

No. 19-

**In the United States Court of Appeals
for the First Circuit**

In re LOESTRIN 24 FE ANTITRUST LITIGATION

WARNER CHILCOTT (US), LLC; WARNER CHILCOTT SALES (US), LLC;
WARNER CHILCOTT COMPANY, LLC; WARNER CHILCOTT PLC;
WARNER CHILCOTT LIMITED; WATSON PHARMACEUTICALS, INC.;
and WATSON LABORATORIES, INC., *Defendants-Petitioners*,

v.

CITY OF PROVIDENCE, A.F. OF L. – A.G.C. BUILDING TRADES WELFARE
PLAN, ALLIED SERVICES DIVISION WELFARE FUND, ELECTRICAL
WORKERS 242 AND 294 HEALTH & WELFARE FUND, FRATERNAL
ORDER OF POLICE, FORT LAUDERDALE LODGE 31, INSURANCE TRUST
FUND, LABORERS INTERNATIONAL UNION OF NORTH AMERICA,
LOCAL 35 HEALTH CARE FUND, PAINTERS DISTRICT COUNCIL NO. 30
HEALTH & WELFARE FUND, TEAMSTERS LOCAL 237 WELFARE
BENEFITS FUND, AND UNITED FOOD AND COMMERCIAL WORKERS
LOCAL 1776 & PARTICIPATING EMPLOYERS HEALTH AND WELFARE
FUND, *Plaintiffs-Respondents*.

On Petition for Permission to Appeal from
The United States District Court for the District of Rhode Island
No. 1:13-md-02472-WES-PAS (The Honorable William E. Smith)

**PETITION PURSUANT TO RULE 23(f) OF THE
FEDERAL RULES OF CIVIL PROCEDURE FOR PERMISSION
TO APPEAL FROM ORDER GRANTING CLASS CERTIFICATION**

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**PARTIES TO THE PROCEEDING
AND CORPORATE DISCLOSURE STATEMENT**

Petitioners, Defendants below, are Warner Chilcott (US), LLC; Warner Chilcott Sales (US), LLC; Warner Chilcott Company, LLC; Warner Chilcott plc; Warner Chilcott Limited; Watson Pharmaceuticals, Inc.; and Watson Laboratories, Inc.

Respondents, Plaintiffs below, are City of Providence, A.F. of L. - A.G.C. Building Trades Welfare Plan, Allied Services Division Welfare Fund, Electrical Workers 242 and 294 Health & Welfare Fund, Fraternal Order of Police, Fort Lauderdale Lodge 31, Insurance Trust Fund, Laborers International Union of North America, Local 35 Health Care Fund, Painters District Council No. 30 Health & Welfare Fund, Teamsters Local 237 Welfare Benefits Fund, and United Food and Commercial Workers Local 1776 & Participating Employers Health and Welfare Fund.

The following are plaintiffs in the proceedings below, but are not among the Respondents in this proceeding: Ahold USA, Inc., Denise Loy, Mary Alexander, CVS Pharmacy, Inc., Rite Aid Corporation, Rite Aid Headquarters. Corp., Walgreen Co., The Kroger Co., Safeway Inc., HEB Grocery Company L.P., and Albertson's LLC.

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure, Petitioners Warner Chilcott (US), LLC; Warner Chilcott Sales (US), LLC; Warner

Chilcott Company, LLC; Warner Chilcott plc; Warner Chilcott Limited; Watson Pharmaceuticals, Inc.; and Watson Laboratories, Inc. state that they are direct or indirect wholly owned subsidiaries of Allergan plc, a public limited company incorporated in Ireland. Allergan plc was formerly known as Actavis plc. No publicly held corporation owns 10 percent or more of Allergan plc's stock.

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Under Rule 23(f) of the Federal Rules of Civil Procedure, Petitioners respectfully request permission to appeal the District Court's order certifying a third-party-payor ("TPP") health insurer class.

INTRODUCTION

The District Court's certification of an insurer-TPP class created an intra-circuit split with the U.S. District Court for the District of Massachusetts, which refused to certify a TPP class on remand from *In re Asacol Antitrust Litigation*, 907 F.3d 42 (1st Cir. 2018). ECF 833 (quoting refusal to certify where, as here, there was no common evidence of "consumer coercion" to prove product hopping). In doing so, the District Court imposed significant pressure on Defendants to settle rather than face billions in damages at the trial set to begin on January 6, 2020. It also committed serious legal errors that may recur unless corrected.

First, the Order (Ex. 1, ECF 1226) ("Order") was not accompanied by an opinion finding that Plaintiffs had proven each element of Rule 23(a) and Rule 23(b)(3), despite the Supreme Court in *Tyson* requiring such findings be made *before* certification. This absence of an opinion thwarts effective judicial review.

Second, Plaintiffs did not show common issues predominate as to impact because their proposed proof finds 25% of insurer-TPPs were uninjured. Insurer-TPPs *partially* reimburse their insureds' purchases of Loestrin 24 ("Loestrin"), Minastrin 24 ("Minastrin"), or generic equivalents. Plaintiffs theorize that, but-for

Defendants’ conduct, their insureds would have taken generic Loestrin, and TPPs would have reimbursed *less* for the generic. But their proof of impact ignored cost-sharing among insurer-TPPs, patients, and others (like Defendants, who pay in part for brand drugs via rebates to TPPs). Instead, Plaintiffs compared average *total* brand and generic prices, and *presumed* injury to all TPPs—even the 25% that would have reimbursed *more* for generic—because the *total* generic price was lower. Plaintiffs’ “joint purchaser theory” is a “fiction” that violates “the Rules Enabling Act.” *In re K-Dur Antitrust Litig.*, No. 01-1652, 2008 U.S. Dist. LEXIS 71771, at *44–45 (D.N.J. Mar. 27, 2008). Class actions do not “create a class entity.” *Asacol*, 907 F.3d at 56.

Plaintiffs’ expert did not dispute that his averages find many insurer-TPPs are uninjured. Rather, after the class certification hearing he suggested using what Plaintiffs call “individual inquiry to prove injury” to such insurer-TPPs. ECF 997-1 at 3. This Court’s *Nexium* and *Asacol* decisions thus required denying certification, but the District Court certified the class anyway.

Third, despite the need to individually assess injury to thousands of class members, Plaintiffs violated *Asacol* by offering no plan to do so that protects Defendants’ Seventh Amendment and Due Process rights. Rather, Plaintiffs have confirmed that, before trial, they will not attempt (1) to ascertain class members’ identities or (2) obtain evidence on their prescription cost-sharing. ECF 1237-1.

Fourth, the District Court certified the class despite a disconnect between Plaintiffs' damages evidence and liability theory, violating the Supreme Court's *Comcast* decision. Plaintiffs seek damages for "injury" Defendants never caused, including for payments (1) by brand-loyalist TPPs (that would not have paid for the generic), (2) where patients chose Minastrin over generic Loestrin and thus were uninjured, (3) for products by pharmacy benefit managers ("PBMs"), which are excluded from the class, and (4) for generics manufactured by non-Defendants.

Fifth, Plaintiffs' reply brief proposed two new classes (including the insurer-TPP class) and nationwide unjust enrichment claims not raised in their opening brief. Also, for the first time, Plaintiffs presented impact/damages evidence for the unjust enrichment claims, and evidence of impact to generic purchasers. But the District Court refused to strike these untimely theories and claims, even though Plaintiffs identified no cause to permit them. ECF 686.

This Court should grant review to confirm that deficient classes cannot be certified, and that courts must find Rule 23 satisfied before granting certification.

QUESTIONS PRESENTED

1. Whether under *Tyson* and *Nexium* the District Court can certify a class before finding each element of Rule 23 satisfied, and without issuing an opinion.
2. Whether *Asacol* and *Nexium* permit certification where Plaintiffs' common proof relies on gross *average* prices, even though insurer-TPP class

members only partially reimburse each transaction, and Plaintiffs' methodology finds approximately 25% of them are uninjured.

3. Whether *Asacol* and *Nexium* allow certification where Plaintiffs admit "individual inquiry to prove injury" to thousands of class members is necessary, yet have no plan for doing so while preserving Defendants' constitutional rights.

4. Whether *Comcast* and *Nexium* permit classes to recover damages not caused by the alleged wrongdoing.

5. Whether Plaintiffs' reply briefing may add back into the class concededly uninjured purchasers (brand-loyalist insurer-TPPs), and for the first time propose new, broader classes, and attempt to establish compliance with Rule 23 for claims (unjust enrichment) and class members (generic-only purchasers) not addressed in Plaintiffs' opening briefing.

STATEMENT OF THE FACTS

Plaintiffs contend that Warner Chilcott attempted "to create and maintain a monopoly" for Loestrin, an oral contraceptive. *In re Loestrin 24 Fe Antitrust Litig.*, 261 F. Supp. 3d 307, 325 (D.R.I. 2017). They allege wrongful Orange Book listing, sham patent-infringement litigation, an unlawful reverse payment to Watson, and a "product hop" to Minastrin that coerced patients from taking generic Loestrin. End-Payor Pls.' Mot. for Class Cert. at 1–2, ECF 528-1 ("Mot."). Plaintiffs' theory of impact is that "[i]f the generic [Loestrin] would have sold for

less than the brand during the Class Period, all class members who would have bought the generic were injured.” *Id.* at 23.

Plaintiffs initially moved to certify a combined consumer/insurer-TPP class under the “antitrust and consumer protection laws” of “30 states, the District of Columbia, and Puerto Rico”—*not* unjust enrichment law. *Id.* at 1, 11. They proposed excluding “‘brand loyalist’ . . . third-party payors who purchased Loestrin 24 Fe and who did not purchase any AB-rated generic equivalent.” *Id.* at 12–13. Plaintiffs admit such purchasers “did not pay overcharges.” *Id.* at 19.

Defendants showed that Plaintiffs did not satisfy Rule 23, because they (1) did not prove ascertainability, (2) ignored that many entities partially pay for prescriptions (consumers, PBMs, insurer-TPPs, and Defendants), and cost-sharing means thousands of purchasers are uninjured, (3) offered no manageable way to assess injury to these purchasers, (4) improperly sought damages for generics not sold by Defendants, and (5) improperly sought damages for purchases where patients *chose* Minastrin over generic Loestrin. Opp’n to End-Payor Pls. Mot. for Class Cert. §§ I–III, ECF 574-2 (“Defs.’ Opp’n”). Defendants also renewed their motion to dismiss many state law claims, including all unjust enrichment claims, which Plaintiffs’ certification motion did not address. *Id.* §§ IV–V.

In response, Plaintiffs requested certification of either a consumer/insurer-TPP class or a TPP-only class. Reply Mem. of Law in Further Supp. of Mot. for

Class Cert. at 1, ECF 633-1. For the first time, Plaintiffs also tried to offer proof of impact and damages under an unjust enrichment theory, and evidence of ascertainability from three new experts. *Id.* at 24–26, 48 n.61.

Defendants moved to strike portions of this reply and the new expert reports because Plaintiffs identified no good cause for failing to offer these arguments and evidence in their opening briefing. ECF 639; ECF 676-1. On December 28, 2018, the District Court provisionally denied the motion to strike without explanation and without finding cause for Plaintiffs’ late submissions, and ordered Defendants to respond to the reply brief and new expert reports in just three weeks. ECF 686.

Defendants then showed that the new classes did not satisfy Rule 23 either. Defs.’ Sur-Reply in Opp’n to End-Payor Pls.’ Mot. for Class Cert., ECF 697-1 (“Defs.’ Sur-Reply”). Among other defects, Plaintiffs added admittedly uninjured and unidentifiable “brand loyalists” to their classes. *Id.* § III.A. Defendants also showed that Plaintiffs’ average price comparison cannot prove impact. Using Plaintiffs’ expert’s (Dr. French’s) average prices and copays for insurer-TPPs that put Loestrin/Minastrin on tier 3 of their prescription formulary—the tier with the highest patient copay—insurer-TPPs *reimbursed less* for Loestrin/Minastrin than they would have for generic Loestrin. *Id.* § III.A.6; ECF 1243-6 at slides 7–12.

After the class certification hearing, Dr. French offered a new declaration admitting that 25% of plans had Loestrin/Minastrin on tier 3. Supp. Decl. of Gary

L. French ¶ 4, ECF 785-2 (“French Supp. Decl.”). This meant they were uninjured according to Dr. French’s average price comparison: they would have reimbursed *more*, not less, for generic Loestrin. But Dr. French claimed this was irrelevant because the largest payment for the brand by any given plan—not an average—is what matters “when assessing injury.” *Id.* ¶¶ 12–13 (injury turns on “maximum plan payment instead of the average”). He suggested comparing the highest brand Loestrin payment by each plan to the *average* plan payment for generic Loestrin, which Plaintiffs call an “individual inquiry to prove injury.” ECF 997-1 at 3.

Defendants sought leave to move to exclude Dr. French’s post-hearing opinions. *See* ECF 826. In response, Plaintiffs did not dispute that Dr. French had retreated from Plaintiffs’ proposed classwide proof. ECF 829. Nevertheless, and without providing any rationale, the District Court denied the motion to strike. Text Order dated Apr. 11, 2019. It then certified only the insurer-TPP class, without issuing a written opinion, and invited Plaintiffs to let it know “which causes of action in which states they continue to press.” Order at 3. On September 27, 2019, the District Court amended the insurer-TPP class definition to set an end date for the class period of September 17, 2019, but still has issued no opinion explaining its reasoning. Ex. 2, ECF 1245 (“Amended Order”).

This Petition is timely filed within 14 days of the September 17, 2019 Order and the September 27, 2019 Amended Order, both of which Defendants appeal.

RELIEF SOUGHT

The Court should grant interlocutory review of the portion of the District Court's Order certifying a health insurer-TPP class, as well as the Amended Order.

STANDARD OF REVIEW

This Court “ordinarily will grant leave to appeal” when the grant of certification likely places “irresistible pressure to settle” on defendants and the district court’s certification decision is “questionable.” *Waste Mgmt. Holdings, Inc. v. Mowbray*, 208 F.3d 288, 293–94 (1st Cir. 2000). Similarly, this Court will grant review when “an appeal will permit the resolution of an unsettled legal issue that is important to the particular litigation as well as important in itself and likely to escape effective review if left hanging until the end of the case.” *Id.* at 294.

REASONS FOR GRANTING THE PETITION

I. THE DISTRICT COURT CERTIFIED THE HEALTH INSURER-TPP CLASS BEFORE MAKING THE FINDINGS REQUIRED BY RULE 23 AND BEFORE ISSUING AN OPINION

Despite certifying an insurer-only (TPP) class and then amending the class definition days later, the District Court has issued no opinion finding that Rule 23(a) and Rule 23(b)(3) were satisfied. This failure alone mandates reversal.

First, *before* a class can be certified a district court must make certain factual and legal findings, including that plaintiffs have proven compliance with Rule 23 by a preponderance of the evidence. *In re Nexium Antitrust Litig.*, 777 F.3d 9, 27

(1st Cir. 2015); *see also* *Tyson Foods, Inc. v. Bouaphakeo*, 136 S. Ct. 1036, 1045 (2016) (district court must make findings “before a class is certified”). Rule 23 was amended in 2003 to *delete* the “provision that a class certification ‘may be conditional.’” Fed. R. Civ. P. 23 advisory committee’s notes to 2003 amendment. Here, however, the District Court has made no such findings.

Indeed, the District Court certified the class before deciding which claims were certifiable. Its Order *asked Plaintiffs* to state “which causes of action in which states they continue to press,” apparently so that it could decide whether to include them in the class. Order at 3 (emphasis added). Moreover, because Rule 12 motions to dismiss remain pending, the District Court has neither determined whether a class can be certified for those causes of action, nor even whether Plaintiffs have stated a claim for relief under them.

By definition, without knowing what claims were in the class before certification, the District Court could not have found Plaintiffs “delve[d] into the specifics of each statute” and proved typicality, as required. *See Loestrin*, 261 F. Supp. 3d at 360. Nor was there a basis to find Rule 23(b)(3) satisfied without conducting the “‘extensive analysis’ of variations in state law” the Rule demands. *See, e.g., Cole v. GMC*, 484 F.3d 717, 724–26 (5th Cir. 2007) (reversing certification); *see also Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 624 (1997) (“[d]ifferences in state law . . . compound” existing disparate questions); *In re*

Celexa & Lexapro Mktg. & Sales Practices Litig., 291 F.R.D. 13, 19 (D. Mass. 2013) (denying certification as courts will not “certify classes under the laws of multiple states in cases involving state consumer-protection laws”).

Second, by issuing an order without an opinion, the District Court’s approach risks frustrating meaningful appellate review. *See Pipefitters Local 636 Ins. Fund v. Blue Cross Blue Shield*, 654 F.3d 618, 628–30 (6th Cir. 2011) (reversing certification because district court “did not issue a written opinion” before certifying a class and thus committed “reversible error”). Under Rule 23(f), a party must appeal a class certification decision within 14 days of the district court’s “order”—but here no opinion was issued within that 14-day period, leaving Defendants to appeal based solely on errors the District Court likely made. Such an approach renders appellate review a guessing game. Moreover, whenever the District Court issues an opinion the parties will have to proceed based only on the Order, start the appeal anew, or submit further briefing. The best way to avoid such inefficiency and preserve judicial review would be to reverse the Order.

II. PLAINTIFFS’ COMMON PROOF, A GROSS AVERAGE RETAIL PRICE COMPARISON, FAILS BECAUSE INSURER-TPPS PAY ONLY PART OF EACH PRESCRIPTION’S COST AND DUE TO COST-SHARING AT LEAST 25% OF PLANS ARE UNINJURED

In “antitrust class actions, common issues do not predominate if . . . antitrust impact cannot be established through common proof.” *In re New Motor Vehicles Canadian Exp. Antitrust Litig.*, 522 F.3d 6, 20 (1st Cir. 2008). No class may be

certified unless Plaintiffs can prove, “without need for individual determinations,” which class members “were impacted by the alleged antitrust violation and which were not.” *Id.*; *see also Nexium*, 777 F.3d at 18 (same). Where common proof fails to establish impact to all or nearly all class members, certification must be denied unless there is a “mechanism that can manageably remove uninjured [members] from the class in a manner that protects” Defendants’ Seventh Amendment and Due Process rights. *Asacol*, 907 F.3d at 53–54 (a “presumption” cannot prove impact). The insurer-TPP class satisfies none of these prerequisites.

A. The District Court Apparently Ignored that Average Total Prices for a Prescription Cannot Establish Impact to Insurer-TPPs, Which Reimburse Only Part of a Prescription’s Cost

Plaintiffs’ proposed proof of classwide impact consists of merely showing that the estimated *gross average* retail price of “the generic would have sold for less than the brand,” and then declaring “all class members who would have bought the generic were injured.” Mot. at 23. Dr. French admits he “presume[s]” injury to all class members that would have purchased generic Loestrin in the but-for world. Defs.’ Sur-Reply at 30 n.28 (quoting Dr. French’s testimony).

1. Courts reject using average total prices to prove classwide impact—including specific analyses offered by Dr. French

Dr. French’s reliance on *averages* cannot prove classwide impact. *See, e.g., In re Optical Disk Drive Antitrust Litig.*, 303 F.R.D. 311, 321 (N.D. Cal. 2014) (rejecting Dr. French’s *average* overcharge as it cannot show “all or nearly all

purchasers were overcharged . . . in any amount” and holding he “simply assumes” classwide impact); Mem. of Decision at 38, *In re Prograf Antitrust Litig.*, No. 1:11-md-02242 (D. Mass. Dec. 17, 2013), ECF No. 350 (rejecting Dr. French’s proof based on total “pharmacy price” without assessing “the unique requirements and features of specific drug benefit plans”), *recons. granted in part by* 2014 U.S. Dist. LEXIS 138429 (D. Mass. June 20, 2014) (certifying violation-only class).

In pharmaceutical cases, evidence that “speaks only to the average price . . . does nothing to show impact to individual end-payors.” *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, plc*, No. 04-5898, 2010 U.S. Dist. LEXIS 105646, at *96, *100–01 (E.D. Pa. Sept. 30, 2010). Because entities *share* in the cost of each prescription, whether a specific insurer-TPP was injured depends on what *it* paid for *its* share of the retail price, given the details of its prescription plan, “consumer contributions[s] (i.e., co-pay, coinsurance)[,] and drug manufacturer rebates” that reduce the brand price to that insurer-TPP. *In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 224–25 (E.D. Pa. 2012).

Where, as here, two pharmaceuticals are close in price, the total price difference “may be less than the difference between the higher co-pay a TPP receives for branded [Loestrin] and the lower co-pay the TPP receives for a generic [Loestrin].” *K-Dur*, 2008 U.S. Dist. LEXIS 71771, at *46–48 & nn.15–16 (loss of brand rebates to insurer-TPPs when patients switch to generics also may contribute

to lack of injury). If so, the insurer-TPP pays more for the generic than the brand, and thus is uninjured. *Id.* For instance, Dr. French found *average* patient copays in one year of \$11 for tier 1 generic drugs and \$59 for tier 3 brand drugs; thus, a patient switching to tier 1 generics would pay \$48 less to buy the generic than it had contributed to buy the brand. ECF 633-17 ¶ 97. If the *total* brand price was within \$48 of the *total* generic price (say, \$60 for the brand and \$20 for the generic), then the insurer-TPP would actually pay *more* for the generic (\$9, after the \$11 copay) than for the brand (\$1, after the \$59 copay). Relying on an average in such a situation “leads to the demonstrably wrong conclusion that one hundred percent of [class members] were injured.” *Asacol*, 907 F.3d at 54.

Dr. French ignored this reality of cost-sharing when assessing impact, even though *K-Dur* denied certification due to his insistence that “total retail price is the proper gauge of antitrust injury” under a legally invalid “joint purchaser theory” of impact. 2008 U.S. Dist. LEXIS 71771, at *45–47 & n.15. Dr. French’s decade-long refusal to accept how the industry works and “account for the effect insurance plan terms have on the prices paid by” insurer-TPPs is fatal to certification. *Sheet Metal*, 2010 U.S. Dist. LEXIS 105646, at *73 (denying certification); *see also Asacol*, 907 F.3d at 56 (“class actions . . . do not create a class entity”); *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 571 (E.D. Tenn. 2014)

(denying certification because plaintiffs could not assess which TPPs were uninjured due to PBMs partially paying brand price through rebates to TPPs).

2. Plaintiffs' proposed common proof—the average price comparison—finds thousands of insurer-TPPs are uninjured because of lower consumer copays on generics

To show why Dr. French's total *average* price comparison does not establish classwide impact, Defendants' expert Dr. Hughes used Dr. French's *average* prices and applied the *average* copays Dr. French relied upon for plans that placed Loestrin 24 or Minastrin on tier 3 (the tier with higher patient copays). ECF 1243-6 at slides 7–12 (hearing exhibit). For these insurer-TPPs, the average portion of the price they paid from 2009 through 2013 *increases* if a member would have switched from the high copay tier 3 brand Loestrin to the low copay tier 1 generic Loestrin. This occurs because the consumer pays less of the cost due to her lower generic copay: the TPP is uninjured because it *would have paid more for the generic* due to the *lower* generic consumer copay. *Id.*; Defs.' Sur-Reply § III.A.6.

Further, Plaintiffs admit that after Affordable Care Act regulations required no-patient-copay coverage for some contraceptives starting in 2012, many insurer-TPPs refused to pay for Minastrin altogether; they were uninjured because they could not have paid less for generic Loestrin than the \$0 they paid for Minastrin. Defs.' Sur-Reply § III.A.6. In fact, PBMs often entered contracts requiring them to pay large, flat-dollar rebates to insurer-TPPs for *each brand prescription* their

members filled. As a result, such insurer-TPPs likely would have lost rebates on each prescription that switched to generic Loestrin, *and* they would have paid more of the retail price for generic Loestrin than they paid for brand Minastrin. *See* Defs.’ Sur-Reply §§ I.B, III.A.6, III.A.8.¹

Neither Plaintiffs nor the District Court explained how a nationwide average retail price that bundles together the individual costs paid by consumers, insurer-TPPs, PBMs, and even Defendants, could establish impact to insurer-TPPs alone. It should be obvious that a single insurer-TPP could not rely on such “average” evidence to establish its specific injury and damages in its own lawsuit, and thus the TPP class here cannot rely on such an average to prove impact to all or nearly all TPP class members. *See Tyson*, 136 S. Ct. at 1048.

In response, Dr. French did not contest that his proposed proof of impact fails to show injury to insurer-TPPs with Loestrin/Minastrin on tier 3 of their formularies. Rather, he admitted that 25% of plans (covering half of all insured patients) placed Loestrin/Minastrin on tier 3. French Supp. Decl. ¶ 4. This translates to more than 10,000 insurer-TPPs using Plaintiffs’ estimated class size.

¹ PBMs, not insurer-TPPs, pay pharmacies for prescriptions. PBMs then seek reimbursement from TPPs for TPPs’ portion of the cost, at times (1) crediting the TPP for guaranteed rebates the PBM owes before the TPP pays anything, or (2) seeking less from the TPP than the PBM paid to the pharmacy. PBMs thus pay part of a prescription’s cost, but Plaintiffs pretend that insurer-TPPs pay all costs other than copays and seek damages for PBMs’ costs, while excluding PBMs from the class. Defs.’ Opp’n §§ III.A.9–10; Defs.’ Sur-Reply §§ I.B, III.A.6, III.A.8.

ECF 1234 at 3; *see also* Issues with IPP Class Certification and Trial Timing at 6, ECF 1230 (informing District Court that more than 6,133 TPPs are at issue). That Plaintiffs’ common proof fails to show injury to so many class members requires the denial of certification for a lack of predominance under Rule 23(b)(3). *Nexium*, 777 F.3d at 18; *see also In re Rail Freight Fuel Surcharge Antitrust Litig.*, No. 18-7010, 2019 U.S. App. LEXIS 24435, at *10–11 (D.C. Cir. Aug. 16, 2019) (affirming denial of certification where proposed proof of impact showed no injury to 12.7% (2,037 members) of class); *New Motor Vehicles*, 522 F.3d at 20.

B. The Need for Individual Inquiry to Prove Injury to Thousands of Insurer-TPP Class Members Required Denying Certification

Despite the failure of his classwide proof of impact, Dr. French argued (in a post-hearing declaration) that tier 3 insurer-TPPs could have been injured if they paid more on one brand purchase than the average but-for generic Loestrin insurer-TPP payment: “the maximum plan payment is more important than the average plan payment when assessing injury.” French Supp. Decl. ¶ 12. He performed this “individual inquiry to prove injury” (ECF 997-1) on the only plans for which Plaintiffs had data, a subset so unrepresentative that Dr. French called it “*a sample of only 67 plans.*” French Supp. Decl. ¶ 9 (emphasis by Dr. French).

The decision to certify despite the need for individual inquiry is erroneous for at least three reasons. First, the fact that Dr. French’s common proof based on averages found no injury to at least 25% of plans indicates that his model does not

show injury to class members—it presumes injury. *See, e.g., Rail Freight*, 2019 U.S. App. LEXIS 24435, at *10–11 (model’s finding of no injury to class members plaintiffs state are injured shows failure of their evidence for all class members).

Second, Plaintiffs offered no “manageable,” “reasonable and workable plan” for Defendants to contest liability to these 10,000 insurer-TPPs “in a manner that is protective of the defendant’s constitutional rights and does not cause individual inquiries to overwhelm common issues.” *Asacol*, 907 F.3d at 58; *Nexium*, 777 F.3d at 19 (certification must be denied absent such a plan). Nor have Plaintiffs offered a way to assess which TPPs were uninjured because PBMs partially paid for these products, as Plaintiffs instead seek damages for payments by PBMs while excluding PBMs from the class. Defs.’ Sur-Reply §§ I.B, III.A.6, III.A.8 (showing this is improper under *Skelaxin*, 299 F.R.D. at 569–71, 574–75).

Third, there is no manageable way to perform an individual inquiry as to these thousands of insurer-TPPs, because Rule 23 does not permit a “trial in which thousands of class members testify.” *Asacol*, 907 F.3d at 57–58; *see also Rail Freight*, 2019 U.S. App. LEXIS 24435, at *20 (same, as to 2,037 class members). Because such testimony is required due to Plaintiffs’ lack of common proof, the insurer-TPP class does not satisfy Rule 23, and the Order should be reversed.

III. THE CLASS SEEKS DAMAGES NOT PROXIMATELY CAUSED BY DEFENDANTS' ALLEGED WRONGDOING

Class plaintiffs are “entitled only to damages resulting from . . . [the] theory of antitrust impact accepted for class-action treatment.” *Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013). Thus, “a class action is improper unless the theory of liability is limited to the injury caused by the defendants,” and “defendants cannot be held liable for damages beyond the injury they caused.” *Nexium*, 777 F.3d at 18. Here, however, the certified class includes two categories of purchasers for which Plaintiffs offered no cognizable proof of classwide impact.

First, Plaintiffs have no impact theory for Minastrin purchases post-generic Loestrin entry in January 2014. Thereafter, 46% of Minastrin patients had not taken Loestrin—they switched from another drug or Minastrin was their first birth control pill. Defs.’ Opp’n § III.A.3; Defs.’ Sur-Reply § III.A.2. All generic Minastrin patients also had access to generic Loestrin, but *chose* chewable, generic Minastrin. *Id.* While coercion is required to prove product hopping, these patients were not coerced—they freely chose to take Minastrin. *See, e.g., New York v. Actavis plc*, 787 F.3d 638, 653–54 (2d Cir. 2015) (product hops lawful unless they “coerce consumers”); *see also Mylan Pharm. Inc. v. Warner Chilcott plc*, 838 F.3d 421, 440 (3d Cir. 2016) (affirming summary judgment for defendants because “there were plenty of other competitors” and “no evidence of consumer coercion”).

Like *Asacol*'s brand-loyalists, there is no proof these patients would have taken generic Loestrin. 907 F.3d at 51. And like the insurer-TPP-only class rejected on remand from *Asacol*, Plaintiffs' claims depend on purchases by uninjured patients they cannot identify. ECF 833. The class cannot seek damages for which there is no common proof of injury. *Comcast*, 569 U.S. at 35 (a model that "does not even attempt" to match a valid liability theory fails Rule 23(b)(3)).

Second, the class includes purchases of generics manufactured and sold by Defendants' competitors at independently set prices for nearly six years after generic Loestrin entered. Defs.' Opp'n § I.B; Defs.' Sur-Reply § II.B. But such claims are "unacceptably speculative and complex," and non-recoverable. *In re Coordinated Pretrial Proceedings in Petrol. Prods. Antitrust Litig.*, 691 F.2d 1335, 1340–41 (9th Cir. 1982). Indeed, proving non-Defendants' prices were proximately caused by Defendants' conduct and not "numerous other pricing considerations" would raise "obstacles to intelligent inquiry [that] become nearly insurmountable." *Id.*; see also *Mid-West Paper Prods. Co. v. Cont'l Grp., Inc.*, 596 F.2d 573, 583–87 (3d Cir. 1979) (rejecting claims for such purchases); *In re Skelaxin (Metaxalone) Antitrust Litig.*, No. 1:12-md-2343, 2014 U.S. Dist. LEXIS 66707, at *29–41 (E.D. Tenn. May 15, 2014) (the "overwhelming majority" of courts reject such claims); *In re TFT-LCD (Flat Panel) Antitrust Litig.*, No. 07-1827, 2012 U.S. Dist. LEXIS 182374, at *60–61 (N.D. Cal. Dec. 26, 2012)

(dismissing such “umbrella” damages claims under state law). Because the class includes these impermissible claims, certification should be reversed.

IV. THE DISTRICT COURT ABUSED ITS DISCRETION BY ALLOWING PLAINTIFFS TO FIRST ATTEMPT TO SATISFY MANY RULE 23 REQUIREMENTS ONLY IN THEIR REPLY

Plaintiffs’ reply briefing contained four arguments and evidence Plaintiffs were required to raise in their opening papers but did not. The Order should be reversed because Plaintiffs “not only failed to show good cause, [they] also failed to show any cause” for their untimely arguments. *SCVNGR, Inc. v. DailyGobble, Inc.*, No. 1:16-cv-00134, 2017 U.S. Dist. LEXIS 123757, at *2–3 (D.R.I. Aug. 3, 2017) (striking expert report offered three weeks late); *see also O’Connell v. Hyatt Hotels of P.R.*, 357 F.3d 152, 155 (1st Cir. 2004) (delay warrants rejecting filing).

First, since 2013 Plaintiffs sought to exclude “brand loyalist” TPPs because they “did not pay overcharges.” Mot. at 12–13, 19. Indeed, last week Plaintiffs argued for certification of a settlement class excluding “‘brand loyalist’ . . . third-party payors.” ECF 1235-1, Ex. 6 at ¶ 3(f). Yet Plaintiffs’ reply brief deleted this exclusion, thereby adding to the insurer-TPP class the uninjured purchasers that led this Court to reverse certification in *Asacol*. Defs.’ Sur-Reply § III.A (Plaintiffs admit they cannot identify brand-loyalists). By allowing this unexplained change in class definition and certifying a class containing uninjured members, the Order created an intra-circuit split with the district court’s decision on remand in *Asacol*

not to certify an insurer-TPP class due to (1) brand loyalty and (2) no classwide proof of “consumer coercion” needed to prove product hopping. ECF 833.

Second, Plaintiffs’ opening brief and Dr. French’s first report did not attempt to satisfy Rule 23 under a nationwide unjust enrichment theory: they did so only on reply. ECF 639 § III; ECF 677 § III. Nonetheless, the District Court certified a nationwide class without finding cause for Plaintiffs’ delay. ECF 686; *but see Crowley v. Chait*, 322 F. Supp. 2d 530, 551 (D.N.J. 2004) (“[r]ebuttal testimony [is not] a chance for a ‘do over’”). It also did not require Plaintiffs to show typicality or predominance for a class including disparate claims under 50 states’ laws. *But see Thompson v. Jiffy Lube Int’l, Inc.*, 250 F.R.D. 607, 626 (D. Kan. 2008) (courts “generally refuse[] to certify a nationwide [unjust enrichment] class”).

Third, Plaintiffs’ opening papers proposed no proof of classwide impact to generic Loestrin/Minastrin purchasers. ECF 639 § III; ECF 677 § III. Plaintiffs had no explanation for doing so only on reply, but the Order included such insurer-TPPs in the class anyway. ECF 686; *but see Crowley*, 322 F. Supp. 2d at 551.

Finally, Plaintiffs’ excuse for proposing new, broader classes on reply was the 2018 *Asacol* decision. But *Asacol* applied the 2015 *Nexium* decision, and Plaintiffs’ opening papers did not comply with *Nexium*—they referred only to an inchoate, post-trial process to assess injury to class members, not an “administratively feasible” way to do so “prior to judgment” while preserving

“defendants’ Seventh Amendment and due process rights.” ECF 677 § I (quoting *Nexium*, 777 F.3d at 19). The District Court certified the new insurer-TPP class anyway, again without finding good cause for Plaintiffs’ delay. ECF 686.

CONCLUSION

For these reasons, the petition for permission to appeal should be granted.

Dated: October 1, 2019

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This Petition complies with the word limit of Rule 5(c)(1) of the Federal Rules of Appellate Procedure. This Petition contains 5,195 words (as calculated by the automatic word count function of Microsoft Word), excluding the parts of the Petition exempted by Rules 5(b)(1)(E) and 32(f) of the Federal Rules of Appellate Procedure.

This Petition complies with the typeface requirements of Rule 32(a)(5)(A) of the Federal Rules of Appellate Procedure and the type-style requirements of Rule 32(a)(6) of the Federal Rules of Appellate Procedure because this Petition has been prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14-point, Times New Roman font.

Dated: October 1, 2019

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CERTIFICATE OF SERVICE

I hereby certify that on October 1, 2019, a true and correct copy of the foregoing Petition Pursuant to Rule 23(f) of the Federal Rules of Civil Procedure for Permission to Appeal from Order Granting Class Certification was filed with the Clerk's Office of the U.S. Court of Appeals for the First Circuit.

In addition, I certify that copies of this Petition were sent via third-party commercial carrier for delivery overnight to the U.S. District Court for the District of Rhode Island, as well as the following counsel:

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I further certify that all parties required to be served have been served.

/s/ J. Mark Gidley

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