**Case No. 15-1290**

**UNITED STATES COURT OF APPEALS FOR THE FIRST CIRCUIT**

In re: PROGRAF ANTITRUST LITIGATION

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

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

v.

ASTELLAS PHARMA US, INC.,
*Defendant - Appellant*.

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

# REPLY BRIEF OF APPELLANT ASTELLAS PHARMA US, INC. (REDACTED VERSION)

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## INTRODUCTION

Reversal is required under *In re Nexium Antitrust Litigation*, 777 F.3d 9 (1st Cir. 2015), because the district court's findings establish that this Court's requirements for certifying a class with uninjured members were not satisfied. The district court found that Plaintiffs failed to show "widespread harm to class members" and that identifying the injured class members would require "myriad individual adjudications [that] would render the case unmanageable." Adden. at 71-72, 73.[1] Plaintiffs offer no reason to set aside these findings.

Plaintiffs have not correctly described Astellas's position on issue classes. Astellas has never advocated "an all-issues-must-be-certifiable requirement." *Cf.* P-Br. at 20. Astellas agrees that issue classes can be certified in cases with individualized questions, as long as the common questions predominate and the other requirements of Rule 23(a) and (b)(3) are satisfied.

The question presented in this appeal concerns cases with common issues that are important but nonetheless "overwhelmed" by individual issues. Neither the Supreme Court nor this Court has ever permitted class certification in such cases. In fact, Plaintiffs do not cite *any* appellate cases since *Amchem Products, Inc. v. Windsor*, 521 U.S. 591 (1997), that permitted class certification, under Rule

[1] "Adden." refers to the Addendum to Astellas's opening brief ("D-Br."). "P-Br." refers to Plaintiffs' brief. "PJ-Br." refers to the *Amicus* Brief of Public Justice, P.C.

23(c)(4) or otherwise, when common questions were overwhelmed by individual questions. Plaintiffs' march through the Circuits merely establishes two uncontroversial propositions – that common questions often predominate despite the need for individualized determinations of damages, and that Rule 23(c)(4) issue classes can be appropriate. Neither proposition justifies the decision below.

## STATEMENT OF FACTS

Plaintiffs devote 10 pages of their oversized, non-compliant brief to arguing the merits of their antitrust claim.[2] But the strength or weakness of the claim has no bearing on whether common issues predominate. *Amgen Inc. v. Conn. Ret. Plans & Trust Funds*, 133 S. Ct. 1184, 1195 (2013). And nowhere in this lengthy discussion do Plaintiffs acknowledge the conflicts in the evidence or what the law requires them to prove. Astellas does not intend to argue the merits here, but simply identifies a few of the issues.

As a matter of law, Astellas's citizen petition to the FDA is protected by the First Amendment and cannot be the basis for antitrust liability unless Plaintiffs prove that it was "objectively baseless in the sense that no reasonable [petitioner] could realistically expect success on the merits." *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60 (1993). First Amendment protection "'requires no more than a reasonable belief that there is a chance that a

[2] Plaintiffs' brief has 16,134 words. *See* Certificate of Compliance, P-Br. at 69.

claim may be held valid upon adjudication.'" *Davric Maine Corp. v. Rancourt*, 216 F.3d 143, 148 (1st Cir. 2000) (quoting *Prof'l Real Estate Investors*, 508 U.S. at 62-63).

In the district court, it was Astellas, not Plaintiffs, that moved for summary judgment on the merits. Although the court denied the motion, it noted evidence that the citizen petition "mirrored longstanding recommendations and concerns of medical experts in the transplantation field," including the National Kidney Foundation, the American Society of Transplantation, and the American Society of Transplant Surgeons. Adden. at 18-19. As further evidence of the objective basis for Astellas's citizen petition, the court pointed out that "regulatory authorities around the world have taken action to address concerns that generic NTI immunosuppressant drugs [the category that includes tacrolimus] may not be fully substitutable in patients." *Id*. at 22. Indeed, the district court noted that the FDA itself decided "to sponsor studies comparing generic and branded tacrolimus," *id.* at 23 – studies of the very issues raised in Astellas's citizen petition.

In short, as the district court later found, Plaintiffs "faced numerous and substantial risks in establishing liability." Dkt. 678 ¶ 7(d) (order approving settlement with direct purchaser class).

## ARGUMENT

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

Plaintiffs fail to come to grips with *In re Nexium Antitrust Litigation*, 777 F.3d 9 (1st Cir. 2015). In an attempt to evade the issues, they state:

> 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.

P-Br. at 54. But Plaintiffs ignore three *other* conclusions in *Nexium*. In upholding class certification, this Court emphasized that (A) "the class includes a de minimis number of uninjured parties," (B) the uninjured class members would be identified "prior to judgment," and (C) the procedure for "distinguishing the injured from the uninjured class members" was "administratively feasible." 777 F.3d at 14, 19; *see also id.* at 33 (Kayatta, J., dissenting) ("The majority correctly recognizes that certification of a class that includes uninjured consumers hinges on there being a method of identifying and removing those consumers prior to entry of judgment, and that any such method must be . . . administratively feasible.").

None of these three requirements was satisfied here.

### A. A Substantial Number of Class Members Did Not Suffer Any Injury and Actually Benefited from the Challenged Conduct.

With regard to the *number* of uninjured class members, Plaintiffs simply ignore the district court's findings. They assert "widespread impact to consumers," P-Br. at 62, but the district court found otherwise: "Plaintiffs have not shown that their methodology demonstrates widespread harm to class members," Adden. at 71-72. They say their expert "opined that 'the vast majority of Class members were injured,'" P-Br. at 62, but the district court rejected that opinion: "her methodology fails to show that all (or nearly all) class members paid supra-competitive prices for Prograf or generic tacrolimus, or that this determination can be made with common proof," Adden. at 64.

One crucial difference between this case and *Nexium* concerns the number of "brand-loyalists" – *i.e.*, "consumers who would continue to purchase *only* brand-name . . . after generic entry." 777 F.3d at 29 (this Court's emphasis). As this Court recognized, brand-loyalists were "likely not injured" by a delay in the entry of generics. *Id*. at 30. In *Nexium*, this Court relied on evidence that only about 2% of users would have been brand-loyalists throughout the class period if generics had been available. *Id.* at 30-31. In striking contrast, more than 50% of Prograf users were brand-loyalists after a year; they had *never* purchased the Generic. Adden. at 59. Plaintiff Janet Paone admits that she did not purchase generic tacrolimus during the class period; [redacted]

[redacted].[3] The other consumer Plaintiff, Judith Carrasquillo, likewise did not purchase the Generic during the class period. After extensive discovery, summary judgment was entered against her because she was unable to establish any injury. Adden. at 25-28.

In fact, a great many brand-loyalists in the class *benefited* from any delay in Generic entry because their copayments rose when the Generic became available. As the district court pointed out, "Dr. Cremieux estimates that 45 percent of brand loyalists in the data set paid more for tacrolimus . . . as a result of generic entry." *Id.* at 60.[4]

Another key difference between this case and *Nexium* is that Astellas showed that some TPPs (including Plaintiff NM Fund) also benefited from any delay because they "paid more for tacrolimus after generic entry than they did before." *Id.* at 59; *see also id.* at 2 n.2 (noting Plaintiffs' "concession that [NM

[3] Dkt. 247-5 (Cremieux Rpt.) ¶ 67 n.72 (under seal). [redacted] P-Br. at 10, 12. Her first purchase of the Generic was outside the class period, which ended on December 31, 2010. *See* Adden. at 34.

[4] Plaintiffs say their expert criticized Dr. Cremieux's analysis for relying on an "incomplete sample." P-Br. at 64. But the district court found that the "data covers 35 to 40 percent of all tacrolimus prescriptions filled through retail and mail order pharmacies in the United States from January 2003 to September 2012." Adden. at 58 n.30. The court considered Plaintiffs' criticisms and found they did not change the conclusion: "Despite such apparent defects in Dr. Cremieux's methodology and sample analyses, the issues Astellas raises about uninjured class members and the need for individualized injuries are nonetheless valid." *Id.* at 69.

Fund] had not suffered injury during the proposed damages period"). TPPs benefited from delay when, under their particular plans, the *copayment* differential between Prograf and the Generic was bigger than the corresponding price differential. That never happened with Nexium. As this Court observed, the expected copayment differential between Nexium and its generics (typically $10 to $20) was much smaller than the expected price differential ($47 to $196). 777 F.3d at 29.

Instead of responding to the points made in Astellas's brief, Plaintiffs challenge the test applied in *Nexium*. They urge this Court to raise the threshold far above the *Nexium* standard of "a de minimis number of uninjured parties." But the *Nexium* opinion does not provide any basis for permitting a class with *more* than a de minimis number of uninjured members. In support of the de minimis standard, this Court cited *Halliburton Co. v. Erica P. John Fund, Inc.*, 134 S. Ct. 2398, 2412 (2014), as indicating "that a class with uninjured members could be certified if the presence of a de minimis number of uninjured members did not overwhelm the common issues for the class." 777 F.3d at 23-24. Specifically, this Court quoted the following passage from *Halliburton*: "That the defendant might attempt to pick off *the occasional class member here or there* through individualized rebuttal does not cause individual questions to predominate." *Id.* (quoting *Halliburton*, 134 S. Ct. at 2412; emphasis added). This passage hardly

supports allowing classes with more than a de minimis number of uninjured members. Plaintiffs also contend that this Court has permitted certification "where 'most,' or even 'a very substantial number' of proposed class members can prove injury at trial." P-Br. at 51-52. That is not a fair reading of the cases.[5]

In any event, Plaintiffs make no attempt to explain how a class can be "sufficiently cohesive to warrant adjudication by representation," as required by *Amchem*, 521 U.S. at 623, when it includes a large number of members who *benefited* from the challenged conduct. This is precisely the sort of "'fatal dissimilarity' among class members that would make use of the class-action device inefficient or unfair." *Amgen*, 133 S. Ct. at 1197.

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

Under *Nexium*, "the court must be satisfied that, prior to judgment, it will be possible to establish a mechanism for distinguishing the injured from the uninjured

[5] *Nexium* described all three of the cases discussed by Plaintiffs as "hold[ing] that the presence of a de minimis number of uninjured class members is permissible at class certification." 777 F.3d at 25 & n.22. When *Waste Management Holdings, Inc. v. Mowbray*, 208 F.3d 288, 297 (1st Cir. 2000), spoke of "most" class members, it was referring to *all* members except a "few" subject to an "idiosyncratic" defense. When *Tardiff v. Knox County*, 365 F.3d 1, 6 (1st Cir. 2004), spoke of "most" class members, it assumed the exceptions "may well not be numerous." And *Gintis v. Bouchard Transportation Co.*, 596 F.3d 64, 67 (1st Cir. 2010), was discussing the situation where "common evidence will suffice to prove injury, causation and compensatory damages for at least a very substantial proportion of the claims." Plaintiffs here failed that "common evidence" test.

class members." 777 F.3d at 19. That requirement was not satisfied here. At Plaintiffs' urging, the district court adopted a procedure in which a judgment would be entered without *ever* determining which class members were injured. Instead, this threshold issue would be left to future lawsuits that absent class members must bring if the class trial finds an antitrust violation and the class members wish to recover. As Astellas explained in its opening brief, that procedure is not permitted by *Nexium*, Rule 23, or the Rules Enabling Act. D. Br. at 16-17.

### C. No Administratively Feasible Mechanism Exists for Distinguishing Injured from Uninjured Class Members.

A third *Nexium* requirement for certifying a class with uninjured members is that the mechanism for separating injured from uninjured class members must be "manageable" and "administratively feasible." 777 F.3d at 14, 19. The district court expressly found that this standard was not satisfied: "myriad individual adjudications would render the case unmanageable." Adden. at 73.

Plaintiffs respond that the process would require nothing more than an examination of "purchase records." P-Br. at 61. That assertion is preposterous. Plaintiffs previously told the district court that if they win the class trial and prove an antitrust violation, they would then present "a phase 2 trial plan" containing "a timetable for submitting supplemental expert opinions pertaining to impact and

damages to the named Plaintiffs, BCBSLA and Paone, expert depositions, and any *Daubert* briefing the parties wanted to submit." Dkt. 532 at 2-3. A procedure that entails expert reports and depositions to determine injury for *each class member* is plainly not administratively feasible.

There is a good reason why Plaintiffs say they need supplemental expert reports to show injury to the named Plaintiffs. Even if Paone's purchase records show payments of $4,357.28 for Prograf during the class period, *see* P-Br. at 12, they do not show how she was injured as a result of the alleged delay in Generic entry, given that she would not have switched to the Generic. [redacted] *See* note 3, *supra*; P-Br. at 11.

The district court correctly found that far more information than purchase records would be needed to determine whether a class member was injured. The court cited evidence of "numerous subsets of class members, both consumers and TPPs, that presumably would not have been harmed by increased prices due to plan-specific variables, including co-payment and co-insurance policies, formulary structures, and patient expenditure limits." Adden. at 67-68. For example:

> Another subset of "unharmed" class members identified in Dr. Cremieux's analysis consists of patients whose health plans provide for capped annual expenditures. . . . [P]atients who hit the cap will pay the same amount annually for all the drugs they purchase, regardless of whether they buy Prograf or generic tacrolimus. Assessing whether these consumers were injured would require

> evaluating the timing and expense of all their prescription drug purchases, of both tacrolimus and other drugs, to determine whether they would have still reached the cap had generic tacrolimus been available earlier.

*Id.* at 61-62 (footnotes omitted); *see also In re Wellbutrin XL Antitrust Litig.*, --- F.R.D. ----, 2015 WL 3970858, at *16-18 (E.D. Pa. June 30, 2015) (finding that pharmaceutical purchase records were not sufficient to ascertain in an administratively feasible manner whether consumers were members of class).

Thus, *Nexium* requires reversal of the class certification order.

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

### A. The Text and History of Rule 23 Require Consideration of *All* Questions Presented by the Class Members' Claims When Deciding Whether Common Questions Predominate.

#### 1. The text of Rule 23(b)(3)

The most telling omission in Plaintiffs' argument is their failure to quote or discuss the text of Rule 23(b)(3), which they admit they must satisfy. *See* P-Br. at 48-49. Instead, Plaintiffs lead off their Argument by parsing language that was formerly found in Rule 23(c)(4) but eliminated in 2007. *See id.* at 22-23.

Rule 23(b)(3) contains two separate requirements: predominance and superiority. It is not enough for the court to find that "a class action is superior to other available methods for fairly and efficiently adjudicating the controversy."

Fed. R. Civ. P. 23(b)(3). Even if a class action would be superior, certification is not permitted under 23(b)(3) unless "the questions of law or fact common to class members predominate over any questions affecting only individual members."

The word "any" is the key: the court must take into account "any" individual questions when determining predominance. This language is not ambiguous. In every case that the Supreme Court and this Court have decided involving Rule 23(b)(3), *all* of the issues presented by the class members' claims – including injury, damages and affirmative defenses – were weighed when deciding whether common questions predominated. *See* D-Br. at 25-27. Plaintiffs do not deny this. Furthermore, in every case where individual questions "overwhelmed" the common questions, the Supreme Court and this Court have held that the predominance requirement was not satisfied. *See id.* at 27-28. Plaintiffs do not deny this either.

Plaintiffs have no answer to the textual conundrum posed by their reading of the Rule, under which the test for 23(b)(3) predominance is *identical* to the test for 23(a)(2) commonality. To satisfy (a)(2), a plaintiff must specify "an issue that is central to the validity of each [class member's] claims" and that can be resolved "in one stroke" for the entire class. *Wal-Mart Stores, Inc. v. Dukes*, 131 S. Ct. 2541, 2551 (2011). Yet, according to Plaintiffs, such a showing is all that is needed to satisfy the (b)(3) predominance requirement for an issue class. *See* P-Br.

at 22, 44. Thus, Plaintiffs' interpretation effectively deletes the predominance requirement from Rule 23(b)(3) when an issue class is sought. Plaintiffs never explain how their interpretation can be reconciled with the Supreme Court's admonition that the (b)(3) predominance requirement is "far more demanding" than (a)(2) commonality. *Amchem*, 521 U.S. at 624; *see also* D-Br. at 33-36.

Plaintiffs attack a straw man when they rail against an "all-issues-must-be-certifiable requirement." P-Br. at 20; *see also id.* at 21, 44, 50. Astellas has never advocated that position. Astellas agrees that *if* the requirements of Rule 23(a) and (b)(3) are satisfied, then Rule 23(c)(4) gives the district court discretion to limit the certification to particular issues. The text of Rule 23(b)(3) is perfectly clear: it requires *predominantly* common issues, not exclusively common issues. As this Court pointed out in *Nexium*:

> Rule 23(b)(3) "does *not* require a plaintiff seeking class certification to prove that each element of her claim is susceptible to classwide proof." Rather, the question is whether there is "reason to think that [individualized] questions will *overwhelm* common ones and render class certification inappropriate. . . ."

777 F.3d at 21 (quoting *Amgen*, 133 S. Ct. at 1196, and *Halliburton*, 134 S. Ct. at 2412; this Court's emphasis, brackets, and ellipsis). This Court italicized "*overwhelm*" for a reason. When the individualized questions overwhelm the common ones, a class cannot be certified under Rule 23(b)(3).

### 2. The text of Rule 23(c)(4)

The critical question is whether, as Plaintiffs argue, Rule 23(c)(4) *changes* the predominance test of Rule 23(b)(3) so that the district court need only find predominance as to the common issues, allowing it to certify a class as to those issues *even if the individualized questions will overwhelm the common ones* when those individualized questions are ultimately litigated.

Instead of trying to support their position with the current language of the rule, Plaintiffs rely on a superseded version. They argue that "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." P-Br. at 22 (Plaintiffs' emphasis). Plaintiffs derive this interpretation from the final clause of (c)(4) that was in effect from 1966 to 2007, which read: "the provisions of this rule shall then be construed and applied accordingly." Plaintiffs try to brush aside the 2007 amendment, calling it "inartful" and "a bit clumsy." *Id.* at 27.

> [T]he 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).

*Id*. This statement is false. The quoted clause ("and the provisions of this rule . . .") did not "go[] with the subclass language to 23(c)(5)"; it was eliminated altogether. In its current form, neither (c)(4) nor (c)(5) contains any language

suggesting that the predominance test of (b)(3) is different when (c)(4) or (c)(5) is invoked.

Plaintiffs' *amicus* argues that Rule 23(c)(4) would be "superfluous" if it were regarded as "a mere 'housekeeping' provision or case-management tool." PJ-Br. at 7. But (c)(4) is not superfluous. In explicitly authorizing bifurcated proceedings for individual issues, (c)(4) resolved what was then a conflict among the Circuits about the permissibility of that procedure. *See* D-Br. at 30-31 & n.6.

Plaintiffs' *amicus* next observes that Rule 23(c)(4) "is a tool district courts may use when determining whether the Rule 23(a) and (b) requirements are satisfied." PJ-Br. at 8. Astellas agrees that (c)(4) provides one of the case management tools that district courts may consider when conducting the "rigorous analysis" required by 23(a) and (b). *See Comcast Corp. v. Behrend*, 133 S. Ct. 1426, 1432 (2013). District judges often demand that Rule 23 movants provide a "case plan" explaining exactly how the proposed class action would work. The use of an issue class may be one component of the case plan, and it may have a bearing on "the likely difficulties in managing a class action," which, under Rule 23(b)(3), is one of the "matters pertinent" when considering predominance and superiority. But to say that (c)(4) is a "tool district courts may use" is a far cry from concluding that (c)(4) *changes* the requirements of 23(a) and (b).

### 3. The drafting history of the Rule

**The 1966 amendment**. Plaintiffs contend that "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." P-Br. at 22. But nothing in the drafting history indicates that the Advisory Committee on Rules of Civil Procedure regarded (c)(4) as an "alternative path to certification." The Committee described (c)(4) as a tool for cases that *did* satisfy (b)(3), rather than as an "alternative path" for cases that did not.

In explaining how (b)(3) was intended to operate, the Committee contrasted two types of fraud claims. On the one hand, the Committee warned that "a fraud case may be unsuited for treatment as a class action if there was material variation in the representations made or in the kinds or degrees of reliance by the persons to whom they were addressed." Fed. R. Civ. P. 23(b)(3) (1966 Adv. Comm. Note). On the other hand, "a fraud perpetrated on numerous persons by the use of similar misrepresentations may be an appealing situation for a class action, and it may remain so despite the need, if liability is found, for separate determination of the damages suffered by individuals within the class." *Id.* Thus, some fraud cases satisfy (b)(3) and others do not. For those that do, the Committee explained that Rule 23(c)(4) would permit the court to determine liability on a class basis, and "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 Adv. Comm. Note). Thus, (c)(4) was not seen as an "alternative path to certification," but as a device for managing the issue of damages in cases with predominantly common issues.

Plaintiffs argue that the "Advisory Committee indicated a broad vision of the types of issue classes that might be appropriate under Rule 23(c)(4)" because it altered an earlier draft of the provision, which had stated that "'an action may be brought or maintained as a class action only with respect to particular issues *such as the issue of liability*.'" P-Br. at 23 (Plaintiffs' emphasis). The italicized words were ultimately omitted, and Plaintiffs read into that omission a "clear message" that "nothing about the rule requires that liability be the only 'issue' that can be certified under 23(c)(4)." *Id.* at 24. This is an odd argument, for the earlier draft would have sent the same "clear message." In any event, that point is not in dispute. Everyone agrees that an issue class can be certified even if some issues pertaining to liability are not common – but those issues must still be *considered* in deciding whether common issues predominate. For instance, predominance is often satisfied despite individualized affirmative defenses to liability, but "we regard the law as settled that affirmative defenses should be considered in making class certification decisions." *Waste Mgmt. Holdings v. Mowbray*, 208 F.3d 288, 295 (1st Cir. 2000).

**The rejected 1995 amendment**. The vision of Rule 23 offered by Plaintiffs and their *amicus* is precisely the vision that was considered, and rejected, by the Advisory Committee in 1995. Plaintiffs try to belittle the significance of that rejection, arguing that the amendment had proposed nothing more than a minor change. P-Br. at 26. Actually, the amendment would have extensively rewritten Rule 23, as is readily apparent from the "blackline" of the proposed amendment, reproduced in an article by the Committee's Reporter, Edward H. Cooper, *Rule 23: Challenges to the Rulemaking Process*, 71 N.Y.U. L. Rev. 13, 53-56 (1996). As Professor Cooper explained:

> [T]he draft transforms the "superiority" requirement of present division (b)(3) into a subdivision (a) prerequisite for any class. The (b)(1), (b)(2), and (b)(3) categories become *merely factors to be considered* in determining superiority. . . .
>
> The subdivision (b)(3) requirement that common questions of fact or law predominate is *mollified* by making "the extent to which" common questions predominate *one factor* in calculating superiority. This change is one of many that are intended to ease the path toward certification of issue classes.

*Id.* at 32-33 (emphasis added). To illustrate the intended change, the proposed Note stated:

> For example, in some mass tort situations, it might be appropriate to certify some issues relating to the defendants' culpability and – if the relevant scientific knowledge is sufficiently well developed – general 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.

*Id.* at 61. That is the interpretation advocated by Plaintiffs and the commentators they cite. *See* P-Br. at 24-28, 36-37, 40-41. But it was rejected by the Advisory Committee in 1995, and repudiated by the Supreme Court two years later in *Amchem*, 521 U.S. at 623-24 (holding that a class could not be certified even if the claims presented an "overarching dispute about the heath consequences of asbestos exposure").

### B. The Circuit Courts Have Not Permitted Certification When Individual Questions Overwhelmed Common Questions.

In their lengthy march through the Circuits, P-Br. at 30-44, Plaintiffs fail to cite a single case in which a Circuit Court *acknowledged* that common questions were overwhelmed by individual questions – *i.e.*, that common questions did *not* predominate – but nevertheless certified an issue class under Rule 23(c)(4). Instead, Plaintiffs proclaim that "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." *Id.* at 1. Astellas agrees. But that anodyne proposition does not help resolve this appeal. Nor does Plaintiffs' citation of cases recognizing that common issues can predominate despite the need for individualized determinations of damages.[6]

[6] For this proposition, Plaintiffs cite *Tardiff*, 365 F.3d at 6; *Chiang v. Veneman*, 385 F.3d 256, 273 (3d Cir. 2004); *In re Deepwater Horizon*, 739 F.3d 790, 806 (5th Cir. 2014); *In re Whirlpool Corp. Front-Loading Washer Prods. Liab. Litig.*,

### 1. First Circuit

Plaintiffs are wrong when they assert that *Smilow v. Southwestern Bell Mobile Systems, Inc.*, 323 F.3d 32 (1st Cir. 2003), "implicitly acknowledged that, even if common issues did *not* predominate, a Rule 23(c)(4) issues class could nevertheless be certified." P-Br. at 43 (Plaintiffs' emphasis). The discussion in *Smilow* was about whether common questions *did* predominate despite the presence of individual questions. This Court made two observations. First, regarding affirmative defenses, *Smilow* stated that "where common issues otherwise predominated, courts have usually certified Rule 23(b)(3) classes even though individual issues were present in one or more affirmative defenses." 323 F.3d at 39. The second observation dealt with damages: "The individuation of damages in *consumer* class actions is *rarely* determinative under Rule 23(b)(3)," although "[c]ourts have denied class certification where these individual damages issues are especially complex or burdensome." *Id.* at 40 & n.8 (emphasis added). *Smilow* thus exemplifies the need to weigh *all* the issues when applying (b)(3).

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722 F.3d 838, 860-61 (6th Cir. 2013); *Sterling v. Velsicol Chem. Corp.*, 855 F.2d 1188, 1197 (6th Cir. 1988); *Butler v. Sears, Roebuck & Co.*, 727 F.3d 796, 800 (7th Cir 2013); and *Wallace B. Roderick Revocable Living Trust v. XTO Energy, Inc.*, 725 F.3d 1213, 1220 (10th Cir. 2013).

### 2. Seventh Circuit

Plaintiffs contend that the Seventh Circuit has permitted issue classes "even when an apparent majority of issues require individualized inquiries." P-Br. at 34. But the Seventh Circuit has never permitted issue classes when, *in its view*, predominance was lacking. It has recognized "that the requirement of predominance is not satisfied if 'individual questions . . . overwhelm questions common to the class.'" *Butler v. Sears, Roebuck & Co.*, 727 F.3d 796, 801 (7th Cir 2013) (Seventh Circuit's omission); *Parko v. Shell Oil Co.*, 739 F.3d 1083, 1085 (7th Cir. 2014). For instance, in the recent *Parko* opinion by Judge Posner, the Seventh Circuit reversed class certification because the district judge never "investigated the realism of the plaintiffs' injury and damage model." 739 F.3d at 1086.

### 3. Fifth Circuit

In *Castano v. American Tobacco Co.*, 84 F.3d 734, 745 n.21 (5th Cir. 1996), the court held that "a cause of action, as a whole, must satisfy the predominance requirement of (b)(3)," even when an issue class is proposed. Plaintiffs, however, argue that since *Castano* the Fifth Circuit's "thinking about issue classes has evolved." P-Br. at 40. But the three cases cited by Plaintiffs show no backtracking. *Rodriguez v. Countrywide Home Loans*, 695 F.3d 360, 364-65 (5th Cir. 2012), involved a (b)(2) class, so the (b)(3) predominance requirement did not

apply. *In re Deepwater Horizon*, 739 F.3d 790, 815-16 (5th Cir. 2014), involved a *settlement* class (not an issue class) in which "the district court set forth a considerable list of issues that were common to all the class members' claims," and the Fifth Circuit agreed that common issues predominated "despite the particular need in such cases for individualized damages calculations." Lastly, in *Mullen v. Treasure Chest Casino, LLC*, 186 F.3d 620, 626-27 (5th Cir. 1999), the Fifth Circuit explicitly weighed *all* the issues to find that the common questions predominated over individual questions of causation, damages, and contributory negligence. *Mullen* is therefore consistent with *Castano*.[7]

**4. Second and Ninth Circuits**

All that remains is Plaintiffs' reliance on Second and Ninth Circuit cases. It is true that opinions from both Circuits contain *statements* consistent with Plaintiffs' interpretation of Rule 23(c)(4). But, as Astellas pointed out in its opening brief, those statements fail to reflect what those Circuits actually *do*. In practice, issue classes are *not* permitted when individual questions overwhelm common questions.

[7] If there has been any "evolv[ing]" by the Fifth Circuit, it was the abrogation of *Mullen* in *M. D. v. Perry*, 675 F.3d 832, 839-41 (5th Cir. 2012), where the Fifth Circuit overruled (and toughened) the test employed in *Mullen* to determine whether issues were indeed common. Thus, it is questionable whether the class that was certified in *Mullen* would still be certified under current Fifth Circuit precedent.

**Ninth Circuit.** In the very opinion quoted by Plaintiffs, the Ninth Circuit *reversed* the certification of an issue class on predominance grounds. *Valentino v. Carter-Wallace, Inc.*, 97 F.3d 1227, 1234 (9th Cir. 1996). In the only other Ninth Circuit case cited by Plaintiffs on this point, the court explicitly considered *all* issues before finding predominance. *Jiminez v. Allstate Ins. Co.*, 765 F.3d 1161, 1164 (9th Cir. 2014) ("[T]he district court held that the common question of whether Allstate had an 'unofficial policy' of denying overtime payments while requiring overtime work predominated over any individualized issues regarding the specific amount of damages a particular class member may be able to prove.").

**Second Circuit.** Plaintiffs regard *In re Nassau County Strip Search Cases*, 461 F.3d 219 (2d Cir. 2006), as their best authority, but it was certainly not a case where common questions were overwhelmed by individual questions. *Nassau* was a jailhouse strip-search case, just like *Tardiff v. Knox County*, 365 F.3d 1 (1st Cir. 2004). In *Tardiff*, this Court carefully considered *all* the issues presented by the class claims and found that common questions predominated, despite individual questions of damages. 365 F.3d at 5-7. Similarly, the Second Circuit's *Nassau* opinion cited "the pervasive character of the common liability issues and the admittedly *de minimis* nature of individualized liability issues," pointing out "that any individualized inquiries will be few and far between." 461 F.3d at 230. Because common issues predominated in *Nassau*, there was no need to decide

whether the final clause then found in (c)(4) modified the test for predominance. Thus, the Second Circuit's interpretation was nothing more than dictum regarding a clause in (c)(4) that was removed a year later. *Nassau* should not be followed.

In practice, the *Nassau* dictum has usually not been followed by the Second Circuit. In later cases, when the court *was* confronted with individual questions that overwhelmed the common questions, it repeatedly rejected the use of issue classes. *See* D-Br. at 44-45.

### C. In Antitrust Cases, Common Questions Do Not Predominate Unless Injury Can Be Established with Common Proof.

Astellas demonstrated in its opening brief that this Circuit and most others have adopted a straightforward guideline for certifying classes in antitrust cases: unless injury to class members can be determined with common proof, the predominance requirement is not satisfied. *See* D-Br. at 40-41 & n.11 (citing decisions of the First, Third, Fourth, Fifth, Seventh, Eighth, and D.C. Circuits). In response, Plaintiffs argue that this line of authority was overruled by *Nexium* and *Halliburton*. That is dead wrong.

In *In re New Motor Vehicles Canadian Export Antitrust Litigation*, 522 F.3d 6, 20 (1st Cir. 2008), this Court stated the following principle: "In antitrust class actions, common issues do not predominate if the fact of antitrust violation and the fact of antitrust impact cannot be established through common proof." Plaintiffs

try to dismiss this principle as "outdated dicta." P-Br. at 58. But it was not dictum. In *New Motor Vehicles*, this Court reversed and remanded the class certification order precisely because the plaintiffs had not adequately established the existence of a common method of proving classwide injury. 522 F.3d at 29-30. Nor is this principle outdated; it was reaffirmed by *Nexium* earlier this year:

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

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

*Nexium* did not overrule this principle. Rather, it added two glosses to the holding in *New Motor Vehicles*. First, *Nexium* stated that predominance can be satisfied by common proof of injury even if "'the defendant might attempt to pick off the occasional class member here or there through individualized rebuttal.'" *Id.* at 23-24 (quoting *Halliburton*, 134 S. Ct. at 2412). The second gloss concerned timing. *Nexium* held that the plaintiffs did not have to succeed in proving impact at the class certification stage; the common proof of impact could be presented at the liability stage:

> Defendants argue that . . . to obtain class certification, plaintiffs must establish *at class certification* that "each class member was harmed by the defendants' practice." . . . To the extent that *New Motor Vehicles* is read to impose such a requirement, it has been overruled by the

> Supreme Court's *Halliburton* decision. But, in fact, *New Motor Vehicles* imposes no such requirement. . . .
>
> *New Motor Vehicles* did not impose a requirement that the injury determination must be completed by the class certification stage – only that "the district court [have] enough information to evaluate *preliminarily* whether the proposed model will be able to establish . . . which consumers were impacted by the alleged antitrust violation and which were not."

*Id.* (quoting *New Motor Vehicles*, 522 F.3d at 28; this Court's emphasis, brackets, and last omission).

Plaintiffs failed this test below, and therefore the order certifying a class should be reversed, just as it was in *New Motor Vehicles.*

### D. Plaintiffs' Policy Arguments Do Not Justify Disregarding the Language of the Rule.

Plaintiffs offer three policy arguments in an attempt to justify class certification. The same arguments could be made – and were made – in nearly every case where courts found that common issues did not predominate.

First, Plaintiffs argue that certifying a class will "prevent defendants from 'escap[ing] liability for . . . harms of enormous aggregate magnitude.'" P-Br. at 29 (Plaintiffs' brackets). But no such "escape" is implicated by state-law indirect purchaser cases such as this. Under the federal antitrust laws, the *direct* purchasers of Prograf – wholesalers – have the right to sue for all alleged overcharges, including any overcharges they passed on to indirect purchasers; and, if they prevail, they recover three times the amount of the total overcharge. *Illinois Brick*

*Co. v. Illinois*, 431 U.S. 720 (1977). In this case, a direct purchaser class was certified (by stipulation), and those plaintiffs sued to recover the entire alleged overcharge, including the amounts allegedly passed on to Plaintiffs. On the eve of trial, the direct purchaser case settled for an amount found to be a "fair, reasonable and adequate" compromise of the claims for *all* the alleged Prograf overcharges. Dkt. 678 ¶ 7. Thus, Astellas has hardly "escaped."

Second, Plaintiffs argue that unless a class is certified, consumers "'are unlikely to have the resources or incentive to litigate.'" P-Br. at 46 (quoting Adden. at 4). But the inescapable fact is that, even if a class is certified, very few consumers are likely to bring claims in a case where individualized issues of injury and damages are overwhelming – *i.e.*, where class members must present significant proof to establish a claim, which is legitimately subject to significant challenge.

Consider the formidable burdens that class members would face here if Plaintiffs prevail at the class trial. First, any class member wishing to submit a claim must file a separate lawsuit. The proposed class notice informs them: "You will be solely responsible for pursuing any such lawsuit, at your own expense and with the assistance of a lawyer of your own choosing." Dkt. 478-2 at 2. Second, the class member must present a credible damages claim, without having the benefit of any judicially-mandated class-wide damages formula. (The class trial

will not address damages.) To establish a claim, consumers will need to obtain records from all their pharmacies and health plans detailing their purchases of tacrolimus, both Prograf and generics. Then, for the same reason that the named Plaintiffs say they need expert reports, a class member will likely need to retain an accounting or economic expert to digest this information and formulate a damages claim.

Moreover, class members will have to undertake these burdens before knowing whether they have a valid claim at all, or whether it is worth much. A cautionary lesson was learned by three of the original five Plaintiffs, who turned out *not* to have damage claims, although presumably they and their counsel believed they did when they brought suit. The consumers in the class face the same uncertainty. If their records show that they purchased only Prograf (and not the Generic) during the class period – and most did – they probably were not injured. If their records show that they paid only a copayment for Prograf or the Generic (as is the case under typical health plans), their damages are probably at most $10 to $30 per prescription. Under these circumstances, there is no basis for believing that any appreciable number of consumers would bring claims.

Third, Plaintiffs insist that "proceeding with an issue class is a win-win for Astellas" because, in their view, Astellas really ought to prefer "a one-time resolution of a truly common issue." P-Br. at 49. That is patronizing, and wrong.

The certification of a class increases the pressure on a defendant to settle. *Coopers & Lybrand v. Livesay*, 437 U.S. 463, 476 (1978). The certification of a class *that cannot manageably be litigated* forces a defendant to incur huge legal expenses if it wishes to vindicate its rights, thus ratcheting up the pressure to settle even more, regardless of the merits. In this case, it is fanciful to argue that Astellas would be better off with a class. If no class is certified, then Astellas may be able to settle with the two remaining Plaintiffs for the fair value of their individual claims. That is not possible if an issue class is certified, at least not prior to trial on the certified issues.

Plaintiffs' policy arguments fail in cases such as this where individual questions overwhelm common questions. In any event, this appeal should not be resolved by making policy judgments. As the Supreme Court has warned, "[t]he text of [Rule 23] limits judicial inventiveness." *Amchem*, 521 U.S. at 620. The text provides that a class action cannot be brought when individual questions predominate.

## CONCLUSION

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

Respectfully submitted,

September 9, 2015

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## CERTIFICATE OF COMPLIANCE

I certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 6,968 words, excluding the parts of the brief exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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

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## CERTIFICATE OF SERVICE

I certify that on September 9, 2015, I caused the foregoing brief to be electronically filed using the ECF system, which will send notice to all counsel of record.

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