

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

IN RE: METFORMIN MARKETING AND  
SALES PRACTICES LITIGATION

Case No. 2:20-cv-2324-MCA-MAH

Hon. Madeline C. Arleo

Hon. Michael A. Hammer

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFFS' UNOPPOSED MOTION  
FOR PRELIMINARY APPROVAL OF CLASS ACTION SETTLEMENTS,  
CERTIFICATION OF THE SETTLEMENT CLASSES, APPROVAL OF NOTICE PLAN,  
AND APPOINTMENT OF CLASS REPRESENTATIVES AND CLASS COUNSEL FOR  
THE SETTLEMENT CLASSES**

## I. INTRODUCTION

After years of litigation, Consumer and Third-Party Payor (“TPP”) Plaintiffs<sup>1</sup> (collectively, “Class Plaintiffs”), by and through their undersigned counsel, pursuant to Rule 23 of the Federal Rules of Civil Procedure, respectfully submit this Memorandum of Law in Support of their Unopposed Motion for Preliminary Approval of Class Plaintiffs’ Settlements with defendants Teva Pharmaceuticals USA, Inc., Actavis Pharma, Inc., and Actavis LLC (collectively, “Teva”) and defendants Granules USA, Inc., Granules Pharmaceuticals, Inc. and Heritage Pharmaceuticals, Inc. d/b/a Avet Pharmaceuticals, Inc. (collectively, “Granules and Heritage”; collectively with Teva, “Defendants”).<sup>2</sup> Class Plaintiffs seek, *inter alia*, certification of the two proposed Classes for settlement purposes (“Settlement Classes”),<sup>3</sup> preliminary approval of the Settlements and Notice Plan, and appointment of Class Counsel and Class Representatives for settlement purposes.

This putative class action alleges that from July 20, 2015 through June 2, 2020 (the “Settlement Class Period”), Defendants violated federal and state consumer protection laws, common law warranty and fraud laws, and other state statutory provisions through the sale of adulterated, misbranded, and unapproved metformin-containing drugs (“MCDs”) that were

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<sup>1</sup> Pursuant to Rule 23, Plaintiffs Joseph Brzozowski, Jacqueline Harris, Kristen Wineinger, Michael Hann, and Masao Hendrix (“Consumer Plaintiffs”) and MSP Recovery Claims, Series LLC, County of Monmouth, and Central Midwest Regional Council of Carpenters Welfare Fund f/k/a Ohio Carpenters’ Health Fund (“TPP Plaintiffs”) (collectively, Consumer Plaintiffs and TPP Plaintiffs are “Class Plaintiffs”) are moving for preliminary approval of the Settlements.

<sup>2</sup> As the Court is aware, these proposed Settlements resolve all claims against Teva and Granules and Heritage, as well as those against the Downstream Defendants who sold or distributed Teva and Granules and Heritage MCDs, but do not resolve claims against any other parties in the above-captioned litigation.

<sup>3</sup> Unless otherwise defined, all capitalized terms have the same meanings as set forth in the Settlement Agreements, which are attached respectively as **Exhibit 1** (Teva) and **Exhibit 2** (Granules and Heritage) to the Declaration of James E. Cecchi in Support of this Motion.

designed, manufactured, marketed, distributed, packaged, and/or sold by Defendants. Class Plaintiffs allege that, as a result, they and other class members paid for or reimbursed purchases of MCDs that were neither of the quality warranted by Defendants nor legally salable under the Food, Drug, and Cosmetic Act.<sup>4</sup>

These Settlements are the result of extensive arm's length negotiations between experienced and committed counsel for all sides who zealously advocated for their clients. Class Plaintiffs and Defendants have reached separate Settlements, which if approved, would fully and finally resolve the litigation between them, as well as, any claims against Downstream Entities/Defendants related to their sale or distribution of Teva's or Granules' and Heritage's MCDs. The Settlements treat all members of the Settlement Classes fairly and equally. The proposed Settlements provide, respectively, that Teva will make a \$3,000,000.00 cash payment and Granules and Heritage will make a \$2,550,000.00 (each a "Settlement Amount" and collectively the "Total Settlement Amount") into an Escrow Account for the benefit of the Settlement Classes in exchange for the release of all claims against Teva and Granules and Heritage, as well as any claims against the Downstream Entities related to their sale or distribution of Teva and Granules' and Heritage's MCD.

As discussed more fully below, the proposed Settlement Classes readily meet the requirements for certification under Rule 23(a) and (b)(3). The Settlement Classes are ascertainable and sufficiently numerous – containing potentially thousands of individuals and third-party payors; common questions of law and fact predominate because the Settlement Classes'

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<sup>4</sup> Defendants deny Class Plaintiffs' allegations, deny any and all wrongdoing in connection with the facts and claims that have been or could have been alleged against them, assert that they have numerous valid defenses to Class Plaintiffs' claims, deny that Class Plaintiffs are entitled to any damages as a result of their allegations and claims, and have not conceded or admitted the propriety of certification of any class for any purpose other than the Settlements.

claims arise from a singular course of alleged conduct (the manufacture, distribution and sale of adulterated and/or misbranded generic metformin-containing drugs in violation of consumer protection statutes and warranty laws); Class Plaintiffs' claims are typical of the Settlement Classes because they arise from the same course of conduct; Class Plaintiffs' and Interim Co-Lead Counsel (proposed "Class Counsel"), who have extensive experience litigating complex consumer and pharmaceutical class actions, have fairly and adequately represented the Settlement Classes; and a class action is the superior mechanism for prosecuting these claims because individual actions by a class this large would be burdensome on the courts and prohibitively expensive for the individual plaintiffs. Accordingly, Class Plaintiffs respectfully request that the Court enter a Preliminary Approval Order, substantially in the form of the proposed Order attached as **Exhibit 7** to the Cecchi Declaration:

- 1) preliminarily certifying the two Settlement Classes for settlement purposes;
- 2) appointing Joseph Brzozowski, Jacqueline Harris, Kristen Wineinger, Michael Hann, and Masao Hendrix ("Consumer Plaintiffs") on behalf of Consumer Plaintiffs and MSP Recovery Claims, Series LLC, County of Monmouth, and Central Midwest Regional Council of Carpenters Welfare Fund f/k/a Ohio Carpenters' Health Fund on behalf of TPP Plaintiffs as the Settlement Classes' Representatives;
- 3) appointing James Cecchi, Conlee Whiteley, David Stanoch, Max Roberts, Ruben Honik, Joseph Guglielmo, Marlene Goldenberg, Charlie Schaffer, Fred Longer, Janpaul Portal, and Michael Fitzgerald ("Interim Co-Lead Counsel") as Class Counsel for the Settlement Classes;
- 4) granting preliminary approval of the proposed Settlements;
- 5) appointing A.B. Data, Ltd. as the Notice and Claims Administrator;
- 6) approving the proposed Notice Plan;
- 7) setting June 18, 2026, or 120 days following entry of an order preliminarily approving the Settlement as the deadline for Class Plaintiffs to move for Final Approval of the Settlements;
- 8) appointing Huntington National Bank as the Escrow Agent; and

- 9) further staying the litigation as to Teva and Granules and Heritage, except for proceedings for purposes of effectuating the Settlements.

## II. SUMMARY OF THE SETTLEMENT AGREEMENTS

1. Teva has agreed to pay \$3,000,000.00 and Granules and Heritage has agreed to pay \$2,550,000.00 to settle all claims by Class Plaintiffs in the Action. Teva has deposited \$3,000,000.00 into the Escrow Account held and administered by Huntington National Bank, who Class Plaintiffs propose as the Escrow Agent.<sup>5</sup> Cecchi Decl. Ex. 1 at ¶2.1. Granules and Heritage will deposit \$2,550,000.00 into the Escrow Account within 14 days of approval by the Court of the Escrow Agent. The two Settlement Classes (the “Teva Settlement Class” and the “Granules and Heritage Settlement Class” respectively) consist of:

All individuals and entities in the United States and its territories and possessions who paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Teva from July 20, 2015 through June 2, 2020 (the “Class Period”). For purposes of the TPP Plaintiffs, persons or entities “purchased” a metformin-containing drug if they paid or reimbursed some or all of the purchase price.

Excluded from the Settlement Class are: (1) Teva and its respective subsidiaries and affiliates; (2) federal governmental entities; (3) State and local governmental entities to the extent their claims may be asserted under applicable state law only by the state Attorney General, or are otherwise prohibited by applicable law from being asserted by private counsel on a contingent fee basis; (4) all persons or entities who purchased metformin-containing drugs for purposes of resale or directly from Teva or its affiliates; (5) fully insured health plans (*i.e.*, Plans that purchased insurance from another third-party payer covering 100% of the Plan’s reimbursement obligations to its members); (6) pharmaceutical benefit managers; and (7) the judges in this case and any members of their immediate families (the “Teva Settlement Class”);

And,

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<sup>5</sup> The National Settlement Team at Huntington National Bank is very experienced and provides one of the leading settlement account programs in the country. Huntington National Bank’s Banking Handbook for Settlement Funds, which sets forth its qualifications and policies & procedures for handling class action settlement funds, is attached as **Exhibit 3** to the Cecchi Declaration.

All individuals and entities in the United States and its territories and possessions who paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Granules or Heritage from July 20, 2015 through June 2, 2020 (the “Class Period”). For purposes of the TPP Plaintiffs, persons or entities “purchased” a metformin-containing drug if they paid or reimbursed some or all of the purchase price.

Excluded from the Settlement Class are: (1) Granules and Heritage and their respective subsidiaries and affiliates; (2) federal governmental entities; (3) State and local governmental entities to the extent their claims may be asserted under applicable state law only by the state Attorney General, or are otherwise prohibited by applicable law from being asserted by private counsel on a contingent fee basis; (4) all persons or entities who purchased metformin-containing drugs for purposes of resale or directly from Granules or Heritage or their respective subsidiaries affiliates; (5) fully insured health plans (i.e., Plans that purchased insurance from another third-party payer covering 100% of the Plan’s reimbursement obligations to its members); (6) pharmaceutical benefit managers; and (7) the judges in this case and any members of their immediate families (the “Granules and Heritage Settlement Class”).

Cecchi Decl. Ex. 1 at ¶1.39. Subject to Court approval, the Total Settlement Amount will be used to: (1) pay Taxes; (2) reimburse the Notice and Claims Administrator for the costs, fees, and expenses related to notice and the administration of the Settlements, (3) reimburse the expenses incurred by Class Counsel in litigating the Action, (4) pay attorneys’ fees of up to 34% of the Total Settlement Amount, and (5) pay service awards of up to \$3,500 to each Class Plaintiff (“Fund Expenses”). *Id.* ¶ 3.1. After subtracting approved Fund Expenses, the remaining balance of the Total Settlement Amount (“Net Settlement Fund”) shall be distributed to the Settlement Classes’ members through the proposed Plan of Allocation (a non-revisionary common fund). *Id.* at ¶¶ 1.21. 1.28, and 3.1.

In exchange for the Settlement Amount, Class Plaintiffs, on behalf of themselves and the Teva Settlement Class, have agreed to dismiss this Action as against Teva and release Teva and its related entities from all claims on account of or arising out of or in connection with “the factual predicate of the Action, including, but not limited to, Teva’s manufacture, distribution, and/or

introduction into the U.S. market by Teva of its generic metformin-containing drugs that were alleged to be contaminated,” including any and all claims “against any Downstream Entity arising out of, by reason of, or in any manner connected with the use of or payment or reimbursement for Teva’s Metformin Product.” Cecchi Decl. Ex. 1 at ¶¶ 1.26, 4.1-4.2.

In exchange for the Settlement Amount, Class Plaintiffs, on behalf of themselves and the Granules and Heritage Settlement Class, have agreed to dismiss this Action as against Granules and Heritage and release Granules and Heritage and their related entities from all claims on account of or arising out of or in connection with “factual predicate of the Action, including, but not limited to, Granules’ and Heritage’s manufacture, distribution, and/or introduction into the U.S. market by Granules or Heritage of its generic metformin-containing drugs that were alleged to be contaminated,” including any and all claims “against any Downstream Entity arising out of, by reason of, or in any manner connected with the use of or payment or reimbursement for Granules’ and Heritage’s Metformin Product.” Cecchi Decl. Ex. 2 at ¶¶ 1.26, 4.1-4.2.

These Releases do not apply to any claims that Class Plaintiffs have against other defendants, or any claims Class Plaintiffs have against any Downstream Entity related to MCDs manufactured by any person other than Teva or Granules and Heritage. The Class Plaintiffs also have agreed to waive their rights under Section 1542 of the California Civil Code and any similar state or federal laws concerning Unknown Claims. *Id.* ¶ 4.3.

### **III. PRELIMINARY APPROVAL OF THE SETTLEMENTS IS WARRANTED**

#### **A. LEGAL STANDARD AND PROCEDURES FOR GRANTING PRELIMINARY APPROVAL**

Rule 23(e) requires the court’s approval of any settlement of a class action, and courts within this Circuit have a “strong judicial policy in favor of class action settlement.” *Ehrheart v. Verizon Wireless*, 609 F.3d 590, 593-95 (3d Cir. 2010); *Ortho-Clinical Diagnostics, Inc. v. Fulcrum*

*Clinical Lab 'ys, Inc.*, No. CV212530MASTJB, 2023 WL 3983877, at \*3 (D.N.J. June 13, 2023) (“in New Jersey, there is a strong public policy in favor of settlements. . . . Courts, therefore, will ‘strain to give effect to the terms of a settlement whenever possible.’”) (citations omitted); *In re Nat. Football League Players Concussion Inj. Litig.*, 775 F.3d 570, 583 (3d Cir. 2014) (“**[P]reliminary** analysis of a proposed class is . . . a tool for settlement used by the parties to fairly and efficiently resolve litigation.”) (emphasis in original); *In re Pet Food Prods. Liab. Litig.*, No. 07-2867 (NLH), 2008 WL 493762, at \*3 (D.N.J. Nov. 18, 2008), *aff'd & vacated on other grounds*, 629 F.3d 333 (3d Cir. 2010) (“Class actions certified for the purposes of settlement are well recognized under Rule 23.”). Moreover, “[c]ertification of a settlement class ‘has been recognized throughout the country as the best, most practical way to effectuate settlements involving large numbers of claims by relatively small claimants.’” *In re IMAX Sec. Litig.*, 283 F.R.D. 178, 186 (S.D.N.Y. 2012) (citations omitted).

“Settlement agreements are to be encouraged because they promote the amicable resolution of disputes and lighten the increasing load of litigation faced by the federal courts.” *Ehrheart*, 609 F.3d at 594. Settlement is particularly favored “in ‘class actions and other complex cases where substantial judicial resources can be conserved by avoiding formal litigation.’” *Id.* (quoting *In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d 768, 784 (3d Cir. 1995)).<sup>6</sup> As such, courts are “hesitant to undo an agreement that has resolved a hard-fought, multi-year litigation,” such as this one. *In re Baby Prod. Antitrust Litig.*, 708 F.3d 163, 175 (3d Cir. 2013).

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<sup>6</sup> See also *In re Google Inc. Cookie Placement Consumer Privacy Litig.*, 934 F.3d 316, 326 (3d Cir. 2019) (for motions seeking approval of “settlement only” class actions, “we favor the parties reaching an amicable agreement” and should not “intrude overly on the parties’ hard-fought bargain[,]” but also, “[a]t the same time, [a] district court has an obligation as a fiduciary for absent class members to examine the proposed settlement with care”).

“The decision of whether to approve a proposed settlement of a class action is left to the sound discretion of the district court.” *Girsh v. Jepson*, 521 F.2d 153, 156 (3d Cir. 1975).

Under Rule 23(e), court approval proceeds in two stages: (1) preliminary approval of the proposed settlement and direction of notice to the class; and (2) a final approval hearing, at which the court considers the fairness, adequacy, and reasonableness of the proposed settlement. *Smith v. Merck & Co.*, No. CV132970MASLHG, 2019 WL 3281609, at \*4 (D.N.J. July 19, 2019). At preliminary approval, the court determines whether the proposed settlement is within the range of possible approval using the criteria set forth in Rule 23(e)(2), but does not conduct a full-fledged inquiry into whether the settlement meets Rule 23(e)’s standard. Unless the court’s initial examination reveals “obvious deficiencies,” the court should preliminarily approve the settlement and order notice to the class. *See* 4 William B. Rubenstein, *Newberg and Rubenstein on Class Actions* § 13:13 (6th ed. 2024); *Kress v. Fulton Bank, N.A.*, No. CV1918985CDJMJS, 2021 WL 9031639, at \*9 (D.N.J. Sept. 17, 2021), *report and recommendation adopted*, No. 119CV18985CDJMJS, 2022 WL 2357296 (D.N.J. June 30, 2022) (“preliminary approval is not binding and is granted unless the proposed settlement is obviously deficient.”).

The December 1, 2018 amendments to Rule 23 clarified the standards guiding a district court’s preliminary review of a proposed settlement. As amended, Rule 23(e)(1)(B)(i)-(ii) now provide specific requirements that a district court should ensure are satisfied before granting preliminary approval. *See* Fed. R. Civ. P. 23, Advisory Committee Note on 2018 Amendment to Subdivision (c)(2) (noting that Rule 23(e)(1) addresses the “decision [that] has been called ‘preliminary approval’ of the proposed class certification in Rule 23(b)(3) actions”). Specifically, the court should determine whether it “will likely be able to (i) approve the proposal under Rule 23(e)(2); and (ii) certify the class for purposes of judgment on the proposal.” Fed. R. Civ. P.

23(e)(1)(B); *see also Maverick Neutral Levered Fund, Ltd. v. Valeant Pharms. Int'l, Inc.*, No. 320CV02190MASLHG, 2021 WL 7872087, at \*5 (D.N.J. Jan. 26, 2021) (“Thus, in connection with an order preliminarily granting approval of a class action settlement, the Court is not certifying the class at the preliminary approval stage, but rather, is making a preliminary determination that it will likely be able to certify the class at the final approval stage.”) (citation omitted). If these requirements are satisfied, then notice of the proposed settlement will be shared with the class. Fed. R. Civ. P. 23(e)(1).

As for the first showing under Rule 23(e)(2)—which governs final approval—courts now consider the following factors in determining whether a proposed settlement is fair, reasonable, and adequate:

- (A) whether the class representatives and class counsel have adequately represented the class;
- (B) whether the proposed settlement was negotiated at arm’s length;
- (C) whether the relief provided for the class is adequate, taking into account:
  - (i) the costs, risks, and delay of trial and appeal;
  - (ii) the effectiveness of any proposed method of distributing relief to the class, including the method of processing class member claims;
  - (iii) the terms of any proposed award of attorneys’ fees, including timing of payment; and
  - (iv) any agreement required to be identified under Rule 23(e)(3); and
- (D) whether the proposal treats class members equitably relative to each other.

Fed. R. Civ. P. 23(e)(2).

Factors (A) and (B) “identify matters . . . described as procedural concerns, looking to the conduct of the litigation and of the negotiations leading up to the proposed settlement,” while

factors (C) and (D) “focus on . . . a substantive review of the terms of the proposed settlement” (*i.e.*, “[t]he relief that the settlement is expected to provide to class members”). *Id.*, Advisory Committee Notes to 2018 Amendments.

These factors are not, however, exclusive. The four factors set forth in Rule 23(e)(2) are not intended to “displace” any factor previously adopted by the courts, but “rather to focus the court and the lawyers on the core concerns of procedure and substance that should guide the decision whether to approve the proposal.” *Id.* at 918. For this reason, the traditional factors that are used by courts in the Third Circuit—known as the “*Girsh* factors”—to evaluate the propriety of a class-action settlement (certain of which overlap with Rule 23(e)(2)) are still relevant:

(1) the complexity, expense and likely duration of the litigation; (2) the reaction of the class to the settlement;<sup>7</sup> (3) stage of the proceedings and the amount of discovery completed; (4) risks of establishing liability; (5) risks of establishing damages; (6) risks of maintaining the class action through the trial; (7) ability of the defendants to withstand a greater judgment; (8) the range of reasonableness of the settlement fund in light of the best possible recovery; and (9) the range of reasonableness of the settlement fund to a possible recovery in light of all the attendant risks of litigation.

*Singleton v. First Student Mgmt. LLC*, No. CIV.A. 13-1744 JEI, 2014 WL 3865853, at \*5 (D.N.J. Aug. 6, 2014) (citing *Girsh*, 521 F.2d at 153); *In re AT&T Corp. Sec. Litig.*, 455 F.3d 160, 164-65 (3d Cir. 2006) (same). The *Girsh* factors “are a guide and the absence of one or more does not automatically render the settlement unfair.” *In re Schering-Plough/Merck Merger Litig.*, No. CIV.A09-CV-1099DMC, 2010 WL 1257722, at \*5 (D.N.J. Mar. 26, 2010).

In sum, “[t]he central concern in reviewing a proposed class-action settlement is that it be fair, reasonable, and adequate.” Fed. R. Civ. P. 23, Advisory Committee Notes to 2018

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<sup>7</sup> Because notice to the Settlement Classes has not yet been issued, this factor cannot be assessed at this time and is thus omitted from the factor-by-factor analysis. The Settlement Classes’ Representatives, however, support the Settlements.

Amendments.

**B. The Court Should Certify the Classes for Purposes of the Proposed Settlements**

When a class has not been certified before settlement, the court considers whether “it likely will be able, after the final hearing, to certify the class.” Fed. R. Civ. P. 23(e)(1), Advisory Committee Notes to 2018 Amendment; *see also In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig.*, 330 F.R.D. 11, 50 (E.D.N.Y. 2019). In this case, because the classes are being certified in the context of a settlement, there are no “manageability” concerns that need to be considered. *Cf. Amchem Prods. v. Windsor*, 521 U.S. 591, 620 (1997); *In re Merck & Co., Inc. Vytorin Erisa Litigation (“Merck/Vytorin”)*, No. CIV.A. 08-CV-285DMC, 2010 WL 547613, \*5 (D.N.J. Feb. 9, 2010).

Here, in accordance with the Settlement Agreements, the two proposed Settlement Classes consist of “all individuals and entities in the United States and its territories and possessions who paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Teva” during the specified Settlement Class Period (Cecchi Decl. Ex. 1 at ¶1.39), and “all individuals and entities in the United States and its territories and possessions who paid any amount of money for a metformin-containing drug (intended for personal or household use) that was manufactured, distributed, or sold by Granules and Heritage” during the specified Settlement Class Period (Cecchi Decl. Ex. 2 at ¶1.39). As shown below, these Settlement Classes meet Rule 23’s prerequisites for certification: numerosity, commonality, typicality, adequacy, predominance, and superiority. Because these criteria are satisfied and the parties have reached fair, reasonable, and adequate agreements resolving the disputed claims, certification of the Settlement Classes is warranted.

**1. The Requirements of Rule 23(a) Are Satisfied**

As shown below, the four requirements of Rule 23(a): numerosity, commonality, typicality and adequacy are met. Fed. R. Civ. P. 23(a)(1)-(4); *see also Russell v. Educ. Comm 'm for Foreign Med. Graduates*, 15 F.4th 259, 265-66 (3d Cir. 2021).

**a. Numerosity**

For certification of the Settlement Classes to be appropriate, its members must be so numerous that their joinder would be “impracticable.” Fed. R. Civ. P. 23(a)(1). In the Third Circuit, this prong is satisfied where “the named plaintiff demonstrates the potential number of plaintiffs exceeds 40.” *In re Modafinil Antitrust Litig.*, 837 F.3d 238, 249-50 (3d Cir. 2016) (quoting *Stewart v. Abraham*, 275 F.3d 220, 226-27 (3d Cir. 2001)); *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 595 (3d Cir. 2012) (noting that classes exceeding 40 are sufficiently numerous). Here, there are potentially thousands of members of the Settlement Classes. Numerosity is thus readily satisfied.

**b. Commonality**

Rule 23 next requires common questions of law or fact among the proposed class. Fed. R. Civ. P. 23(a)(2). “Meeting this requirement is easy enough,” as commonality is satisfied if “the Settlement Class Representatives share at least one question of fact or law with the grievances of the prospective class.” *In re Nat'l Football League Players Concussion Inj. Litig.*, 821 F.3d 410, 426-27 (3d Cir. 2016), *as amended* (May 2, 2016) (“*In re NFL Players Concussion IP*”) (quoting *Rodriguez v. Nat'l City Bank*, 726 F.3d 372, 382 (3d Cir. 2013)); *Rodriguez*, 726 F.3d at 380-81 (citing *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 306 (3d Cir. 2011)) (“That burden is not onerous. It does, however, require an affirmative showing that the class members share a common question of law or fact.”).

Here, Class Plaintiffs allege that Defendants manufactured, distributed, or sold MCDs that were adulterated, misbranded, or otherwise unmerchantable due to NDMA contamination and/or failures in current Good Manufacturing Practices (“cGMP”) compliance. As alleged, this singular

course of conduct - Defendants' purported misrepresentations and omissions regarding the safety and purity of their MCDs - constitutes a factual and legal issue common to all members of the Settlement Classes' claims. *See, e.g., Roofer's Pension Fund. v. Papa*, 33 F.R.D. 66, 75 (D.N.J. 2019) (finding commonality requirement met where "[t]he class claims are predicated upon the same underlying misrepresentations and omissions by Defendants, presenting common issues of both fact and law arising thereunder"); *In re Remicade Antitrust Litig.*, No. 17-cv-04326, 2022 WL 3042766, at \*5 (E.D. Pa. Aug. 2, 2022) ("Commonality is met in this case because each Class Member's claim depends on whether Defendants unlawfully engaged in anticompetitive behavior.").

This litigation also involves claims arising from Defendants' alleged breaches of warranties and consumer protection statutes, including whether Defendants' conduct rendered the MCDs unfit for their ordinary purpose and thus legally unsalable. All these central questions flow from Defendants' alleged uniform course of conduct and will be resolved with common legal and factual inquiries – further confirming that Rule 23(a)'s commonality requirement is satisfied. *See, e.g., Smith*, 2019 WL 3281609, at \*3 (finding where the same conduct underlies each claim, the class satisfies the commonality and predominance requirements of Rules 23(a)(2) and 23(B)(3)).

Thus, the commonality requirement is met.

**c. Typicality and Adequacy**

"The adequacy and typicality analyses under Rules 23(a)(3) and 23(a)(4), often merge and may, therefore, be discussed together." *Smith*, 2019 WL 3281609, at \*3; *see also Beck v. Maximus, Inc.* 457 F.3d 291, 296 (3d Cir. 2006) (quoting *Amchem*, 521 U.S. at 626 n.20) ("The Supreme Court has noted the typicality and adequacy inquiries often 'tend[] to merge' because both look to potential conflicts and to 'whether the named plaintiff's claim and the class claims are so

interrelated that the interests of the class members will be fairly and adequately protected in their absence.”).

The typicality predicate set forth in Rule 23(a)(3) requires that “each class member’s claim arises from the same course of events, and each class member makes similar legal arguments to prove the defendant’s liability.” *Se. Pennsylvania Transp. Auth. v. Orrstown Fin. Servs., Inc.*, No. 1:12-CV-00993, 2012 WL 3597179, at \*3 (M.D. Pa. Aug. 20, 2012) (citation omitted). “[E]ven relatively pronounced factual differences will generally not preclude a finding of typicality where there is a strong similarity of legal theories’ or where the claim arises from the same practice or course of conduct.” *In re Prudential Ins. Co. Am. Prac. Litig. Agent Actions*, 148 F.3d 283, 311 (3d Cir. 1998) (“*Prudential II*”) (quoting *Baby Neal for & by Kanter v. Casey*, 43 F.3d 48, 58 (3d Cir. 1994)); *see also Russell*, 15 F.4th at 271 n.4 (quoting *In re NFL Players Concussion II*, 821 F.3d at 428 (“We have ‘set a low threshold for typicality.’”).

Here, the claims of the Class Plaintiffs and of the Settlement Classes arise from the identical course of alleged unlawful conduct—the sale of adulterated, misbranded, and unapproved MCDs that were designed, manufactured, marketed, distributed, packaged, and/or ultimately sold by Teva or Granules and Heritage. The purported contamination or other asserted cGMP-related defects are alleged to have uniformly affected Class Plaintiffs and the Settlement Classes who purchased or reimbursed Teva’s or Granules’ and Heritage’s MCDs. *See, e.g., Remicade*, 2022 WL 3042766, at \*6 (citing *In re Wellbutrin XL Antitrust Litig.*, 282 F.R.D. 126, 138 (E.D. Pa. 2011)) (“Here, because the Named Plaintiffs’ and Class Members’ claims arise out of the same conduct and are based on the same legal theories . . . the Court concludes the typicality factor is satisfied.”); *In re Amaranth Nat. Gas Commodities Litig.*, 269 F.R.D. 366, 379 (S.D.N.Y. 2010) (typicality requirement met where plaintiffs and the class “transacted in the same contracts, in the same

centralized marketplace, [and] were allegedly negatively impacted by the same common course of manipulative conduct from which the same group of defendants is alleged to be legally responsible for the damages”).

Rule 23(a)(4) requires that “the representative parties will fairly and adequately protect the interests of the class.” Fed. R. Civ. P. 23(a)(4). The adequacy inquiry “serves to uncover conflicts of interest between named parties and the class they seek to represent” [and] “[i]t assures that the named plaintiffs’ claims are not antagonistic to the class and that the attorneys for the class representatives are experienced and qualified to prosecute the claims on behalf of the entire class.” *Beck*, 457 F.3d at 296 (quoting *Amchem*, 521 U.S. at 625; *Baby Neal*, 43 F.3d at 55). This predicate to class certification mandates two steps of inquiry “‘designed to ensure that absentees’ interests are fully pursued.’” *In re Schering Plough Corp. ERISA Litig.*, 589 F.3d 585, 602 (3d Cir. 2009) (quoting *Georgine v. Amchem Prods, Inc.*, 83 F.3d 610, 630 (3d Cir. 1996), *aff’d*, *Amchem*, 521 U.S. 591).

The first step of the inquiry “‘tests the qualifications of the counsel to represent the class’” while the second step “seeks ‘to uncover conflicts of interest between named parties and the class they seek to represent.’” *Schering*, 589 F.3d at 602. “When examining settlement classes, [the Third Circuit] ‘ha[s] emphasized the special need to assure that class counsel: (1) possessed adequate experience; (2) vigorously prosecuted the action; and (3) acted at arm’s length from the defendant.’” *In re NFL Players Concussion II*, 821 F.3d at 429 (quoting *In re Gen. Motors Corp. Pick-Up Truck*, 55 F.3d at 801). “The burden to prove that the representation is not adequate rests with the party challenging the class’ representation.” *Buzzarro v. Ocean County*, No. 07-5665 (FW), 2009 WL 1617887, at \*14 (D.N.J. June 9, 2009).

As to the first step, Class Counsel is well qualified to represent the interests of the Settlement Classes. Class Counsel is very experienced in class actions in general, and pharmaceutical class litigation in particular, and have been appointed class counsel on numerous occasions within this Circuit and throughout the United States. Class Counsel vigorously litigated this Action, including several motions to dismiss and engaging in targeted discovery. The negotiations with counsel for the Defendants were conducted at arm's length. As reflected in their firm resumes, proposed Class Counsel have substantial experience, individually and collectively, successfully prosecuting class actions and other complex litigation throughout the United States. Thus, Class Counsel are more than qualified to represent the Settlement Classes here.

As to the second step, Class Plaintiffs are not pursuing any unique claims or seeking different damages from those of the Settlement Classes. Likewise, Class Plaintiffs are unaware of any unique defenses that might undermine their adequacy as representatives for the Settlement Classes. Accordingly, the interests of Class Plaintiffs and the Settlement Classes' Members are aligned because they stem from the same alleged course of conduct by Defendants and rest on identical legal theories. *See In re NFL Players Concussion II*, 821 F.3d at 432 (affirming the district court's conclusion that the incentives of class members were aligned because they allegedly were injured by the same scheme).

Thus, the typicality and adequacy requirements are met.

**d. The Settlement Classes Are Ascertainable.**

Although not explicitly set forth in the Federal Rules of Civil Procedure, courts have read into Rule 23 an implicit requirement that a class be "definite" or "ascertainable." A proper class definition is necessary to ensure clarity as to who is entitled to relief, who is bound by a final judgment, and who is entitled to the "best notice practicable" in a Rule 23(b)(3) action. *Byrd v.*

*Aaron's, Inc.*, 784 F.3d 154, 175 (3d Cir. 2015); Manual § 21.222; “For a class to be sufficiently defined, the court must be able to resolve the question of whether class members are included or excluded from the class by reference to objective criteria.” 5 James W. Moore et al., *Moore's Federal Practice* 23.21[3] (3d ed. 1997); *see also Byrd*, 784 F.3d at 164. The Third Circuit has recognized that this prerequisite must be met regardless of whether a litigation or settlement class is sought. *Prudential II*, 148 F. 3d at 308.<sup>8</sup>

Building on the Third Circuit's previous decisions in *Carrera v. Bayer Corp.*, 727 F.3d 300 (3d Cir. 2013), and *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583 (3d Cir. 2012), the Third Circuit has explained that ascertainability requires: 1) that the class members be identifiable by objective criteria and 2) that there is “a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition.” *Byrd*, 784 F.3d at 163. “The ascertainability requirement consists of nothing more than these two inquiries. It does not mean that plaintiffs must identify all class members at class certification ... .” *Id.* Nor must plaintiffs “demonstrate that a single record, or set of records, conclusively establishes class membership.” *City Select Auto Sales Inc. v. BMW Bank of N. Am., Inc.*, 867 F.3d 434, 441 (3d Cir. 2017). Rather, at this stage of the litigation, a plaintiff need only show that “class members *can* be identified.” *Byrd*, 784 F.3d at 163 (quoting *Carrera*, 727 F.3d at 308 n.2) (emphasis in original).

Here, the Settlement Classes' definitions provide objective criteria to identify the Settlement Classes' members – the payment of money for an MCD (intended for personal or household use) that was manufactured, distributed, or sold by Teva or Granules and Heritage

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<sup>8</sup> More recently, however, in *In re Comcast Corp. Set-Top Cable Television Box Antitrust Litig.*, 656 Fed. Appx. 8, 8-9 (3d Cir. 2016), the Third Circuit reversed the denial of certification of a settlement class for lack of ascertainability. The Third Circuit noted that the existence of an administratively feasible method for ascertaining a class “is not implicated by this case, because the settlement agreement removes the need for a trial.” *Id.*

during the relevant Settlement Class period. The collection and review of claims and pharmaceutical data can be used to identify and confirm membership in the Settlement Classes and allow for the recording of exclusions to the Settlement Classes. Thus, the Settlement Classes meet both prongs of the Third Circuit’s ascertainability standard.

## **2. Rule 23(b) Supports Class Certification**

As to the predominance and superiority requirements, the Third Circuit has noted that it is “more inclined to find the predominance test met in the settlement context.” *In re NFL Players Concussion II*, 821 F.3d at 434 (quoting *Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 304 n.29 (3d Cir. 2011)). Likewise, superiority is easily met because when “[c]onfronted with a request for settlement-only class certification, a district court need not inquire whether the case, if tried, would present intractable management problems...for the proposal is that there will be no trial.” *Amchem*, 521 U.S. at 620 (explaining that Rule 23(b)(3)(D) drops out of the analysis). As shown below, the predominance and superiority requirements are met for purposes of these Settlement Classes.

### **a. Common Legal and Factual Questions Predominate over Any Individual Issues**

The predominance inquiry tests the cohesion of the class, “ask[ing] whether the common, aggregation-enabling, issues in the case are more prevalent or important than the non-common, aggregation-defeating, individual issues.” *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 453 (2016) (citation omitted). Focusing on defendants’ uniform conduct is critical. *See Sullivan*, 667 F.3d at 298 (“[T]he focus of the predominance inquiry is on whether the defendant’s conduct was common as to all of the class members, and whether all of the class members were harmed by the defendant’s conduct.”). Thus, predominance is ordinarily satisfied, for settlement purposes, when the claims arise out of the defendant’s common conduct. *See, e.g., Zeno v. Ford Motor Co.*, 238 F.R.D. 173, 194 (W.D. Pa. 2006) (finding predominance met because the plaintiff’s breach of

contract theory “can be proved or disproved by reference to and interpretation of standard form documents”); *Yaeger v. Subaru of Am., Inc.*, No. 114CV4490JBSKMW, 2016 WL 4541861, at \*7 (D.N.J. Aug. 31, 2016) (predominance satisfied for purposes of settlement where Subaru vehicles had allegedly common, undisclosed design defect).

The rule, however, “does *not* require a plaintiff seeking class certification to prove that each ‘elemen[t] of [her] claim [is] susceptible to classwide proof.’” *Amgen Inc. v. Conn. Ret. Plans. & Tr. Funds*, 568 U.S. 455, 469 (2013) (emphasis and alterations in original). Rather, predominance is determined by whether “the efficiencies gained by class resolution of the common issues are outweighed by individual issues.” *Varacallo v. Mass. Mut. Life Ins. Co.*, 226 F.R.D. 207, 231 (D.N.J. 2005) (citation omitted); *In re Mercedes-Benz Antitrust Litig.*, 213 F.R.D. 180, 186 (D.N.J. 2003) (predominance requires that “common issues be both numerically and qualitatively substantial in relation to the issues peculiar to individual class members”).

Here, the predominance requirement under Rule 23(b)(3) is satisfied for the same reasons that the commonality requirement of Rule 23(a) is met. According to Class Plaintiffs, Defendants alleged single and uniform conduct—manufacturing, distributing and selling MCDs that were adulterated and/or misbranded because of NDMA contamination and cGMP failures – resulted in each member of the Settlement Classes purchasing or reimbursing a product unfit for its ordinary purpose and thus legally unsalable. As alleged, all members of the Settlement Classes’ claims turn on the same key questions: whether Defendants’ representations concerning the MCDs quality or cGMP compliance were uniformly false or misleading, and whether Defendants’ actions violated consumer protection and warranty laws. Because these common issues dominate the litigation, common questions of law and fact will predominate over any potential individual inquiries.

**b. Superiority**

The Rule 23(b)(3) superiority inquiry “asks the court to balance, in terms of fairness and efficiency, the merits of a class action against those of alternative available methods of adjudication.” *In re Warfarin Sodium Antitrust Litig.*, 391 F.3d 516, 528 (3d Cir. 2004); *Amchem*, 521 U.S. at 615.

Here, each member of the Settlement Classes’ losses may be small compared to the expense of retaining individual counsel and shouldering the costs of pursuing a separate lawsuit. Likewise, the burden on the courts would be large if each member of the Settlement Classes pursued individual litigation as such suits would need to be pursued in multiple jurisdictions. Consequently, “[t]he Settlement Class contains [thousands] of members, ‘and, absent certification, they would have to conduct individual trials, which would likely prove too costly for individuals[,] [and] would burden the Court.’” *Smith*, 2019 WL 3281609, at \*4 (quoting *Alfaro v. First Advantage LNS Screening Sols., Inc.*, No. 17-5813 (MAS) (TJB), 2017 WL 3567974, at \*4 (D.N.J. Aug. 16, 2017)). Because a class action ensures consistent adjudication of class-wide claims and is the most economical and efficient way to resolve these common allegations, a class action is superior to any other available method. *See, e.g., Varacallo*, 226 F.R.D. at 233 (finding the superiority requirement satisfied where it was “unlikely that individual Class Members would have the resources to pursue successful litigation on their own”).

**C. The Court Should Approve the Proposed Settlements Under Rule 23(e)(2)**

Having established that the Court will likely be able to certify the Settlement Classes proposed herein, Class Plaintiffs turn to the merits of the proposed Settlements. “Review of a proposed class action settlement is a two-step process: (1) preliminary approval, and (2) a subsequent fairness hearing.” *Atis v. Freedom Mortg. Corp.*, No. 15-03424 (RBK/JS), 2018 WL 5801544, at \*2 (D.N.J. Nov. 6, 2018).

At the first stage, the parties submit the proposed settlement to the court, which makes a preliminary fairness evaluation. If the proposed settlement is preliminarily acceptable, the court then directs that notice be provided to all class members who would be bound by the proposed settlement in order to give them a chance to be heard on, object to, and opt out of the settlement. *Id.* (citing *Shapiro v. All. MMA, Inc.*, No. 17-2583 (RBK/AMD), 2018 WL 3158812, at \*2 (D.N.J. June 28, 2018)); Fed. R. Civ. P. 23(c)(2), (e)(1), (e)(5). “Preliminary approval is not binding, and it is granted unless a proposed settlement is obviously deficient.” *Smith*, 2019 WL 3281609, at \*4; *accord Remicade*, 2022 WL 3042766, at \*10.

“Instead, [this preliminary evaluation] solely establishes an initial presumption of fairness . . . ‘if the court finds that: (1) the negotiations occurred at arm’s length; (2) there was sufficient discovery; (3) the proponents of the settlement are experienced in similar litigation; and (4) only a small fraction of the class objected.’” *Lupian v. Joseph Cory Holdings*, No. 16-CV-5172, 2019 WL 3283044, at \*5 (D.N.J. July 22, 2019) (citations omitted). These considerations align with those previously applied under *Girsh* and *Prudential II*, though streamlined. *See Prudential II*, 148 F.3d at 323-24; *Girsh*, 521 F.2d at 157. This brevity serves to “direct[] the parties to present the settlement to the court in terms of a shorter list of core concerns, by focusing on the primary procedural considerations and substantive qualities that should always matter to the decision on whether to approve the proposal.” Fed. R. Civ. P. 23(e)(2) advisory committee’s notes to 2018 amendments.

The Settlements readily satisfy the standard for preliminary approval under Rule 23(e). Here, the parties negotiated each Settlement separately and at arm’s length and the discussions were informed by discovery. Interim Co-Lead Counsel for Class Plaintiffs have extensive experience in complex class actions involving pharmaceutical marketing, adulteration, and related

consumer claims. Moreover, given the size and scope of the Settlement Classes, it is likely that only a small fraction – if any – would object, especially considering the Settlements’ beneficial terms and the *pro rata* Plan of Allocation.<sup>9</sup> As a result, the Settlements are entitled to a presumption of fairness at this preliminary stage.

Because the Rule 23(e)(2) inquiry substantially overlaps with the four-factor presumption of fairness and the *Girsh* factors, Class Plaintiffs address these points together in the following sections. After the Court grants preliminary approval, by June 18, 2026, or 120 days following entry of an order preliminarily approving the Settlements, Class Plaintiffs will move for Final Approval and the Settlement Classes will receive formal notice and have a full opportunity to raise objections, opt-out, or otherwise be heard. Accordingly, Plaintiffs respectfully request that the Court grant preliminary approval of the Settlements under Rule 23(e).

**1. The Settlements are the Product of Good Faith, Arm’s Length Negotiations Conducted by Well-Informed and Experienced Counsel**

Throughout the negotiations, the parties were mindful of the strengths and weaknesses of their claims and defenses. This evaluation included analysis of potential issues regarding Defendants’ liability under consumer protection and warranty laws, possible defenses including, but not limited to, those based on causation and standing, and the availability and scope of damages or restitution. The Settlements were reached only after extensive efforts since the litigation commenced. Thus, the third *Girsh* factor, which focuses on the stage of the proceedings and the amount of discovery completed, is satisfied.

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<sup>9</sup> The second *Girsh* factor, the reaction of the class to the settlement, does not yet apply, and will be addressed at the final approval stage after the Settlement Classes’ Members have been given notice of the Settlements and have had an opportunity to be heard. Class Plaintiffs will file their motion for Final Approval by June 18, 2026, or 120 days following entry of an order preliminarily approving the Settlements.

Interim Co-Lead Counsel have extensive experience in class action litigation, including pharmaceutical and consumer cases relating to product defects, adulteration, and false advertising. This collective expertise informed Counsel’s judgment that the Settlements are in the best interests of the Settlement Classes. *See Varacallo*, 226 F.R.D. at 240 (citing *In re Prudential Ins. Co. of Am. Sales Pracs. Litig.*, 962 F. Supp. 450, 543 (D.N.J. 1997) (“*Prudential I*”) (“the Court credits the judgment of Plaintiff’s Counsel, all of whom are active, respected, and accomplished in this type of litigation”)) (“Class Counsel’s approval of the Settlement also weighs in favor of [its] fairness.”); *In re NASDAQ Mkt.-Makers Antitrust Litig.*, 187 F.R.D. 465, 474 (S.D.N.Y. 1998) (Courts have consistently given “‘great weight’ . . . to the recommendations of counsel, who are most closely acquainted with the facts of the underlying litigation.”). The Settlement Classes’ Representatives also fully support the Settlements.

The fact that the Settlements resulted from arm’s length negotiations between experienced counsel demonstrates that the process was fair and free from collusion. *See Glaberson v. Comcast Corp.*, No. 03-6604, 2014 WL 7008539, at \*4 (E.D. Pa. Dec. 12, 2014) (a settlement is presumed to be fair “when the negotiations were at arm’s length, there was sufficient discovery, and the proponents of the settlement are experienced in similar litigation”); *see also, e.g., Smith*, 2019 WL 3281609, at \*5. As such, Class Plaintiffs respectfully contend that the way the parties reached the proposed Settlements support a presumption of fairness, weighing strongly in favor of preliminary approval by the Court.

**2. The Relief Provided to the Settlement Classes is Fair, Reasonable, and Adequate**

Under Rule 23(e)(2)(C), which overlaps with several of the *Girsh* factors (*i.e.*, factors 1, 4-9), the Court considers whether: the relief provided for the class is adequate, taking into account: (i) the costs, risks, and delay of trial and appeal; (ii) the effectiveness of any proposed method of

distributing relief to the class, including the method of processing class-member claims; (iii) the terms of any proposed award of attorney's fees, including timing of payment; and (iv) any agreement required to be identified under Rule 23(e)(3). *See* Fed. R. Civ. P. 23(e)(2)(i)-(iv); *Girsh*, 521 F.2d at 157 (factor one focuses on the complexity, expense, and likely duration of the litigation; factors four through nine focus on risks). As discussed above, Teva has agreed to pay \$3,000,000.00 and Granules and Heritage have agreed to pay \$2,550,000.00 to resolve the claims against them on a class-wide basis.

**a. The Costs, Risks, and Delay of Trial and Appeal**

Pharmaceutical cases are often lengthy and complex. This case was filed five years ago, and no doubt faces many risks and delays if litigation continues, including the pending motion to dismiss the Fourth Amended Complaint, future briefing on class certification and summary judgment, and through trial and appeal. Proceeding through these stages of litigation would significantly prolong the time until any member of the Settlement Classes could receive a financial recovery. Thus, the first *Girsh* factor is satisfied, and the adequacy of the Settlements is strongly supported by the risks and delays associated with continued litigation.

The fourth *Girsh* factor examines “the risks of establishing liability.” *Girsh*, 521 F.2d at 157. Under this factor, “[b]y evaluating the risks of establishing liability, the district court can examine what the potential rewards (or downside) of litigation might have been had class counsel elected to litigate the claims rather than settle them.” *Beneli v. BCA Fin. Servs., Inc.*, 324 F.R.D. 89, 103 (D.N.J. 2018) (quoting *In re Gen. Motors Corp. Pick-Up Truck Fuel Tank Prod. Liab. Litig.*, 55 F.3d 768, 814 (3d Cir. 1995) (“*GMC Truck*”). In considering this factor, courts have recognized that “[a] trial on the merits always entails considerable risk[s].” *Pro v. Hertz Equip. Rental Corp.*, 2013 WL 3167736, at \*4 (D.N.J. June 20, 2013) (citing *Weiss v. Mercedes-Benz of*

*N. Am., Inc.*, 899 F. Supp. 1297, 1301 (D.N.J. 1995), aff'd, 66 F.3d 314 (3d Cir. 1995)). And “no matter how confident one may be of the outcome of [the] litigation, such confidence is often misplaced.” *In re Auto. Refinishing Paint Antitrust Litig.*, 617 F. Supp. 2d 336, 343 (E.D. Pa. 2007).

Even though Class Plaintiffs believe their claims regarding adulterated or misbranded MCDs (as well as their causes of action under federal and state consumer protection and warranty laws) are meritorious, they face many hurdles. In this case, both Teva and Granules and Heritage have defended themselves at every step of the litigation and would certainly continue to press forward with its defenses through trial. For instance, Defendants could challenge class certification based on purported variations in state laws or issues related to reliance, and whatever the outcome of that motion, there likely would be a Rule 23(f) appeal. Likewise, Defendants would probably move for summary judgment or mount other procedural and substantive defenses up to and through trial and any subsequent appeals.

Similarly, the fifth *Girsh* factor ““attempts to measure the expected value of litigating the action rather than settling it at the current time.”” *In re Cendant Corp. Litig.*, 264 F.3d 201, 238 (3d Cir. 2001) (quoting *GMC Truck*, 55 F.3d at 816). The court considers the potential damage award if the case were to proceed to trial against the benefits of immediate settlement. *In re Prudential Ins. Co. Am. Sales Prac. Litig. Agent Actions*, 148 F.3d 283, 319 (3d Cir. 1998). In *Warfarin Sodium*, the trial court found that the risk of establishing damages strongly favored settlement, observing that “[d]amages would likely be established at trial through ‘a “battle of experts,” with each side presenting its figures to the jury and with no guarantee whom the jury would believe.”” *In re Warfarin Sodium Antitrust Litig.*, 212 F.R.D. 231, 256 (D. Del. 2002), aff'd, 391 F.3d 516, 537 (3d Cir. 2004). Here, if the case were to proceed through trial, Defendants would likely assert complex scientific and regulatory arguments requiring costly expert testimony on

manufacturing processes, NDMA levels, and the causal connection to any claimed economic loss. Thus, a battle of the experts would occur at trial rather than the certainty that these Settlements offer.

In complex cases, “[t]he risks surrounding a trial on the merits are always considerable.” *Weiss*, 899 F. Supp. at 1301. As a result, settlements are favored where “continuing litigation through trial would have required additional discovery, extensive pretrial motions addressing complex factual and legal questions, and ultimately a complicated, lengthy trial.” *In re Ins. Brokerage Antitrust Litig.*, 282 F.R.D. 92, 103 (D.N.J. 2012) (quoting *In re Warfarin*, 391 F.3d at 536). Even if Class Plaintiffs ultimately prevailed at trial, the appeals process and potential delays in administering relief to the Classes would be protracted and costly. “Compared to the costs and risks of continued litigation, the settlement avoids these uncertainties and provides the . . . class with substantial and certain relief.” *Teh Shou Kao v. CardConnect Corp.*, No. 16-CV-5707, 2021 WL 698173, at \*7-\*8 (E.D. Pa. Feb. 23, 2021).

The Settlements avoid these risks and ensure prompt relief to members of the Settlement Classes, reflecting a fair and adequate resolution in light of all the litigation uncertainties.

**b. Whether the Settlements Fall Within the Range of Reasonableness**

*Girsh* requires the court to evaluate the proposed Settlements alongside “a range of reasonable settlements in light of the best possible recovery (the eighth *Girsh* factor) and . . . in light of all the attendant risks of litigation (the ninth factor).” *Merck/Vytorin*, 2010 WL 547613, at \*9. In making a “range of reasonableness” assessment, courts do not need to make a precise estimate of damages. Compare *In re N.J. Tax Sales Certificates Antitrust Litig.*, No. CV121893MASTJB, 2016 WL 5844319, at \*8 (D.N.J. Oct. 3, 2016) (granting final approval where “it is not possible to predict the precise value of damages that Plaintiffs would recover if

successful”).

Given the complexity of this case and the risks and delays associated with continued litigation, these Settlements with a combined total \$5.55 million common fund, which are non-reversionary as opposed to claims-made settlements, are a significant outcome. Considering that the case has been litigated for five years, and the amount of recovery, the Settlements here fall well within the range of reasonableness given the attendant risks and uncertainties of continued litigation and should be preliminarily approved. *See Girsh*, 521 F.2d at 157.

**c. The Effectiveness of Any Proposed Method of Distributing Relief to the Classes, Including the Method of Processing the claims of the members of the Classes**

“Approval of a plan of allocation of a settlement fund in a class action is governed by the same standards of review applicable to approval of the settlement as a whole: the distribution plan must be fair, reasonable, and adequate.” *Kanefsky v. Honeywell Int’l Inc.*, No. 18-cv-15536 (WJM), 2022 WL 1320827, at \*6 (D.N.J. May 3, 2022) (quoting *In re AremisSoft Corp. Sec. Litig.*, 210 F.R.D. 109, 126 (D.N.J. 2002)). “In general, a plan of allocation that reimburses class members based on the type and extent of their injuries is reasonable.” *Kanefsky*, 2022 WL 1320827, at \*6 (quoting *In re Ikon Off. Sols., Inc., Sec. Litig.*, 194 F.R.D. 166, 184 (E.D. Pa. 2000)).

Here, the proposed Plan of Allocation will be developed by Class Counsel in consultation with one or more experts who specialize in damage allocation and healthcare economics to create a distribution method that treats each member of the Settlement Classes equitably. Under the Plan of Allocation, each member of the Settlement Classes who submits a valid claim form will be compensated *pro rata* from the Net Settlement Fund – *i.e.*, the Total Settlement Amount minus any Court-approved fees, expenses, and other allowable costs – in an amount commensurate with each member of the Settlement Classes’ damages.

**d. The Terms of Any Proposed Award of Attorneys' Fees,  
Including Timing of Payment**

Following preliminary approval, during the final approval process, Interim Co-Lead Counsel will file a motion for an award of attorneys' fees. Interim Co-Lead Counsel will limit their attorneys' fee request to no more than thirty-four percent (34%) of the \$5,550,000.00 Total Settlement Amount, payable upon Final Approval by the Court. The anticipated fee request is in line with fee awards in other cases of similar complexity and size. *See, e.g., Castro v. Sanofi Pasteur Inc.*, No. 11-7178 (JMV) (MAH), 2017 WL 4776626, at \*9 (D.N.J. Oct. 23, 2017) ("The one-third fee is within the range of fees typically awarded within the Third Circuit through the percentage-of-recovery method; the Circuit has observed that fee awards generally ranged from 19% to 45% of the settlement fund. Thus, the requested fee in this matter [of one-third of the settlement fund] is within the normal range."); *Marchbanks Truck Serv., Inc. v. Comdata Network, Inc.*, No. 07-1078-JKG, 2014 WL 12738907, at \*2 (E.D. Pa. July 14, 2014) ("fee awards of one-third of the settlement amount are commonly awarded in this Circuit"); *In re Fasteners Antitrust Litig.*, No. 08-md-1912, 2014 WL 2969654, at \*7 (E.D. Pa. Jan. 27, 2014) ("Counsel's request for one third of the settlement fund is consistent with other direct purchaser antitrust actions."); *Ikon*, 194 F.R.D. at 194 ("Percentages awarded have varied considerably, but most fees appear to fall in the range of nineteen to forty-five percent.").

**e. There Are No Side Agreements that Impact the Adequacy of  
the Relief for the Settlement Classes**

Under Rule 23(e)(3), "[t]he parties seeking approval must file a statement identifying any agreement made in connection with the proposal. Fed. R. Civ. P. 23(e)(3). The Settlement Agreements themselves set forth all relevant terms and agreements related to the Settlements; there are no undisclosed side agreements. Defendants do maintain a standard, qualified right to terminate

the Settlements if certain conditions – such as excessive opt-outs – are met prior to Final Approval. Courts routinely acknowledge that these clauses are common in complex class action settlements and do not affect the fairness of the Settlements. *See, e.g., In re Carrier IQ, Inc., Consumer Privacy Litig.*, No. 12-md-02330, 2016 WL 4474366, at \*5, \*7 (N.D. Cal. Aug. 25, 2016) (court “not troubled” by similar agreement because “those kind of opt-out deals are not uncommon as they are designed to ensure that an objector cannot try to hijack a settlement in his or her own self-interest.”).

**3. The Proposal Treats the members of the Settlement Classes Equitably Relative to Each Other**

Finally, Rule 23(e)(2)(D) instructs courts to evaluate whether the proposed Settlements “treats class members equitably relative to each other.” As discussed in connection with the proposed Plan of Allocation, the Settlements provide for a proportional distribution of the Net Settlement Fund based on the criteria set forth therein, with final allocations determined by the Claims Administrator in compliance with the Plan of Allocation. This means each Settlement Class Member’s recovery will correspond to the extent of their alleged economic harm (*e.g.*, out-of-pocket costs or reimbursements for the at-issue Teva or Granules and Heritage MCDs). Courts within this Circuit have consistently approved similar approaches as equitable. *See Becker v. Bank of N.Y. Mellon Tr. Co., N.A.*, No. 11-6460, 2018 WL 6727820, at \*7 (E.D. Pa. Dec. 21, 2018) (“Allocating settlement proceeds to class members based on their proportional shares of the [transactions] satisfies this factor.”). Accordingly, based on the foregoing, Class Plaintiffs respectfully contend that the Court should preliminarily approve the proposed Settlements.

**D. The Court Should Approve the Proposed Notice Plan to the Classes**

Rule 23(e)(1)(B) provides that a court must “direct notice in a reasonable manner to all class members who would be bound by the proposal.” Fed. R. Civ. P. 23(e)(1)(B). In a Rule

23(b)(3) class settlement, the notice must also satisfy Rule 23(c)(2)(B), which requires “the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort.” Fed. R. Civ. P. 23(c)(2)(B). The Third Circuit has consistently recognized a court’s broad discretion in directing the manner of notice, so long as the notice program is reasonably calculated, under the circumstances, to apprise interested parties. *See Mullane v. Cent. Hanover Bank & Tr. Co.*, 339 U.S. 306, 314 (1950); *see also In re Warfarin*, 391 F.3d at 536 (affirming a district court’s approval of notice plan that apprised the class members of the nature of the action and the proposed settlement and gave the class members an opportunity to raise objections).

Class Plaintiffs propose the appointment of AB Data as the Notice and Claims Administrator. AB Data is a nationally recognized company that specializes in providing notices in class actions and in administering class settlements. Indeed, AB Data has been appointed as the notice and claims administrator in numerous class action settlements in this District and throughout the country. A copy of AB Data’s resume/CV is attached as **Exhibit 4** to the Cecchi Declaration.

AB Data has created a robust Notice Plan that employs direct notice via email (where feasible) to third-party payors, supplemented by publication notice to consumers and a dedicated settlement website. A true and correct copy of the Notice Plan is attached as **Exhibit 5** to the Cecchi Declaration.

Courts in this Circuit have routinely approved a combination of direct mail/email notice and publication as satisfying the “best notice practicable” standard. *See Warfarin*, 391 F.3d at 536 (approving mailed and published notice). This Notice Plan will ensure due process and easily permit class members to object, opt-out, or otherwise voice concerns at a later final approval hearing. The Short Form and Long Form Notices were developed by AB Data and agreed to by

the parties, and will be shared with all persons who fall within the definitions of the Settlement Classes and whose mailing and/or email addresses can be identified with reasonable effort from the parties and/or pharmaceutical purchase records. In addition, AB Data will administer the Settlement Website containing relevant information about the Settlements.

Moreover, Rule 23(h)(1) requires that “[n]otice of the motion [for attorneys’ fees] must be served on all parties and, for motions by class counsel, directed to class members in a reasonable manner.” Fed. R. Civ. P. 23(h)(1). The proposed Notice Plan satisfies the requirements of Rule 23(h)(1), as it notifies the Settlement Classes’ Members that Interim Co-Lead Counsel will apply to the Court for an award of attorneys’ fees of no more than 34% of the \$5,550,000 Common Fund, plus litigation expenses. The Notice Plan complies with Federal Rule of Civil Procedure 23 and due process because, among other things, it informs the Settlement Classes’ Members of: (1) the nature of the Action; (2) the essential terms of the Settlements, including the definitions of the Settlement Classes, the claims asserted, and the benefits offered; (3) the binding effect of a judgment if the Settlement Classes’ Member does not request exclusion; (4) the process for submitting objections and exclusions, including the time and method for objecting or requesting exclusion and that Settlement Classes’ Members may make an appearance through counsel; (5) information regarding Interim Co-Lead Counsel’s request for awards of fees and expenses; and (6) how to make inquiries. Fed. R. Civ. P. 23(c)(2)(B).

As a result, Plaintiffs respectfully request that the Court approve the proposed Notice Plan.

### **CONCLUSION**

For all these reasons, Class Plaintiffs respectfully request that the Court enter the proposed Order:

- 1) preliminarily certifying the two Settlement Classes for settlement purposes;

- 2) appointing Joseph Brzozowski, Jacqueline Harris, Kristen Wineinger, Michael Hann, and Masao Hendrix (“Consumer Plaintiffs”) on behalf of Consumer Plaintiffs and MSP Recovery Claims, Series LLC, County of Monmouth, and Central Midwest Regional Council of Carpenters Welfare Fund f/k/a Ohio Carpenters’ Health Fund on behalf of TPP Plaintiffs as the Settlement Classes’ Representatives;
- 3) appointing James Cecchi, Conlee Whiteley, David Stanoch, Max Roberts, Ruben Honik, Joseph Guglielmo, Marlene Goldenberg, Charlie Schaffer, Fred Longer, Janpaul Portal, and Michael Fitzgerald (“Interim Co-Lead Counsel”) as Class Counsel for the Settlement Classes;
- 4) granting preliminary approval of the proposed Settlements;
- 5) appointing AB Data as the Notice and Claims Administrator;
- 6) approving the proposed Notice Plan;
- 7) setting June 18, 2026, or 120 days following entry of an order preliminarily approving the Settlements as the deadline for Class Plaintiffs to move for Final Approval of the Settlements;
- 8) appointing Huntington National Bank as the Escrow Agent; and
- 9) further staying the litigation as to Teva and Granules and Heritage, except for proceedings for purposes of effectuating the Settlements.

Dated: February 11, 2026

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I certify that on February 11, 2026, a true and correct copy of the foregoing was served on all counsel of record via the Court's CM/ECF system.

/s/ James E. Cecchi

James E. Cecchi