellas's actions as "another instance in which a manufacturer of a pioneer drug product in fear of losing its lucrative monopoly has attempted to block generic competition by challenging the scientific basis for the FDA's approval of a generic." (A-00017). Astellas's motion was denied the same day the FDA filed its response. (SA-00681). Astellas then dropped the case (as it no longer could be used to block competition).

The absence of generic tacrolimus on the U.S. market for the prolonged period of over a year had significant, widespread impact on Prograf end payors. During that time, all TPPs and consumers had no choice but to pay for the branded Prograf—at the monopoly prices set by Astellas. Once Prograf went generic,

generics were increasingly used and prices (both brand and the generic) declined, revealing a fair proxy for what would occurred earlier were it not for Astellas's interference with the FDA processing of generic applications.

To be sure, Prograf experienced a lower generic penetration rate than expected (an intended consequence of Astellas's disparagement of generics), but penetration increased over time towards usual levels of widespread acceptance. (SA-00699–70; SA-00760). The aggregate damages estimated for the applicable state antitrust claims are a modest approximate $25 million. (SA-00693, SA-00705–06).

The two class representatives are examples of the widespread impact of the delay of generic tacrolimus.

The consumer representative Janet Paone is typical of the class. [redacted]

[redacted]

Proof of her injury is straightforward. Ms. Paone produced detailed pharmacy records of her purchases during the proposed class period.[6] According to Ms. Paone's pharmacy records, she paid 20% co-insurance for numerous Prograf prescriptions during the class period, spending a total out-of-pocket of $4,357.28 from December 18, 2008, through November 22, 2010. (Dkt. 273). [redacted]

The TPP representative is Blue Cross Blue Shield of Louisiana ("BCBS LA"), a non-profit health care insurance company based in Baton Rouge, Louisiana. (D. Mass. No. 11-cv-11621, Dkt. 21). BCBSLA, as a TPP, paid over $1.8 million towards the cost of both brand and generic tacrolimus on behalf of its

[6] Astellas subpoenaed additional records from her pharmacy that it believed necessary.

[7] Astellas suggests Ms. Paone's claim is undocumented or too complex to understand. Astellas Br. at 19. [redacted] Astellas's claim that Ms. Paone suffered no injury is insincere; it had an economist review Ms. Paone's records and it deposed Ms. Paone, but did not move for summary judgment against her.

members and beneficiaries during the relevant period. Immediately after generic tacrolimus became available, BCBS LA began to pay for generic tacrolimus claims.

B. Procedural History

Starting in March 2011, a series of cases was filed against Astellas on behalf of two groups of plaintiffs, direct purchasers (wholesalers and other institutions that purchased Prograf directly from Astellas during the class period), and indirect purchasers or "end payors" (consumers and health plans who paid for Prograf for purposes other than resale). The complaints were similar in charging Astellas with violating antitrust laws by making sham demands on the FDA with the intended consequence of delaying approval for, and market entry of, less-expensive generic alternatives to Prograf.

On June 3, 2011, the Judicial Panel on Multidistrict Litigation transferred the all direct purchaser and end payor actions to the U.S. District Court for Massachusetts (Zobel, J.) for pre-trial purposes. (Dkt. 1; 12).

On January 18, 2013, the end payors moved for class certification under Rule 23(b)(3) on all issues in the case. The class sought a trial on behalf of Prograf consumers and health plan payors covering (i) objective baselessness of the petition, (ii) Astellas's intent in filing it, (iii) whether Astellas had market power over Prograf/tacrolimus, (iv) whether, and how long, FDA approval for generic

tacrolimus had been delayed, and (iv) aggregate damages to the class of all end payors engendered by the frivolous filing. (Dkt. 155, at 16, § IV(B)).[8]

On December 17, 2013, the district court ruled. (Dec. 17, 2013, Initial Mem. of Dec, "Init."; Appellant's Addendum "Adden." 30–73).

The court held the class to be ascertainable. (Init. at 8; Adden. 37). The district court found, and Astellas did not dispute, that the criteria for "membership in the proposed class are objective." (Init. at 7; Adden. 36). To the extent records of consumer purchases no longer existed, the district court observed that potential class members may sign affidavits certifying their membership criteria.

As to the requirements of Rule 23(a), the district court found the end payors met all requirements. The proposed class is numerous (thousands of health plans and many thousands of consumers); commonality is satisfied (issues of antitrust violation, at a minimum); typicality is satisfied (plaintiffs have claims for overcharges during the class period); and representation is adequate. (Init. at 8–10; Adden. 37–39).

As to the requirements of Rule 23(b)(3), the district court found most issues in the case to be common. Proof of Astellas's alleged misconduct would be the

[8] Direct Purchaser Plaintiffs moved for class certification on February 7, 2013. Astellas stipulated and the district court certified the class on April 23, 2013. (Dkt. 216). The court found that "the issues of the alleged antitrust violation . . . are capable of proof at trial using evidence that is common to the class." (Dkt. 216, at 4–5).

same classwide. The court confirmed "Plaintiffs assert, and Astellas does not dispute, that common issues predominate with respect to the first element, violation of antitrust law." (Init. at 21; Adden. 50). "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." (*Id*.).

The district court also determined that variations in state laws did not preclude 23(b)(3) certification: "[d]ifferences in the applicable antitrust and consumer protection laws are not so significant as to preclude a finding of predominance." (Init. at 15; Adden. 44). "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." (Init. at 16; Adden. 45). The court made similar findings concerning end payors' unjust enrichment claims, holding that "the same core elements form the basis . . . and largely predominate over the various differences among them." (Init. at 19; Adden. 48).

However, the district court concluded the end payors' request to certify did not predominate on "the *issue* of antitrust impact." (Init. at 35; Adden. 64

(emphasis added)).[9] While the district court (i) was of the view that class membership was objective and definite (Init. 8; Adden. 37), and (ii) the aggregate damages approach of the end payors was based on economic evidence in which "the 'yardstick' approach [employed by plaintiffs' expert] is a commonly used method of economic analysis in antitrust cases," (Init. at 24 n. 25; Adden. 53), the court nevertheless remained troubled that the class was defined in a way to include some purchasers of Prograf who, in the end, may not be able to prove they suffered "net" injury, (Init. at 30; Adden. 59).

The district court recognized the downside of its decision:

> Without class certification, plaintiffs warn that 'Astellas's conduct will go unchallenged and Class members will go uncompensated.' 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."

(Init. at 43–44; Adden. 72–73 (internal citations omitted)).

The end payors did not request a Rule 23(f) appeal. Instead, on January 3, 2014, the end payors opted for three-quarters of a loaf, moving for reconsideration of the full denial by seeking certification under Rule 23(c)(4) of a class "as to the issue of Astellas's alleged antitrust conduct." (Dkt. 371 at 2).

[9] All emphases added unless otherwise noted.

On June 10, 2014, the district court certified an issue class "to resolve the question of antitrust violation in one efficient and economical stroke." (June 10, 2014, Order Granting Reconsideration "Recon." at 4; Adden. 4).[10] The issue class jury would answer the questions (i) whether the petition was objectively baseless; (ii) Astellas's motivation in filing the petition; (iii) whether Astellas had monopoly power, and (iv) whether, and by how much, the filing delayed FDA's approval of would-be generic maker Sandoz's ANDA. (Recon. at 9; Adden. 9).

The court recognized the efficiency, both for Astellas and end payors, of proceeding as a class to adjudicate the plurality of issues:

> [I]f 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.

(Recon. at 4 n.4; Adden. 4). "Class certification, in contrast, would provide Astellas with 'the benefit of finality and repose,' that issue preclusion cannot, since a victory in this action would apply consistently to all class members' claims

[10] In this same order, the court denied Astellas's motion for summary judgment on all claims against it. The court also granted Astellas's summary judgment motion against end payor named plaintiff, Judith Carrasquillo. (Recon. at 13–28; Adden. 13–28).

grounded in antitrust conduct." (Recon. at 5; Adden. 5 (internal citations omitted)).

The district court correctly rejected Astellas's argument that splitting questions of antitrust impact would result in overlapping jury deliberations:

> [T]his "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.

(Recon. at 9 n.6; Adden. 9).

Unlike the prior certification denial, the district court in this 23(c)(4) order was untroubled by the theoretical possibility that some class members may not be able to prove injury; by not certifying the impact question, Astellas could try class member injuries individually. The court held end payors "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,' and Astellas does not challenge the standing of at least one named. . . plaintiff, BCBSLA." (Recon. at 7–8; Adden. 7–8 (internal citations omitted)).

The district court emphasized the purpose of class certification:

> [M]any 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.

(Recon. at 4; Adden. 4).

The court found the antitrust violation issues were common to the class:

> [L]itigation 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.

(Recon. at 9; Adden. 9).

Having found all elements of Rule 23 satisfied, including that "partial certification would materially advance the litigation," the district court held that end payors "need not demonstrate predominance for the entire action in order to certify an issue-specific class in this case." (Recon. at 6; Adden. 6).

Astellas sought, and was granted, a Rule 23(f) appeal.

II. SUMMARY OF ARGUMENT

The rules grant discretion to certify particular issues. Federal Rules of Civil Procedure 23(c)(4) provides that, "[w]hen appropriate, an action may be brought or maintained as a class action with respect to particular issues." Rule 23 affords discretion to the district courts to grant certification of one or more issues in a case even if not all issues in the case are capable of certification. The plain language of Rule 23(c)(4) permits certification of "particular issues." The decisions of seven circuit courts endorse the broad view that Rule 23(c)(4) permits issue classes, and no circuit now rejects the view that Rule 23(c)(4) issue classes can serve an important function in the efficient administration of complex cases. No decision of this or any other court counsels a contrary conclusion, and no sound policy or purpose is served by an all-issues-must-be-certifiable requirement. Certification of some but not all issues in a case can expedite fair and non-duplicative proceedings, and is the kind of well-worn discretion granted by the rules in many contexts.

The district court did not abuse its discretion. The district court certified the issues of (1) whether Astellas violated antitrust law by pursuing a frivolous petition with the FDA to delay generic competition, and, if so, (2) the amount of generic delay. The district court left to individual trials the economic consequences of that delay. In doing so, the district court assured that several issues involving

unquestionably common proof would be addressed in a common trial. The district court gave Astellas exactly what it had been demanding—a process for challenging what Astellas had characterized as individual intra-class variation in injury.

Even if there were an all-issues-must-be-certifiable requirement, in this case common issues predominate even when all issues are considered, including antitrust injury. The district court's earlier ruling on full class certification preceded this Court's decision in *Nexium*, 777 F.3d 9. Applying the analysis in *Nexium* (a decision that directly addressed how a district court can properly certify a class of indirect drug purchasers for all purposes, including antitrust injury), the accepted facts show the proposed class here was capable of certification on all issues in the case, including impact and damages.

III. ARGUMENT

A. Rule 23 affords district courts discretion to certify issue classes.

The Federal Rules empower district court judges to administer the "just, speedy and inexpensive" resolution of civil actions. Fed. R. Civ. P. 1. Rule 23 vests the court with significant discretion to fulfill that purpose. A district court judge is "often in the best position to assess the propriety" of whether a certified class satisfies the rules and will lead to effective disposition of the case. *Sumitomo Copper Litig. v. Credit Lyonnais Rouse, Ltd.*, 262 F.3d 134, 139 (2d Cir. 2001).

1. The text, rule-making, and traditional use of Rule 23 supports issue certification.

The plain language of Rule 23(c)(4), the history behind the rule-making and amendments, and the traditional use and purpose of class certification all support a reading of 23(c)(4) that grants a district court issue-only certification discretion.

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." (Adden. 2). The language of the rule empowers a court to certify "particular issues."

The history of the Rule shows the drafters intended 23(c)(4) to provide an alternative path to certification when certification of the entire action under 23(b)(3) would not be possible. *See In re Pharm. Indus. Average Wholesale Price Litig.* ("*AWP*"), 588 F.3d 24, 39 (1st Cir. 2009) ("To resolve any ambiguities [in Rule 23], we may also consider the rule's drafting history."). As initially drafted in 1966, Rule 23(c)(4)'s original language instructed courts to apply Rule 23's other provisions only *after* narrowing the scope of the inquiry to the sub-class or certified issues. That original language of 23(c)(4) read:

> 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.

The text expressly informs courts using Rule 23(c)(4) to first divide the case into issue-classes or subclasses, and then apply the provisions of Rule 23(a) and (b) to those issues or sub-classes.

The Advisory Committee's intent is also revealed by what the Committee chose *not* to do with the Rule. By rejecting potentially limiting language during the drafting, the Advisory Committee indicated a broad vision of the types of issue classes that might be appropriate under Rule 23(c)(4). The 1966 Committee rejected the original proposed phrasing of Rule 23(c)(4), which read: "[W]hen appropriate . . . an action may be brought or maintained as a class action only with respect to particular issues *such as the issue of liability*." Hannah Stott-Bumstead, *Severance Packages: Judicial Use of Federal Rule of Civil Procedure 23(c)(4)(A)*, 91 Geo. L.J. 219, 223 (2002); A-00532–33. Instead, the Committee endorsed a more flexible vision for Rule 23(c)(4) by omitting the "such as the issue of liability" language. *Id.* at 224; A-00533. The Committee gave one example of using an issue class to adjudicate liability in the Advisory Notes:

> *Note to 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.

Fed. R. Civ. P. 23(c)(4) (1966 Advisory Committee's Note). The Committee observed that an issue class can be appropriate even when each class member must later prove his or her own damages—*i.e.*, when common issues do not predominate as to every element of class members' claims.[11]

The Committee noted that the liability-versus-damages demarcation is but one *example* of issue certification, not the only avenue; one "example" implies that others exist. By removing the liability-damages example from the text of the rule itself, the Advisory Committee sent a clear message: nothing about the rule requires that liability be the only "issue" that can be certified under 23(c)(4).

The late Supreme Judicial Court Justice Benjamin Kaplan, who in the mid-1960's was the Advisory Committee's reporter, identified an antitrust case[12] as the prime example of how Rule 23(a)(4) could be usefully applied, explaining that "[t]he clause says that an action maintained as a class action need not be such as to each and every issue." Stott-Bumstead, *supra*; A-00532–33.[13] This is consistent

[11] *See* Jenna C. Smith, *"Carving at the Joints": Using Issue Classes to Reframe Consumer Class Actions*, 88 Wash. L. Rev. 1187, 1214 (2013) ("Thus, the Advisory Committee specifically intended for Rule 23(c)(4) to be used to carve out the common issues for class treatment even if the claim as a whole would not satisfy Rule 23(b)(3)'s predominance requirement."); A-00406.

[12] *Union Carbide & Carbon Corp. v. Nisley*, 300 F.2d 561 (10th Cir. 1961).

[13] In a stretch of creative revisionism, Astellas argues that Justice Kaplan and the Committee intended that Rule 23(c)(4) *only* apply to bifurcations of liability and damages, (Astellas Br. at 30-32), but that theory simply cannot be squared

with the understanding of courts and scholars following the 1966 revision of Rule 23.[14]

In 1995, the Advisory Committee considered modifying the language of Rule 23(a)(4) to read: "[a]n action may be certified as a class action with respect to particular claims, defenses, or issues." The Committee announced the proposed modification's purpose was to:

> *[E]mphasize* the potential utility of [the Rule 23(a)(4) Issue Class] procedure. For example, in mass tort situations, it might be appropriate to certify *some* issues relating to the defendants' culpability and . . . general

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with the Committee's deletion of the potentially limiting "such as the issue of liability" language from the text of the Rule itself. Further, the Advisory Committee would not have stated that the liability-versus-damages dichotomy is an "example" of intended Rule 23(c)(4) issue separation if it is the *only* intended separation.

[14] *See, e.g.*, 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, 274 (2002) (quoting Arthur R. Miller, *Of Frankenstein Monsters and Shining Knights: Myth, Reality, and the "Class Action Problem"*, 92 Harv. L. Rev. 664, 680 (1979) ("[M]ore judges are aware that there are possibilities other than an across-the-board grant or denial of certification. Instead of wielding a meat axe, courts increasingly are operating with a scalpel.")); A-00252; Jeffrey W. Stempel, *Class Actions and Limited Vision: Opportunities for Improvement Through a More Functional Approach to Class Treatment of Disputes*, 83 Wash. U.L.Q. 1127, 1224 (2005) ("Rule 23(c)(4)(A) permits certification of issues smaller than the question of liability."); A-00460. *See also Hydrite Chem. Co. v. Calumet Lubricants Co.*, 47 F.3d 887, 891 (7th Cir. 1995) ("[T]here is no rule that if a trial is bifurcated, it must be bifurcated between liability and damages. The judge can bifurcate (or for that matter trifurcate, or slice even more finely) a case at whatever point will minimize the overlap in evidence between the segmented phases or otherwise promote economy and accuracy in adjudication."); section A.3, *infra*.

> causation for class action treatment, while leaving issues relating to specific causation, damages, and contributory negligence for potential resolution through individual lawsuits brought by members of the class.

Romberg, *supra*. at 278-79; A-00254 (quoting Proposed Amendments to Federal Rules of Civil Procedure, Rule 23, Class Actions (Feb. 1995 draft)). The use of "emphasize" shows that the Advisory Committee read Rule 23(a)(4) to *already* allow for class treatment of "particular claims, defenses, or issues" and the proposed "emphasis" is intended for clarity and, perhaps, to encourage courts to consider certifying issue classes. The Committee would only call it an "emphasis" if it recognized that Rule 23(c)(4) could be used to certify a variety of "claims, defenses, or issues."

The Committee ultimately rejected the proposed language change. Given the straightforward plain language of the Rule—allowing for certification of particular issues, without limitation—and fact that the Committee considered broader, more specific Rule language to merely be an "emphasis," it is likely that the Committee ultimately decided the change would be superfluous. Astellas argues that the Committee's omission of the additional "emphasis" means that the Committee intended Rule 23(b)(3) predominance—as to *all* issues and claims in a case—"remain" a requirement for the certification of an issues class. (Astellas Br.

at 36-37). That interpretation is inconsistent with the Advisory Committee's use of the word "emphasize" and the plain language of the pre-2007 Rule.

In fact, the intent of the Rule has never changed, despite later stylistic changes to its language. In 2007, the Advisory Committee renumbered the sub-parts of the original Rule 23(a)(4) by dividing the original language of 23(c)(4) down the middle. It left the first half (issue classes) as 23(c)(4) and made the second half (subclasses) into 23(c)(5). While intended as a purely "stylistic" change, it was perhaps also a bit clumsy, as the splitting of the original rule into two resulted in the clause "When appropriate" staying with the issue-classes piece, and the clause "and the provisions of this rule shall then be construed and applied accordingly" going with the subclasses language to 23(c)(5). However, each of those clauses was originally meant to apply to both issue classes and subclasses, and the stylistic—if inartful—renumbering did not change that intent from the Advisory Committee's perspective.[15] Commentators agree: "[The 2007] amendment to Rule 23 renders its language plain and clear—particular issues and subclasses that meet the requirements of Rules 23(a) and (b) may be certified for class treatment, even if the action as a whole could not." Patricia Bronte,

[15] Fed. R. Civ. P. 23 2007 Advisory Committeee's Note; A-00599 ("[T]he language of Rule 23 has been amended as part of the general restyling of the Civil Rules to make them more easily understood and to make style and terminology consistent throughout the rules.")

"Carving at the Joint": The Precise Function of Rule 23(c)(4), 62 DePaul L. Rev. 745, 751 (2013); A-00044.

2. Certification of discrete issues serves the purposes of Rule 23 and efficient judicial administration.

Rule 23's overall purpose "is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights." *Smilow*, 323 F.3d at 41 (1st Cir. 2003). "The genius of Rule 23 is that the trial judge is invested with both obligations and a wide spectrum of means to meet those obligations." *Yaffe v. Powers*, 454 F.2d 1362, 1367 (1st Cir. 1972), *overruled on other grounds by Gardner v. Westinghouse Broadcasting Co.*, 437 U.S. 478 (1978). Rule 23(c)(4) is one of the means a trial judge can employ to actively manage his or her docket.[16]

As the American Law Institute has explained:

> [The] aggregate treatment of a common issue will materially advance the resolution of multiple civil claims more frequently when the issue concerns "upstream" matters focused on the generally applicable conduct of those opposing the claimants in the litigation, as distinct

[16] Joseph A. Seiner, *The Issue Class*, 56 B.C.L. Rev. 121, 123 (2015) ("Rule 23(c)(4) allows the judge to separate specific common questions in the case and resolve other issues individually. The judge can thereby tailor the certified issues to the facts of the specific case, thus leading to more efficient litigation. In this way, issue class certification also results in more streamlined proceedings. Courts can resolve claims that touch on a common issue a single time, while allowing the remaining issues in the case to be litigated separately."); A-00362.

> from "downstream" matters focused on those claimants themselves."

Robert H. Klonoff, *The Future of Class Actions: The Decline of Class Actions*, 90 Wash. U.L. Rev. 729, 809 (2013) (quoting Principles of the Law of Aggregate Litigation § 2.02 cmt. a, at 84 (Am. Law Inst. 2010)); A-00185.

The Federal Judiciary also touts the advantages:

> Selectively used, this provision may enable a court to achieve the economies of class action treatment for a portion of a case, the rest of which may either not qualify under Rule 23(a) or may be unmanageable as a class action . . . . Certification of an issues class is appropriate only if it permits fair presentation of the claims and defenses and materially advances the disposition of the litigation as a whole.

Federal Judicial Center, Manual for Complex Litigation (Fourth) § 21.24 (2004) (citations omitted). "[I]ssue classes can allow for more efficient disposition on those cases in which some issues, but not all, are susceptible to class treatment." William B. Rubenstein, NEWBERG ON CLASS ACTIONS § 4:90 (5th ed. 2012); A-00319.

As the Seventh Circuit put it, Rule 23(c)(4) issue classes prevent defendants from "escap[ing] liability for tortious harms of enormous aggregate magnitude [by being so] widely distributed as not to be remediable in individual suits." *Butler v. Sears Roebuck and Co.*, 727 F.3d 796, 801 (7th Cir 2013).

3. The Circuit Courts uniformly construe Rule 23(c)(4) to permit certification of discrete issues.

Legal scholars and courts have sometimes described the conflict over the proper use of 23(c)(4) as either "broad" or "narrow." *See, e.g.*, NEWBERG §4:91; A-00324. But this is pseudosymmetry. The Circuit Courts of Appeals that have grappled with this alleged dichotomy—the First, Second, Third, Fourth, Sixth, Seventh, Ninth, and Tenth—either explicitly accepted a broad reading of 23(c)(4), upheld certification of issue classes where common questions do not predominate for all issues involved in the cause of action, or encouraged the use of issue classes. Even those circuits that earlier expressed reservations—particularly the Fifth—have come around. This Court is in accord. The professed circuit split has all but vanished.

a. The Second, Seventh, and Ninth Circuits explicitly endorse Rule 23(c)(4) issue classes when common questions do not predominate for the cause of action as a whole.

Three circuits—the Second, Seventh, and Ninth—explicitly hold that Rule 23(c)(4) issues classes can be appropriate. *In re Nassau Cnty. Strip Search Cases*, 461 F.3d 219 (2d Cir. 2006); *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227 (9th Cir. 1996); *Mejdrech v. Met-Coil Sys. Corp.*, 319 F.3d 910 (7th Cir. 2003).

Second Circuit. In *Nassau*, the Second Circuit held that "a court may employ subsection (c)(4) to certify a class as to liability regardless of whether the claim as a whole satisfies Rule 23(b)(3)'s predominance requirement." 461 F.3d at

227. The Second Circuit found support for this position in the plain language of Rule 23 and concluded that "a court must first identify the issues potentially appropriate for certification 'and . . . then' apply the other provisions of the rule, *i.e.*, subsection (b)(3) and its predominance analysis." *Id.* at 226. Even before *Nassau*, the Second Circuit rejected a narrow analysis of Rule 23(c)(4) and encouraged district courts to embrace issue certification where it would "both reduce the range of issues in dispute and promote judicial efficiency." *See Robinson v. Metro-North Commuter R.R. Co.*, 267 F.3d 147, 168 (2d Cir. 2001) (vacating a dismissal and instructing the district court to reconsider certifying a class); *Cordes & Co. Financial Services v. A.G. Edwards & Sons, Inc.*, 502 F.3d 91, 95 & n.15, 109 (2d Cir. 2007) (applying the reasoning from *Nassau* to an antitrust claim, and stating the plaintiffs "may seek certification of a class to litigate the first element of their antitrust claim—the existence of a Sherman Act [antitrust] violation—pursuant to Rule 23(c)(4)(A)"); *see also In re Visa Check/MasterMoney Antitrust Litig.*, 280 F.3d 124, 141 (2d Cir. 2001) (citations omitted).

Ninth Circuit. The Ninth Circuit similarly found it proper to certify an issue class "[e]ven if the common questions do not predominate over the individual questions so that class certification of the entire action is warranted." *Valentino*, 97 F.3d at 1234. Since *Valentino*, the Ninth Circuit looks particularly favorably on

issue classes, "[s]o long as the plaintiffs were harmed by the same conduct." *Jiminez v. Allstate Ins. Co.*, 765 F.3d 1161, 1168 (9th Cir. 2014) (upholding certification of an issue class). District courts within the Ninth Circuit have time and again certified issue classes, noting that whether the "non-certified issues or classes would violate Rule 23 is irrelevant."[17]

Seventh Circuit. The Seventh Circuit, and Judge Posner individually, have assuaged their earlier concerns about issue classes and now embrace them as an efficient judicial tool.[18] In *Mejdrech*, class plaintiffs sued factory owners, alleging

[17] *In re Paxil Litigation*, 212 F.R.D. 539, 543 (C.D. Cal. 2003); *see also Kamakahi v. American Soc'y for Reprod. Med.*, 305 F.R.D. 164 (N.D. Cal. 2015) (certifying an "liability only class" under Rule 23(c)(4) to determine whether a policy violates the Sherman Act); *Campion v. Credit Bureau Services, Inc.*, 206 F.R.D. 663 (E.D. Wa. 2001) (certifying multiple issue classes and reserving for individual trials questions regarding injury and damages); *Amador v. Baca*, No. 10-cv-1649, 2014 WL 10044904 at *9 (C.D. Cal. Dec. 18, 2014) (granting order for subclass and liability issue class and noting that "[t]he Ninth Circuit—and respected jurists across the country—have energetically endorsed the [issue class]"); *Ellis v. Costco Wholesale Corp.*, 285 F.R.D. 492, 544 (N.D. Cal. 2012) (certifying class but finding that "[e]ven if the common questions do not predominate over the individual questions so that issue class certification of the entire action is warranted, Rule 23 authorizes the district court in appropriate cases to isolate the common issues under Rule 23(c)(4)(A) and proceed with class treatment of these particular issues" (internal citations omitted)).

[18] In *Matter of Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293 (7th Cir. 1995) (Posner, J.), the Seventh Circuit raised policy concerns about putting an entire industry on trial and noted that bifurcating the case could lead to subsequent juries reexamining the first jury's findings, potentially running afoul of the Seventh Amendment. But in *McReynolds v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, the Seventh Circuit reversed a district court decision denying class certification under Rule 23(b)(2), distinguishing *Rhone-Poulenc* and explaining that

that toxic substances leaked from a storage tank, contaminating the soil and water of plaintiff's homes. 319 F.3d at 911. The Seventh Circuit affirmed the certification of an issue class as to "whether or not and to what extent [Met-Coil] caused contamination of the area in question," even though the court left other issues to be determined by "individual hearings." *Id.* Acknowledging that class members would have varying levels of damage—and in some cases no injury or damage—the Seventh Circuit nevertheless explained:

> Often, and as it seems to us here, these competing considerations can be reconciled in a "mass tort" case by *carving at the joints* of the parties' dispute. If there are genuinely common issues, issues identical across all the

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> [When] there are genuinely common issues, issues identical across all the claimants, issues moreover the accuracy of the resolution of which is unlikely to be enhanced by repeated proceedings, then it makes good sense, especially when the class is large, to resolve those issues in one fell swoop while leaving the remaining, claimant-specific issues to individual follow-on proceedings.

672 F.3d 482, 491 (7th Cir. 2012) (Posner, J.) (quoting *Mejdrech*, 319 F.3d at 911). It held that, although "[a]s far as pecuniary relief is concerned, there may be no common issues," "[w]e have trouble seeing the downside of the limited class action treatment [for issues relevant to injunctive relief] that we think would be appropriate in this case." *Id.* at 492. And in *Butler v. Sears, Roebuck & Co.*, the court applied *McReynolds* to a class in which the plaintiffs sought damages, observing that "a class action limited to determining liability on a class-wide basis, with separate hearings to determine—if liability is established—the damages of individual class members, or homogeneous groups of class members, is permitted by Rule 23(c)(4) and will often be the sensible way to proceed." 727 F.3d 796, 800 (7th Cir. 2013) (Posner, J.) *cert denied* 134 S.Ct. 1277 (2014).

> claimants, issues moreover the accuracy of the resolution of which is unlikely to be enhanced by repeated proceedings, then it makes good sense, especially when the class is large, to resolve those issues in one fell swoop while leaving the remaining, claimant-specific issues to individual follow-on proceedings.

Id. (internal citations omitted).

In a series of cases following *Mejdrech*, the Seventh Circuit has confirmed that the presence of uninjured class members and the need for individual damages determinations do not preclude courts from certifying issue classes,[19] even when an apparent majority of issues require individualized inquiries.

b. The Fourth, Sixth, and Tenth Circuits have endorsed issue classes in line with the broad approach to Rule 23(c)(4).

While not as explicit as the Second, Seventh, and Tenth Circuits, three other circuit courts have, in one way or another, implicitly endorsed Rule 23(c)(4)'s broad applicability.

Fourth Circuit. The Fourth Circuit instructs district courts to "take full advantage of the provision in [Rule 23(c)(4)] permitting class treatment of separate

[19] *See McReynolds*, 672 F.3d 482 (7th Cir. 2012); *Pella Corp. v. Saltzman*, 606 F.3d 391 (7th Cir. 2010) (certifying a class of window purchasers who had already replaced their defective windows in spite of needing to have individual determinations relating to causation and damages); *In re Factor VII or IX Concentrate Blood Products Litig.*, No. 93-cv-7452, 2005 WL 497782, at *2 (N.D. Ill. Mar 1, 2005) ("Defendants rely on the *Castano* footnote, and we concede that the footnote has gained a following. But we are not persuaded by it. *Castano* is not an interpretation of Rule 23(c)(4)(A) but a simple rejection of its language." (internal citations omitted)).

issues in order to promote the use of the class device and to reduce the range of disputed issues in complex litigation." *Central Wesleyan College v. W.R. Grace & Co.*, 6 F.3d 177, 185 (4th Cir. 1993) (internal citations and quotations omitted). The court illustrated the advantages to class treatment: limiting the wasteful practice, and associated time and costs, repeatedly trying identical issues again and again. *Id.*

In *Gunnells v. Healthplan Services, Inc.*, the Fourth Circuit affirmed a class certification order for causes of action against one of the named defendants and rejected the argument that (1) Rule 23's subparts must be addressed in chronological order (because it would make Rule 23(c)(4) "superfluous" and is against the plain reading of Rule 23) and (2) that the trial judge must find an "entire law suit 'as [a] whole' . . . satisfies the predominance and superiority requirements imposed by 23(b)(3)." 348 F.3d 417, 438-9, 441 (4th Cir. 2003). At least one district court in the Fourth Circuit has held "[u]nder [*Gunnells*], which appears to follow the practice of the Second, Seventh, and Ninth Circuits . . . it may use Rule 23(c)(4) to certify a class as to an issue regardless of whether the claim as a whole satisfies the predominance test in Rule 23(b)(3)." *Parker v.*

Asbestos Processing, LLC, No. 11-cv-01800, 2015 WL 127930, at *11 (D.S.C. Jan. 8, 2015).[20]

Tenth Circuit. Similarly, the Tenth Circuit has considered the issue and signaled their preference for the "broad" approach to Rule 23(c)(4). In *Wallace B. Roderick Revocable Living Trust v. XTO Energy, Inc.*, the court vacated and remanded a certification order, finding that individual damage issues may destroy predominance. But it advised the district court that "there are ways to preserve the class action model . . . . [A] class may be certified for liability purposes only, leaving individual damages calculations to subsequent proceedings." 725 F.3d 1213, 1220 (10th Cir. 2013). As described by a district court within the Tenth Circuit:

> Although the Tenth Circuit has not addressed the question, this Court has generally followed the approach of the Second, Seventh and Ninth Circuits, and has used Rule 23(c)(4) to certify parts of claims where doing so

[20] *See also In re Am. Honda Motor Co. Inc. Dealer Relations Litig.*, 979 F. Supp. 365 (D. Md. 1997) (certifying a liability issues class with individual damages trials to follow); *Pruitt v. Allied Chemical Corp.*, 85 F.R.D. 100 (E.D. Va. 1980) (" A finding that common questions of law or fact do not predominate over the questions affecting only individuals within the class does not, however, end the Court's inquiry . . . Rule 23(c)(4) requires the Court to consider employment of these restructuring measures where an apparently unmanageable class action could be converted to a manageable one."); *Chisolm v. TranSouth Fin. Corp.*, 184 F.R.D. 556, 566 (E.D. Va. 1999) ("[F]urther, *A.H. Robins* and Rule 23(c)(4) make plain that district courts may separate and certify certain issues for class treatment.").

> would materially advance the disposition of the litigation of the whole. This appears to be the majority approach.[21]

Sixth Circuit. In *Sterling v. Velsicol Chemical Corp.*, the Sixth Circuit affirmed a class certification order of landowners alleging personal injury and property damage. 855 F.2d 1188 (6th Cir. 1988). In affirming the order, the Sixth Circuit noted that "[n]o matter how individualized the issue of damages may be, these issues may be reserved for individual treatment with the question of liability tried as a class action." *Id* at 1197. The Sixth Circuit recognized that allowing the action to move forward as a class action "avoided duplication of judicial effort and prevented separate actions from reaching inconsistent results." *Id.*

Recently, the Sixth Circuit held that a district court properly certified a liability class under Rules 23(a) and (b)(3) finding that questions common to the class predominated over individual damage determinations. *In re Whirlpool Corp. Front-Loading Washer Products Liability Litigation*, 722 F.3d 838 (6th Cir. 2013), *cert. denied sub nom. Whirlpool Corp. v. Glazer*, 134 S. Ct. 1277 (2014). The court explained that, because the class trial would address only issues of liability,

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[21] *Morris v. Davita Healthcare Partner Inc.*, No. 13-cv-573, 2015 WL 3814361, at *10 (D. Colo. June 18, 2015) (internal citations omitted); *see also In re Motor Fuel Temp. Sales Practices Litig*., 292 F.R.D. 652, 664–65 (D. Kan. 2013); *Fulghum v. Embarq Corp.*, No. 07-cv-2602, 2011 WL 13615, at *2 (D. Kan. Jan. 4, 2011); *Law v. Nat'l Collegiate Athletic Ass'n*, 167 F.R.D. 178, 184-85 (D. Kan. 1996).

under Rule 23(c)(4), the existence of individualized damages issues was largely irrelevant to the propriety of certification. *Id.* at 860–61.

c. The Third Circuit supports thoughtful certification of issue classes.

The Third Circuit claims not to side with "either camp," but in practice supports certification of broad issue classes. *Gates v. Rohm & Haas Co.*, 655 F.3d 255, 267 (3d Cir. 2011); *see also In re School Asbestos Litig.*, 789 F.2d 996, 1011 (3d Cir. 1986) (approving issue certification in asbestos litigation because it would conserve judicial resources).

More recently, the Third Circuit has provided guidance for courts considering certifying issue classes. In *Chiang v. Veneman*, the Third Circuit held that, because the issue of whether the defendant engaged in the alleged discriminatory course of conduct was easily distinguishable from the issue of whether class members were individually harmed by that conduct, it would affirm certification on the former and leave it to the district court to determine whether class certification might be appropriate on the latter. 385 F.3d 256 (3d Cir. 2004). The Third Circuit identified factors that district courts should consider when deciding whether to certify issue classes, including "the efficiencies to be gained by granting partial certification in light of realistic procedural alternatives" and "the potential preclusive effect or lack thereof that resolution of the proposed issue class will have." *Gates*, 655 F.3d at 273

The Third Circuit also directs district courts to ensure that the issues to be tried are "clearly enumerated" and to "explain how the remaining issues will be resolved."[22]

In a recent decision, the Third Circuit vacated and remanded a district court's certification order of six state-specific subclasses, instructing it to first "define the class membership, claims, and defenses" and then analyze whether common issues predominate. *Neale v. Volvo Cars of N. America, LLC*, No. 14-cv-1540, 2015 WL 4466919 at *17 (3d Cir. July 22, 2015). The court stated that the "precise analysis of the predominance question is 'best conducted with the benefit of a clear initial definition of the claims, *issues*, and defenses to be treated on a class basis," and concluded "the District Court erred, therefore, by failing to analyze predominance in the context of Plaintiffs' actual claims." *Id.* at *13. On remand, the district court "should evaluate the relevant claims (grouping them where logical and appropriate)." *Id.* at *15.

[22] *Romero v. Allstate Ins. Co.*, 52 F. Supp. 3d 715, 724-25, 738 (E.D. Pa. 2014) (denying class certification for an issue class because certification would not "materially advance the litigation" and too many individual issues remained); *Wallace v. Powell*, No. 09-cv-286, 2013 WL 2042369 (M.D. Pa. May 14, 2013) (certifying a liability issue class under Rule 23(b)(3) and Rule 23(c)(4)); *see also Rice v. City of Philadelphia*, 66 F.R.D. 17, 21 (holding in civil rights action that action could be maintained as a class action with respect to issues relating to grant of injunctive or declaratory relief).

d. The Fifth Circuit has moved beyond the infamous *Castano* footnote and now embraces issue certification.

Astellas's narrow interpretation of the Fifth Circuit's Rule 23(c)(4) *Castano* footnote is properly understood as a piece of 90's nostalgia.

Astellas correctly observes that the Fifth Circuit stated via footnote that "a cause of action, as a whole, must satisfy the predominance requirement of (b)(3)." (Astellas Br. at 21, 30 (citing *Castano v. American Tobacco Company*, 84 F.3d 734, 745 n.21 (5th Cir. 1996)). This interpretation cannot be squared with the text of the Rule, the history of the rule making, or the purposes of Rule 23. Circuit courts have explicitly rejected *Castano*'s reasoning,[23] as have numerous other jurists and legal scholars.[24] But more importantly, the Fifth Circuit's own thinking about issue classes has evolved.

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[23] *See, e.g.*, *Gunnells*, 348 F.3d at 439 (finding the Fifth Circuit's approach illogical because it would render Rule 23(c)(4) superfluous if a manageability determination has already been made in considering predominance under Rule 23(b)(3)(D)); *Nassau*, 461 F.3d at 226-27 (stating, "the Fifth Circuit's view renders subsection (c)(4) virtually null, which contravenes the well-settled principle that courts should avoid statutory interpretations that render provisions superfluous" (internal quotation and citation omitted)).

[24] *See* Romberg, at 334 (advocating for the use of issue classes "because it brings the core of a legal controversy into closer alignment with the essence of the underlying dispute"), *supra* note 14; A-00274; Smith, *supra* note 11 (endorsing the broad view and advocating its adoption by the courts); A-00406; Seiner, *supra* note 14 (arguing for the broad use of 23(c)(4) to advance employment discrimination cases); A-00361; Michael C. Harper, *Class-Based Adjudication of Title VII Claims in the Age of the Roberts Court*, 95 B.U.L. Rev. 1099, 1120-21 (2015) ("[The] unambiguous and generally accepted meaning of (c)(4) does not obviate the

Recent decisions in the Fifth Circuit show that the court has moved away from the strict, narrow view in the *Castano* footnote and now embraces issue certification. In *Mullen v. Treasure Chest Casino, LLC*, the Fifth Circuit limited *Castano*'s application by explaining that the true concern was to avoid organizing litigation in a way where a second jury would reconsider a decision of the first jury; *Mullen* noted that the district court's proposed trial split in *Castano* created no such possibility. 186 F.3d 620, 628-29 (5th Cir. 1999), abrogated on other grounds by *M.D. v. Perry*, 675 F.3d 832 (5th Cir. 2012). The *Mullen* court upheld the district court's certification of an issues class and noted the "the issues to be

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predominance and superiority requirements of (b)(3)."); A-00093–94; Michael J. Wylie, *In the Ongoing Debate Between the Expansive and Limited Interpretations of Fed. R. Civ. P. 23(c)(4)(A), Advantage Expansivists!*, 76 U. Cin. L. Rev. 349 (2007) (concluding that the expansive interpretation of 23(c)(4) articulated in *Nassau* "is the better interpretation"); A-00553; Klonoff, *supra*, at 812 ("[T]he strict *Castano* approach is difficult to defend. If Rule 23(c)(4) is merely a 'housekeeping' device, then plaintiffs would never utilize it. Why certify just an issue if the entire case satisfies predominance?"); A-00186; *see also* Jenna G. Farleigh, *Splitting the Baby: Standardizing Issue Class Certification*, 64 Vand. L. Rev. 1585, 1591 (2011) ("[M]ost courts interpret Rule 23(c)(4) to allow certification of single issues, even when they deem it inappropriate to certify the entire constellation of issues in a given litigation."); A-00053; Zachary B. Savage, *Scaling Up: Implementing Issue Preclusion in Mass Tort Litigation Through Bellwether Trials*, 88 N.Y.U.L. Rev. 439, 448-49 (2013) ("[M]ost courts hold that Rule 23(c)(4) certification may be appropriate even when a court declines to certify the "entire constellation of issues in a given litigation."); A-00337. Even the narrow view's most vocal supporter concedes "the weight of academic support for an expansive partial class action." Laura J. Hines, *Challenging the Issue Class Action End-Run*, 52 Emory L.J. 709, 713 (2003); A-00112–13.

tried commonly . . . were significant in relation to the individual issues[.]" *Id.* at 626.

In *Rodriguez v. Countrywide Home Loans*, the Fifth Circuit acknowledged that "Rule 23(c)(4) explicitly recognizes the flexibility that courts need in class certification by allowing certification with respect to particular issues." 695 F.3d 360, 369 n.13 (5th Cir. 2012) (internal quotations and citations omitted). It affirmed a class certification order limited to the issues of declaratory and injunctive relief, instructing that "a court should certify a class on a claim-by-claim basis, treating each claim individually and certifying the class with respect to only those claims for which certification is appropriate." *Id.*

And most recently, in affirming the class certification orders in *In re Deepwater Horizon*, the Circuit noted that "the district court anticipated that 'issues relating to damage' could and would be 'severed and tried separated' from other issues relating to liability, in accordance with this court's previous case law and Rule 23(c)(4)." 739 F.3d 790, 806 (5th Cir. 2014) (citing *Butler*, 727 F.3d 796).

e. The First Circuit encourages district courts to certify issue classes when individualized damages determinations may otherwise prevent certification.

As the district court noted here, "[t]he First Circuit . . . has endorsed the certification of liability-only classes despite individualized damage issues . . .

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." (Recon. at 6; Adden. 6). Indeed, the First Circuit's pronouncements on the issue of issues classes demonstrate it falls squarely in line with all other circuits to have considered the issue.

First, in *Smilow* the First Circuit reversed a decertification order and remanded, instructing the district court to find predominance under Rule 23(b)(3). 323 F.3d at 39-40. The court instructed that,

> [i]f later evidence disproves Buchakian's proposition [that damages can be aggregated through a computer program], the district court can at that stage modify or decertify the class or use a variety of management devices. Indeed, even if individualized determinations are necessary to calculate damages, Rule (23)(c)(4)(A) would still allow the court to maintain the class action with respect to other issues.

*Id.*at 41 (internal citations and quotations omitted). Thus, the *Smilow* court, like the Fourth, Sixth, and Tenth Circuits, implicitly acknowledged that, even if common issues did *not* predominate, a Rule 23(c)(4) issues class could nevertheless be certified.[25]

[25] Astellas misreads *Smilow* as simply treating "Rule 23(c)(4) as a bifurcation procedure." (Astellas Br. at 49.) Even though the court in *Smilow* found that damage issues predominated, they instructed the district court that if in the future it found that damages issues did not predominate, the case could *still* go forward as a class action using Rule 23(c)(4) to create a subclass *or* bifurcate the trial.

In *Tardiff v. Knox County*, the First Circuit upheld certification of a class despite questions of predominance due to damages issues. 365 F.3d 1 (1st Cir. 2004). The court reasoned, "the need for individualized damage decisions does not ordinarily defeat predominance where there are still disputed common issues as to liability." 365 F.3d at 6 (citing *Smilow*, 323 F.3d at 40). Thus, the *Tardiff* court, like the Seventh Circuit in *Pella* and the Second Circuit in the factually similar *Nassau* has at least implicitly endorsed class certification as to all common issues, even where aspects of a cause of action may require individualized inquiry.

4. Rule 23(c)(4) grants district courts discretion to formulate sensible case management, a goal achieved by other rules as well.

In summary, the plain meaning of Rule 23(c)(4), along with its history, purposes, and construction by the circuit courts, all direct one to the conclusion that district courts have discretion to certify particular issues even if not all the issues in the case satisfy the requirements of the Rule 23. A contrary reading would make Rule 23(c)(4) superfluous; if all issues needed to be capable of certification, why would a court ever stop short and only certify some if all met the rule?

The language and tenor of the civil rules generally equip district courts with discretionary tools to sensibly manage complex cases. *See, e.g.*, Fed. R. Civ. P. 1 (advising that the rules should be "construed and administrated to serve the just, speedy and inexpensive determination" of matters and recognizing in the 1933

advisory committee notes, "the affirmative duty of the court to exercise the authority conferred"); Fed. R. Civ. P. 16 (directing judges to "establish[] early and continuing control" to schedule conferences, form discovery parameters, set trial dates, and encourage resolution); Fed. R. Civ. P. 26 & 30 (granting judges wide powers to limit or expand the amount and form of pre-trial discovery); Fed. R. Civ. P. 42 & 46 (granting the power to oversee the performance of trial, permitting a judge to order one or more separate trial, and commanding persons to appear or testify in court). Rule 23(c)(4) is no exception.

B. The district court did not abuse its discretion in certifying particular issues.

1. The district court thoughtfully carved the common issues from those Astellas argued needed individual treatment.

In this case, the district court "carved at the joint," *i.e.*, it separated the end payors' common substantive antitrust issues from the economic impact of generic delay on individual class members. The district court correctly found "all [end payor] class members . . . present the same allegations and proof of misconduct by Astellas." (Recon. at 4; Adden. 4). The issues certified had no overlap with issues left for individual adjudication; the "[violation] issues are so distinct and separable that they could be cleanly divided amongst separate trials without injustice." (*Id.* (internal quotations omitted)). At bottom, "the only issue [addressed during the initial end payor class trial] will be whether Astellas engaged in conduct that

violates the relevant state antitrust and consumer protection laws." (Dec. 2, 2014 Stay Order at 1; Adden. 74).

The district court will simply ask the first jury to decide whether Astellas violated the antitrust laws, and when, in the absence of Astellas's anticompetitive conduct, a generic tacrolimus would have entered the market. (*Id.*). "[T]he 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." (*Id.*). This manner of carving the case ensures that there will be no violation of defendants' Seventh Amendment and due process rights. The district court followed well-established precedent within this Circuit in considering the policy goal of Rule 23(b)(3), which 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, and the purpose of Rule 23(c)(4).

It was a sound use of discretion for the district to observe that "individual indirect purchaser plaintiffs are unlikely to have the resources or incentive to litigate an entire antitrust case against Astellas on their own." (Recon. 4; Adden. 4). This is especially true for transplant patients. It is highly unlikely that an individual patient who is already spending large amounts of money on their transplant drug regimens would have the financial resources to personally litigate a complex antitrust case. (SA00623–24).

The district court acted within its discretion.

2. Astellas identifies no harm flowing from the court's certification of particular issues.

In the face of the district court's sharp carving, the text of Rule 23(c)(4), the history of the Rule, the comments to the Rule, the counsel of the Reporter, and the overwhelming case law supporting the broad use of issue classes, what does Astellas offer in support of its anachronistic interpretation?

First, Astellas offers a citation to *Castano*. But we—and a number of courts, including the Fifth Circuit itself—have dispensed with that already.

Second, Astellas offers citations to three articles written by Laura J. Hines. Ms. Hines represented the American Tobacco Company during its class certification advocacy in *Castano*. She advocates for the continued viability of the defunct *Castano* footnote. Her views are not binding on this Court and—particularly in light of their conflict with other, more authoritative sources—her arguments are unpersuasive.

Third, Astellas offers citations to *Comcast*, *Halliburton*, and *Amchem*. None involve issue certification.[26] None deterred courts from continuing to certify issue

[26] *Cf. Behrend v. Comcast Corp.*, 655 F.3d 182, 209 n.5 (3d Cir. 2011) *rev'd*, 133 S. Ct. 1426 (2013) ("Of course, where only some elements of a claim require individual treatment, while others can be litigated collectively, it may be appropriate to certify a class for those elements that can be treated collectively,

classes in their wake. The Sixth Circuit in *Whirlpool*[27] and the Seventh Circuit in *Butler*[28] quickly dispensed with the argument that *Comcast* doomed issue classes to obsolescence, as did the *Comcast* dissent: "at the outset, a class may be certified for liability purposes only, leaving individual damages calculations to subsequent proceedings." *Comcast*, 133 S.Ct. at 1437, n.* (citing Rule 23(c)(4) and NEWBERG § 4:54).

Contrary to Astellas's and the U.S. Chamber of Commerce's casual dismissal of the judiciary's obligations in certifying any class,[29] certification is always approached with rigor and never automatic or a foregone conclusion. To

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while certifying subclasses or requiring individual treatment for those that cannot.").

[27] 722 F.3d at 860 ("This case is different from *Comcast Corp.* Here the district court certified only a liability class and reserved all issues concerning damages for individual determination; in *Comcast Corp.* the court certified a class to determine both liability and damages. Where determinations on liability and damages have been bifurcated, *see* Fed.R.Civ.P. 23(c)(4), the decision in *Comcast*—to reject certification of a liability and damages class because plaintiffs failed to establish that damages could be measured on a classwide basis—has limited application.")

[28] *Butler*, 727 F.3d at 800 *cert. denied*, 134 S. Ct. 1277, 188 L. Ed. 2d 298 (2014) ("[A] class action limited to determining liability on a class-wide basis, with separate hearings to determine—if liability is established—the damages of individual class members, or homogeneous groups of class members, is permitted by Rule 23(c)(4) and will often be the sensible way to proceed." (internal citation omitted)).

[29] Astellas Br. 12, 33-36; Chamber Br. at 5 ("Under the approach taken by the court below, certification of an issue class action is almost trivially easy."); *id.* at 16 ("[U]nder the rule adopted by the district court, certification of a class action on that single element of a single claim was a foregone conclusion."); *id.* at 18 ("[C]ertification would seemingly become automatic.").

certify under Rule 23(c)(4), the requirements of Rules 23(a) and 23(b)(3) must be met for the particular issues.

a. Astellas identifies no harm flowing from the district court's issue class certification.

Nowhere in its briefing does Astellas try to identify any harm or undue prejudice flowing from certification of an issue class. Perhaps this is because Astellas is getting what it argued was necessary: individual inquiries into the fact of class members' injuries. As the district court recognized, proceeding with an issue class is a win-win for Astellas. (Recon at 9 n.6; Adden. 9). If a liability trial returns a verdict for Astellas, this litigation is over. If a liability trial returns a verdict for the issue class, and if some class members pursue damages claims based on that verdict, then Astellas will be able to defend itself by challenging the extent and amount of each suing class member's injury in later proceedings, but it will not face aggregate damages in a single trial. The alternative to proceeding with an issue class is potentially thousands of individual liability and damages trials; that cannot be better for Astellas than a one-time resolution of a truly common issue. There is no harm to Astellas.[30]

[30] The U.S. Chamber of Commerce makes sweeping policy arguments about the evil befalling society from abusive class actions. But "[m]ere pressure to settle is not a sufficient reason for a court to avoid certifying an otherwise meritorious class action suit." *Klay v. Humana, Inc.*, 382 F.3d 1241, 1275 (11th Cir. 2004); *see also Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 295 (1st Cir. 2000) ("[N]o

C. Even if Rule 23(c)(4) requires *all* issues be capable of certification to determine predominance before certification of an issues class, that standard is met in this case.

Because Rule 23(c)(4) does not require *all* issues be capable of certification in order to certify *some*, and because the district court did not abuse its discretion in so holding, this Court need not go further to decide this appeal.

But for two reasons we press on. First, Astellas predicates its appeal on the assumption that the end payors could not satisfy Rule 23(b)(3) requirements on the issues of antitrust impact and damages—an assumption that is incorrect as a matter of law and fact. Second, the procedural context of this appeal presents a conundrum: Astellas relies upon an aspect of the district court's first class certification decision (*i.e.*, the finding that antitrust impact for the class could not be proven at trial by common proof), yet that first certification order is technically not before this Court on an appeal. To rule in favor of Astellas here, this Court should not blindly accept Astellas's characterization of the first, all-issues class certification decision, or the evidence underlying it—particularly since the end payors have yet to exercise their appellate rights with respect to that decision.

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matter how strong the economic pressure to settle, a Rule 23(f) application, in order to succeed, also must demonstrate some significant weakness in the class certification decision."). The Chamber's position that permitting issue-only classes is "bad for business" is belied by the case at hand. This antitrust case challenges *anti*competive behavior, not *pro*competive acts.

We first discuss how the law treats Rule 23(b)(3) class certification when the disputed evidence shows that there may be some class members who may not be able to prove injury at trial. We then address how the facts here (largely as found by the district court) warrant a finding of predominance even considering all issues.

1. Rule 23 permits certification of all issues even where some number of class members may be proven uninjured at trial, so long as a definite class—with a fair aggregate damages methodology and a plan to ultimately cull uninjured members—is proposed.

The First Circuit and Supreme Court recognize that the possibility of uninjured class members does not preclude certification. The holding in *Nexium* is founded in earlier controlling precedent.

The First Circuit's precedents leading up to *Nexium* make clear that where "most,"[31] or even just "a very substantial number,"[32] of proposed class members

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

[32] *Gintis v. Bouchard Transp. Co.*, 596 F.3d 64, 67 (1st Cir. 2010) (Souter, J.) (vacating and remanding district court's denial of class certification and stating that "on remand, the focus will be on the plaintiffs' claim that common evidence will suffice to prove injury, causation and compensatory damages for *at least a very*

can prove injury at trial, the possibility that some number of class members may have escaped the defendants' conduct unscathed does not justify depriving the class as a whole of the benefits of the class action mechanism.

In *AWP*, a class action TPPs alleging a fraudulent pricing scheme for prescription pharmaceuticals, defendant AstraZeneca argued that the need for each class member to prove that it was injured by AstraZeneca's pricing practices should have precluded class certification and the classwide damages award should be set aside. 582 F.3d at 190, 197. AstraZeneca contended that the district court's failure to require individualized proof of injury and damages for class member violated its "'fundamental right' to defend against each class member's claim of injury and damages." *Id.*[34] The First Circuit panel disagreed and upheld the

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substantial portion of the claims that can be brought by the putative class members").

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

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

classwide damages award, observing that the possibility that some class members may have evaded injury by the defendants' fraudulent scheme did not prevent the application of the class action mechanism, or render a class action unfair. *Id.* at 197.

In *In re Neurontin Mktg. & Sales Practices Litigation*, the First Circuit considered the grant of summary judgment and denial of class certification of a proposed class of TPPs who paid for Neurontin, and suggested that class members did not need to individually establish injury by looking at their purchases prescription by prescription. 712 F.3d 60, 69 (1st Cir.) (Lynch, C.J.) *cert. denied sub nom. Pfizer Inc. v. Kaiser Found. Health Plan, Inc.*, 134 S. Ct. 786, (2013). The First Circuit vacated and remanded a denial of class certification after rejecting the argument that class plaintiffs had to adduce individual evidence to prove they were injured. The Court, focusing on the availability of classwide evidence of Neurontin's ineffectiveness to treat class members' ailments, found the district court should not have denied class certification based on the defendants'

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

argument that plaintiffs' claims required "the individual, subjective ineffectiveness of each off-label prescription in order to establish injury." *Id.*[35]

The First Circuit thus spoke clearly well before *Nexium*: the presence in a class of some members that ultimately may be found uninjured does not defeat class certification.

In *Nexium*, the district court concluded that plaintiffs met the predominance requirement, "despite finding that the certified class included *some number* of uninjured class members," and it certified a Rule 23(b)(3) class of end payors who bought Nexium. 777 F.3d at 18. In an opinion issued after the district court certified an issue class here, the First Circuit explicitly confirmed that the presence of uninjured members in the class does not preclude class certification, citing "the obvious utility of allowing the inclusion of some uninjured class members . . . and the lack of harm in doing so." *Id.* at 23.

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

[35] *Neurontin* is one of a trio of decisions, all of which favorably cited the analysis of Professor Rosenthal, the same expert put forward by the class in this case. *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 21, 41-45 (1st Cir. 2013) (Lynch, C.J.); *In re Neurontin Mktg. & Sales Pracs. Litig.*, 712 F.3d 51, 56, 58-59 (1st Cir. 2013) (Lynch, C.J.); *Neurontin*, 712 F.3d at 68 (1st Cir. 2013).

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

Id. at 21-22 (footnote omitted).

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

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

Second, it acknowledged that the defendants asked for the impossible—the exclusion of all uninjured class members at the class certification phase. It recognized the "almost inevitable tension" involved in the effort to craft a class

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

The First Circuit concluded that the possibility of some uninjured members in the class did not violate the defendants' Seventh Amendment rights or eliminate plaintiffs' standing. The Court held that certifying a class that could potentially include uninjured members would not violate the Seventh Amendment as long as there is "a mechanism to establish injury." *Id*. at 21. Since the named plaintiffs

had paid supracompetitive prices on "at least one . . . transactions" during the proposed damages period, they had standing. *Id.*at 32.

The district court here did not have the benefit of *Nexium* at the time of its first certification ruling, but *Nexium* provided important guidance as to some of the precedents the district court relied on in its initial order denying class certification.

For example, in initially denying full class certification, the district court relied upon *New Motor Vehicles* for the dispositive proposition that: "[i]n antitrust actions, common issues do not predominate if . . . the fact of antitrust cannot be established through common proof." (Init. at 22; Adden. 51). But *Nexium* explains: "[t]o the extent that *New Motor Vehicles* is read to impose such a requirement,[36] it has been overruled by the Supreme Court's *Halliburton* decision." *Nexium*, 777 F.3d at 24.

Without the guidance of *Nexium*, the district court also lacked the First Circuit's precedential application of *Amgen Inc. v. Conn. Retirement Plans & Trust Funds*, 133 S. Ct. 1184 (2013)—which established that a single element of a cause of action could not be dispositive of the predominance analysis. *Nexium*, 777 F.3d at 21 ("Rule 23(b)(3) 'does not require a plaintiff seeking class certification to

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

prove that each element of her claim is susceptible to classwide proof.'") (quoting *Amgen*, 133 S. Ct. at 1196)). The district court recognized that the vast majority of questions in this case were common (*i.e.*, predominance), but it relied on outdated dicta from *New Motor Vehicles* for the proposition that antitrust impact—alone—was dispositive of predominance. (Init. at 22; Adden. 51).

Astellas contorts *Nexium* to argue that precedent mandates denying certification of an issue class here. Quite the opposite. Even though *Nexium* did not involve a Rule 23(c)(4) class at all, its principles support the certification of an issues class. If (as in *Nexium*) the potential presence of allegedly uninjured class members does not prohibit class certification as to *all* issues, how could the potential presence of some uninjured members prohibit class certification of *some* common, *non-injury* issues? The logic behind *Nexium*'s conclusion—that including uninjured class members creates "obvious utility" and a "lack of harm"—applies with even stronger force here, where injury is not even a class issue. *Id.* at 25.

2. The evidence of widespread injury to Prograf end payors supports certification of all issues.

Under *Nexium* and its founding precedents, the accepted facts show the proposed class here should have been certified on all issues in the case, including impact and damages.

a. The district court determined that the class satisfied the *Nexium* factors.

Though the district court did not have the benefit of the First Circuit's *Nexium* decision at the time of its class certification decisions, the district court *de facto* addressed the three factual requirements the *Nexium* Court emphasized in affirming certification of an antitrust drug end payor class.

The class is definite. The district court considered and rejected Astellas's challenge to ascertainability based on Astellas's claim that individualized investigation would be required to identify potential members. (Init. at 7; Adden. 36). The class is defined using objective criteria.

Aggregate recovery is limited to the amount of the injury. Professor Meredith Rosenthal, Professor of Health Economics and Policy at the Harvard School of Public Health, developed "yardsticks" based on actual prices and quantities after the entry of generic tacrolimus in August 2009. (Init. at 24; Adden. 53). She then applied those yardsticks to an earlier time frame, April 2008, when generic entry would have occurred but for the alleged antitrust violation.[37] In this manner, Professor Rosenthal constructed a "but-for world" and estimated what prices of the drug would have been for class members during the class period "but-

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

for" Astellas's anticompetitive conduct. (Init. at 24–25; Adden. 53–54). She concluded that delayed generic entry through the fourth quarter of 2009 injured class members. (Init. at 26; Adden. 55).

Professor Rosenthal's calculations provide the total damages to the class; Astellas will never have to pay more than that amount, no matter how allocation ultimately breaks down between individual class members. It is entirely appropriate to enter an aggregate damages judgment for the class, followed by a post-judgment claims process, or, in this case, follow up proceedings to prove impact *and* damages. "The use of aggregate damages calculations is well established in federal court and implied by the very existence of the class action mechanism itself." *AWP*, 582 F.3d at 197. The court did not find that the aggregate overcharge damage methodology was in error. The court only found that the end payors' methodology did not show *injury* for *every* member of the class. (Init. at 40; Adden. 69).

Only injured parties will recover. Ultimately, should a jury find Astellas liable and specify an aggregate damages award, then the end payors, pursuant to the proposed trial plan submitted with full class certification briefing (Dkt. No. 155-3), would cull uninjured class members (if any) based upon the submission of payment records.

The process would be, as a practical matter, the same as that endorsed in for the pharmaceutical end payor claims in *AWP*, *Neurontin*, and *Nexium*. TPP class members would obtain purchase records (patient identifiers, prescription units, pharmacy or provider states, fill dates, and amounts paid by the patient versus the TPP) for each prescription. Such information is commonly maintained in one database by either the TPP or its PBM. For consumers, pharmacy and payor records are available to consumer class members, and additional cost-sharing details—such as copay level and effective deductible—are tracked in consumers' typical explanation of benefits package provided by insurers. For uninsured cash-payer claimants, damage allocation can use receipts and pharmacy records (pharmacies are required by law to maintain prescription records), in addition to the sworn affidavit. *See Mullins v. Direct Digital, LLC*, No. 15-1776, 2015 WL 4546159, *12-13 (7th Cir. July 28, 2015) (affirming class certification and noting that "treason, under Article III of the U.S. Constitution, is the only type of case in which testimony of a "witness is legally insufficient to prove a fact.").

Although the damage allocation process involves a review of class member data, "the need for some individualized determinations at the liability and damages stage does not defeat class certification." *See Nexium*, 777 F.3d at 21. Uninjured class members will not recover here.

No Seventh Amendment concern. In certifying the issues class (and the separation it contemplates between proof of violation as opposed to the economic consequences to individual class members), the district court weighed and rejected Astellas's argument that uninjured members of the class would violate the Seventh Amendment. (Recon. at 7; Adden. 7).

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

b. The proof of widespread impact to consumers.

Professor Rosenthal explained that her methodology for showing impact "could be uniformly applied to all of the Class members." (SA-00697). She opined that "the vast majority of Class members were injured."[38] She also expressly addressed Astellas's misplaced criticism that peculiar generic penetration rates were dispositive of class impact in this case:

[38] SA-00767; *see also* SA-00961 ("[I]t's my opinion, as an economic, based on what I see in the data, . . . that all or virtually all third-party payors would be impacted in the sense of overcharges."). When Astellas says that Professor Rosenthal "did not attempt to show injury to *each* class member from the alleged delay in Generic entry," (Astellas Br. at 7 (emphasis in original)), it ignores the material cited above, as well as the applicable legal standard. A plaintiff does not have to actually prove impact on every class member at the class certification stage. *Nexium*, 777 F.3d at 24 & n.20. A plaintiff's methodology does not have to rule out the possibility of any uninjured class members. *Id.* at 25.

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

(SA-00760). And when dispensing with Astellas's expert's pontifications regarding the problems with mathematical averages, she answered, "[t]here is no question that there exists variability within pharmaceutical markets and variation in prices paid by payers. Averages are useful indicators when there is variation." (SA-00763). Averages are only problematic in an applied economic analysis when they mask substantial variation; here, that is not the case. As another court explained when analyzing Professor Rosenthal's methodology:

> *The use of averages in this case does not mask meaningful variations in overcharges*, and it provides a reliable method to provide a reasonable estimate of the damages based on relevant purchase data.[39]

c. Astellas's "unrebutted evidence" is, in fact, hotly contested.

Astellas argues the "unrebutted evidence" shows that the class included some number of members who were allegedly not injured. In fact, Astellas's "unrebutted evidence" was hotly disputed, and at times was discredited by the district court. (*See, e.g.*, SA-00762–67).

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

First, Astellas's expert made a fundamental mistake. Instead of comparing actual prices to *but-for prices* at a given time, he compared actual prices before generic entry to *actual prices* after generic entry. (SA-00764-65). In other words, he did not even *address* the but-for inquiry, which is the basis of any proper impact analysis. *See Coastal Fuels, Inc. v. Caribbean Petroleum Corp.*, 175 F.3d 18, 25 n.3 (1st Cir. 1999) ("'But for' is what plaintiffs must prove.").[40]

Second, Astellas's longitudinal pharmacy data was an incomplete sample, so averages drawn from it were unreliable. (SA-00764). The district court credited Professor Rosenthal's criticisms ("Dr. Rosenthal faults Dr. Cremieux for making actual-to-actual comparisons instead of conducting a but-for analysis, thereby arriving at incorrect conclusions. Her criticism on this point is well taken") and referred to the "apparent defects in Dr. Cremieux's methodology and sample analyses." (Init. at 39–40; Adden. 68–69.)

Third, Astellas incorrectly pointed to "offsets" to overcharge transactions in order to eliminate antitrust injury for some class members. This is wrong as a matter of law. Relying on well-settled antitrust law from the Supreme Court, the First Circuit rejected this exact same argument in *Nexium*:

[40] When Professor Rosenthal corrected this error in Dr. Cremieux's conceptual framework, she used his own data set to show that 481 of the 491 TPPs in his sample were, in fact, injured. (SA-00766).

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

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

Before *Nexium*, the parties "fiercely debated" whether so-called offsets should be considered when determining whether a class member was injured. In other words, Astellas argued that antitrust impact was a "net" calculus of all transaction experiences. The district court was "inclined to agree" with Astellas that lower prices on some transactions offset and negated overcharges on other transactions. (Init. at 39–40 n.34; Adden. 68–69). Astellas's expert claimed that Astellas's unlawful conduct did not injure subsets of the class based on longitudinal pharmacy data, but to do so he only considered a purchaser to be impacted if his calculations showed a "net" overcharge.[41] In other words, he avoided counting overcharges as impact by using other events to offset them. Without *Nexium*, the district court credited this approach. *Nexium*, and the seminal Supreme Court cases that it relied upon, hold that a single overcharge constitutes impact, even if a class member is only injured for part of the class period. *Nexium*, 777 F.3d at 27.

[41] Dkt. 272 at 13-14.

The same approach applies to so-called brand loyalists. In *Nexium*, the First Circuit stated the "defendants incorrectly assume that a class member who is injured for only a part of the class period did not suffer injury." *In re Nexium*, 777 F.3d at 27. The First Circuit acknowledged that some brand loyalists were likely not injured by the defendants' conduct, but rejected the argument that this was more than a de minimis amount, in part because "a consumer was injured if he or she would have purchased generic *even once* during class period," and that given that Nexium is a "maintenance drug," there is a high likelihood that a consumer would purchase a generic at least once. *Id.* at 30. The *Nexium* Court then credited Professor Rosenthal's observation that defendants had not presented evidence but were relying on the mere hope that there is a "likelihood of there being a substantial number of consumers who *only* purchases during the entire Class Period were brand purchases." and concluded that "[t]he defendants' speculation cannot defeat the plaintiffs' showing" that "the vast majority of class members were probably injured." *Id.* at 30-31 (emphasis in original).

Here, similar to the defendant in *Nexium*, Astellas also incorrectly assumes that the hypothetical existence of a transplant patient who may have once bought the brand after generic entry defeats fact of injury. Prograf, like Nexium, is a maintenance drug so repeated transactions for a given consumer increase the likelihood of generic purchasing for at least *one* transaction. Even more

importantly, here, like *Nexium*, "brand loyalists" paying the retail price of Prograf *do* suffer injury for a substantial time during the class period, as evidenced Professor Rosenthal's uncontroverted finding that brand prices in fact went down after generic entry. (SA-000693).

While unnecessary for the district court's Rule 24(c)(4) ruling, the end payor class was, in fact, susceptible of certification of all issues, and in a manner consistent with *AWP*, *Neurontin*, and *Nexium*.

IV. CONCLUSION

The Court should uphold the order granting certification of a class of end payors.

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Respectfully Submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 32(a)(7)(C) of the Federal Rules of Appellate Procedure, the foregoing brief is in 14-point Times New Roman proportional font and contains 16,134 words and thus is in compliance with the type-volume limitations set forth in Rule 32(a)(7)(B) of the Federal Rules of Appellate Procedure.

CERTIFICATE OF SERVICE

I hereby certify that I caused a copy of the Brief of Appellees (Filed Under Seal) to be filed via electronic mail and via UPS.

Dated: August 7, 2015

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