UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: CHANTIX (VARENICLINE) MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION II	22-MD-3050 (KPF) 22-MC-3050 (KPF)

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR UNOPPOSED MOTION FOR PRELIMINARY APPROVAL OF PROPOSED SETTLEMENT, PRELIMINARY CERTIFICATION OF SETTLEMENT CLASS, AND APPROVAL OF NOTICE PLAN

TABLE OF CONTENTS

I. FACTUAL AND PROCEDURAL BACKGROUND 2

A. PROCEDURAL HISTORY 2

B. NEGOTIATION OF THE SETTLEMENT AND THE TERMS OF THE PROPOSED SETTLEMENT 4

II. ARGUMENT 6

A. PRELIMINARY APPROVAL OF THE SETTLEMENT IS WARRANTED 6

1. Standards for Preliminary Approval of a Proposed Class Action Settlement 6

2. Rule 23(e)(2)(A): Adequate Representation 8

3. Rule 23(e)(2)(B): The Settlement Is the Product of Good Faith, Informed, and Arm's-Length Negotiations by Experienced Counsel 9

B. RULE 23(e)(2)(C): THE SETTLEMENT PROVIDES SIGNIFICANT AND CERTAIN BENEFITS 10

1. Despite Strong Claims, Many Risks to Recovery Remained 10

2. The Effective Process for Distributing Relief to the Settlement Class 12

3. The Settlement Does Not Excessively Compensate Class Counsel 13

C. RULE 23(e)(2)(D): SETTLEMENT CLASS MEMBERS ARE TREATED EQUITABLY RELATED TO ONE ANOTHER 13

D. THE REMAINING *GRINNELL FACTORS* SUPPORT PRELIMINARY APPROVAL 14

III. PRELIMINARY CERTIFICATION OF THE SETTLEMENT CLASS 16

A. RULE 23(a)'S REQUIREMENTS ARE READILY MET 16

1. Numerosity 16

2. Commonality 17

3. Typicality 17

4. Adequacy 19

B. THE PROPOSED SETTLEMENT CLASS SATISFIES THE REQUIREMENTS OF RULE 23(b)(3) 20

1. Common Questions Predominate 20

2. A Class Action Is a Superior Mechanism 21

IV. THE PROPOSED NOTICE PROGRAM SHOULD BE APPROVED 22

CONCLUSION 23

TABLE OF AUTHORITIES

Page(s)

Cases

Amchem Prods. v. Windsor,
521 U.S. 591 (1997)....................16, 20, 21

Berk v. Choy,
607 U.S. 187 (2026)....................3

Bodon v. Domino's Pizza, LLC,
2015 WL 588656 (E.D.N.Y. Jan. 16, 2015)....................11, 12

Bolanos v. Norwegian Cruise Lines Ltd.,
212 F.R.D. 144 (S.D.N.Y. Nov. 26, 2002)....................19

Cavalieri v. Gen. Elec. Co.,
2009 WL 2426001 (N.D.N.Y. Aug. 6, 2009)....................15

Cent. States Se. & Sw. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C.,
504 F.3d 229 (2d Cir. 2007)....................13

City of Detroit v. Grinnell Corp.,
495 F.2d 448 (2d Cir. 1974)....................7, 15

Consol. Rail Corp. v. Town of Hyde Park,
47 F.3d 473 (2d Cir. 1995)....................16

D'Amato v. Deutsche Bank,
236 F.3d 78 (2d Cir. 2001)....................10, 15

Dziennik v. Sealift, Inc.,
2007 WL 1580080 (E.D.N.Y. May 29, 2007)....................19

Ebin v. Kangadis Food Inc.,
297 F.R.D. 561 (S.D.N.Y. 2014)....................18

Green v. Wolf Corp.,
406 F.2d 291 (2d Cir. 1968)....................21

Hecht v. United Collection Bureau, Inc.,
691 F.3d 218 (2d Cir. 2012)....................22

Hurtado v. 183 Food Mkt. Corp.,
2022 WL 2294074 (S.D.N.Y. June 24, 2022)....................13

In re Am. Int'l Group, Inc. Sec. Litig.,
689 F.3d 229 (2d Cir. 2012)....................21

In re Barclays PLC Sec. Litig.,
2024 WL 6070023 (S.D.N.Y. Dec. 5, 2024) 6, 8

In re Barclays PLC Sec. Litig.,
2025 WL 842939 (S.D.N.Y. Mar. 18, 2025) 13

In re GSE Bonds Antitrust Litig.,
414 F. Supp. 3d 686 (S.D.N.Y. 2019)....................9, 10

In re IMAX Sec. Litig.,
283 F.R.D. 178 (S.D.N.Y. 2012) 14, 21

In re Initial Pub. Offerings Sec. Litig.,
471 F.3d 24 (2d Cir. 2006)....................11

In re J.P. Morgan Stable Value Fund ERISA Litig.,
2019 WL 4734396 (S.D.N.Y. Sept. 23, 2019)....................13

In re Kind LLC "Healthy & All Natural" Litig.,
337 F.R.D. 581 (S.D.N.Y. 2021) 18

In re Merrill Lynch Tyco Rsch. Sec. Litig.,
249 F.R.D. 124 (S.D.N.Y. 2008) 13

In re NASDAQ Mkt.-Makers Antitrust Litig.,
176 F.R.D. 99 (S.D.N.Y. 1997) 9

In re NASDAQ Mkt.-Makers Antitrust Litig.,
187 F.R.D. 465 (S.D.N.Y. 1998) 10

In re Nassau Cnty. Strip Search Cases,
461 F.3d 219 (2d Cir. 2006)....................21

In re Nissan Radiator/Transmission Cooler Litig.,
2013 WL 4080946 (S.D.N.Y. May 30, 2013) 18

In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig.,
330 F.R.D. 11 (E.D.N.Y. 2019)....................8, 16

In re Petrobras Sec.,
862 F.3d 250 (2d Cir. 2017)....................11, 20

In re Sinus Buster Prods. Consumer Litig.,
2014 WL 5819921 (E.D.N.Y. Nov. 10, 2014)....................15

In re Sony SXRD Rear Projection Television Class Action Litig.,
2008 WL 1956267 (S.D.N.Y. May 1, 2008) 15

In re Vitamin C,
2012 WL 5289514 (E.D.N.Y Oct. 23, 2012) 23

Johnson v. Nextel Commc'ns Inc.,
780 F.3d 128 (2d Cir. 2015) 17

Kelwin Inkwel, LLC v. PNC Merch. Servs. Co., L.P.,
2022 WL 3127633 (E.D.N.Y. Apr. 12, 2022) 13

Marisol A. v. Giuliani,
126 F.3d 372 (2d Cir. 1997) 17

Meredith Corp. v. SESAC, LLC,
87 F. Supp. 3d 650 (S.D.N.Y. 2015) 22

Moses v. New York Times Co.,
2026 WL 364231 (2d Cir. Feb. 10, 2026) 11

Moses v. New York Times Co.,
79 F.4th 235 (2d Cir. 2023) 7

Schutter v. Tarena Int'l, Inc.,
2024 WL 4118465 (E.D.N.Y. Sept. 9, 2024) 15

Stinson v. City of New York,
282 F.R.D. 360 (S.D.N.Y. 2012) 18

Sykes v. Mel Harris & Assocs.,
LLC, 285 F.R.D. 279 (S.D.N.Y. 2012) 17

Tart v. Lions Gate Entm't Corp.,
2015 WL 5945846 (S.D.N.Y. Oct. 13, 2015) 22

Toure v. Cent. Parking Sys.,
2007 WL 2872455 (S.D.N.Y. Sept. 28, 2007) 19

U.S. Fid. & Guar. Co. v. Madison Fin. Corp.,
2002 WL 31731020 (S.D.N.Y. Dec. 4, 2002) 16

Viafara v. MCIZ Corp.,
2014 WL 1777438 (S.D.N.Y. May 1, 2014) 15

Wal-Mart Stores, Inc. v. Dukes,
564 U.S. 338 (2011) 17, 20

Wal-Mart Stores, Inc. v. Visa U.S.A., Inc.,
396 F.3d 96 (2d Cir. 2005)....................6, 11, 22

Zivkovic v. Laura Christy LLC,
329 F.R.D. 61 (S.D.N.Y. 2018)....................17

Other Authorities

FED. R. CIV. P. 23.................... *passim*

After years of litigation, Plaintiffs' Interim Co-Lead and Liaison Counsel, on behalf of Consumer Plaintiffs[1] and Third-Party Payor Plaintiffs[2] and all other Settlement Class Members[3] (collectively "Plaintiffs"), announce the parties have reached an agreement on a proposed class-wide settlement of this matter with Defendant Pfizer, Inc. ("Pfizer" or "Defendant"), which will provide substantial relief to Plaintiffs and the Settlement Class. This settlement would resolve the claims of purchasers and payors of Pfizer's Chantix®—the branded version of varenicline, which is prescribed for smoking cessation—who allege that they were deceived into purchasing and/or paying for a drug that was contaminated with a genotoxic, probable human carcinogen, a nitrosamine known as N-nitroso varenicline ("NNV"), and as such, they overpaid for their purchases of the drug. As part of the settlement, Pfizer will establish a Settlement Fund of $44,000,000, with no right to reversion, that will compensate eligible and participating Settlement Class Members, pay for Notice and Settlement Administration costs, pay Court-approved reasonable attorneys' fees and expenses, and pay Court-approved Service Awards to Plaintiffs.

Plaintiffs respectfully submit that the Settlement warrants preliminary approval and meets all the requirements of FED. R. CIV. P. 23 and Second Circuit precedent, as it is the result of arm's length negotiations overseen by a seasoned mediator[4], performed by experienced legal counsel whose opinions were informed after extensive discovery of the merits of the claims. Plaintiffs and Class Counsel were aware of the strengths and weaknesses of Plaintiffs' claims and made a well-

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[1] Juan Abreu, Teresa Baptiste, Timothy Bleeker, Harold Bradley, Sharon Carroll, Karen Duff, Albert Edwards, Tara Evans, Lillian Forrest, Kimberly Hill, Valerie Hogue, Douglas Houghton, James Jacobson, Tammy LaMotte, Kathleen Lima, Debra Seeley, Daniel Spence, Hazel Taylor, Carita Thompson, Daphne Walter, Shannon Webb a/k/a Shannon Alicea (the "Consumer Plaintiffs").

[2] County of Monmouth, MSP Recovery Claims, Series 44, LLC, MSP Recovery Claims, Series LLC, and Ohio Carpenters' Health Fund (the "TPP Plaintiffs").

[3] Unless otherwise defined, capitalized terms shall have the same meaning as the Class Action Settlement Agreement.

[4] Fouad Kurdi, Esq. of Resolutions LLC. *See* https://resolutionsllc.com/fouad-kurdi/.

informed evaluation of the risks of continued litigation of this complex case against the benefits of settlement at this time. The $44 million Settlement is a favorable recovery that falls well within the range of reasonableness. If the Court grants preliminary approval, Plaintiffs will provide notice of the Settlement's terms and conditions to potential Settlement Class Members. A final approval hearing will then be conducted so that the Parties and Settlement Class Members may present arguments and evidence for and (if there are any objectors against) the Settlement, and the Court will then make a final determination as to whether the Settlement is fair, reasonable, and adequate. The Court will also be asked to approve the proposed plan of allocation for distributing the Settlement Fund and to consider Class Counsel's motion for a Fee and Expense Award, including a request for Service Awards to Plaintiffs.

The proposed Preliminary Approval Order has been negotiated by the Parties and will, among other things: (i) preliminarily approve the Settlement on the terms set forth in the Settlement Agreement; (ii) preliminarily certify the Settlement Class and appoint the Class Representatives and Class Counsel, for purposes of the Settlement only; (iii) appoint a Settlement Administrator and Escrow Agent; (iv) approve the form and content of the Class Notice; and (v) set a schedule for the Final Approval Hearing, including an opt-out and objection deadlines and the claim submission deadline; *See* Declaration of Joseph P. Guglielmo in Support of Plaintiffs' Unopposed Motion for Preliminary Approval, Ex.1 (Proposed Order Granting Preliminary Approval, attached as Ex. 7 to Settlement Agreement). For the reasons stated herein, Plaintiffs respectfully request that the Court enter the Preliminary Approval Order.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. PROCEDURAL HISTORY

This Action was centralized on December 22, 2022, by the Judicial Panel on Multidistrict Litigation, which consolidated eight pending cases in this transferee Court, *see* ECF No. 1, followed by eight more on January 4, 2023, *see* ECF No. 2, and Ohio Carpenters' Health Fund's related action following its filing of a related complaint on January 17, 2023. These cases now comprise the present Action.

Following written submissions, on May 1, 2023, the Court appointed interim co-lead counsel and liaison counsel for the proposed classes. *See* ECF No. 39. Thereafter, Plaintiffs filed their Consolidated Master Class Action Complaint on May 5, 2023 (the "Complaint"). ECF No. 40. The Complaint alleges economic damages on behalf of a nationwide class of consumers and third-party payors ("TPPs") that paid for Chantix that was contaminated with NNV, a genotoxic, probable human carcinogen. The central allegation of the Complaint is that Pfizer failed to disclose the presence of NNV in Chantix and that Plaintiffs overpaid for their purchases of the drug.

After extensive briefing on Pfizer's Motion to Dismiss, ECF No. 42-45, 49-52, on May 28, 2024, the Court denied in part Pfizer's motion to dismiss and allowed Plaintiff's consumer protection, and certain unjust enrichment claims to proceed on the basis that Pfizer did not disclose that Chantix was not manufactured in compliance with current Good Manufacturing Practices ("cGMPs"). *See* ECF 58 at 18, 91. The Court required supplemental briefing on the breach of warranty and negligence-based claims. *See* ECF 58 at 91. After another round of letter briefing, *see* ECF No. 62, 70, the Court dismissed all express and implied warranty claims and the negligence-based claims except for negligent misrepresentation under two states laws on May 6, 2025, *see* ECF No. 83. Pfizer filed its answer on July 15, 2025, ECF No. 99, and discovery commenced. Although the pleadings were joined, more recently, Plaintiffs sought reconsideration of the breach of warranty dismissal in light of *Berk v. Choy*, 607 U.S. 187 (2026). *See* ECF No. 116.

In the interim, the Parties engaged in extensive discovery, including non-party discovery. Requests for production of documents were exchanged by the Parties. Document production was substantially completed as of February 2026. By that time, Plaintiffs reviewed over 250,00 documents totaling approximately 2.11 million pages produced by Pfizer and third parties. Plaintiffs also served 118 requests for production of documents, 7 interrogatories, and 95 requests for admission on Pfizer. Defendant served 71 requests for production of documents on each Consumer Plaintiff and 73 to 86 requests for production of documents on each TPP Plaintiff, 16 interrogatories on each Consumer Plaintiff and 17 to 21 interrogatories on each TPP Plaintiff, and 41 requests for admission on each Consumer Plaintiff and 143 requests for admission on each TPP Plaintiff. Plaintiffs also subpoenaed seven non-parties (SQA, Express Scripts, Apotex, MedImpact, Walgreens, Roquette, and Caremark) and Defendant subpoenaed 6 non-parties (Walgreens, Walmart, CVS, Express Scripts, OptumRx, and MedImpact) for relevant documents and data. Defendant deposed several Consumer Plaintiffs. Plaintiffs deposed, pursuant to Rule 30(b)(1), Pfizer's Global Solids Quality Leader, in Dublin, Ireland. At the time the Settlement was reached, Plaintiffs were preparing to defend several additional Consumer Plaintiffs and Third-Party Payor Plaintiffs for their depositions while preparing to depose several additional Pfizer deponents pursuant to Rule 30(b)(1) and Rule 30(b)(6).

B. NEGOTIATION OF THE SETTLEMENT AND THE TERMS OF THE PROPOSED SETTLEMENT

In December 2025, as fact and non-party discovery were already well underway, the Parties began exploring the possibility of a negotiated resolution of the Action through mediation, ultimately agreeing that the Parties' counsel would attend a mediation. The Parties agreed to employ the services of Fouad Kurdi, Esq. In connection with the mediation, Plaintiffs requested significant mediation discovery to evaluate the claims and to position themselves to negotiate a settlement that would be fair and reasonable on behalf of the Settlement Class. Defendant produced confidential documents and information regarding the pricing, profits, and quantities of Chantix sold throughout the Class Period. Plaintiffs also conducted their own due diligence, including consultations with experts in pharmaceuticals, cGMP compliance, and toxicology.

The Parties and their counsel conducted a full-day in-person mediation on March 11, 2026, before mediator Fouad Kurdi, at which the Parties agreed in principle to settle the Action for $44,000,000.00 through a non-reversionary cash settlement fund (the "Settlement Fund"). On March 12, 2026, the Parties wrote to the Court to inform it of their agreement to settle the Action and requested a stay of the action. ECF No. 122. On March 13, 2026, the Court granted the Parties' request for a 45-day stay of the case pending the filing of the motion for preliminary approval of the Settlement. ECF No. 123. On April 23, 2026, the Court granted the Parties' request to extend the stay until May 18, 2026, so the Parties could continue their negotiations. ECF Nos. 126, 127. The Court granted an additional stay until May 26, 2026, so the Parties could complete their discussions. ECF No. 128.

Thereafter, the Parties further negotiated the specific terms of their agreement and ultimately executed the Settlement Agreement on May 22, 2026. The Settlement Agreement provides that Defendant will pay or cause to be paid $44 million in cash into an interest-bearing Escrow Account. After the Settlement becomes final, Settlement Class Members who submit valid and timely Approved Claims will be entitled to a Cash Award from the Available Settlement Fund. Settlement Agreement ¶1.5.

Further, for settlement purposes only, the Parties agreed to certification of a Settlement Class consisting of "all individuals and third-party payors who paid any amount of money for retail purchases of Chantix in the United States and its territories from September 29, 2015 through

September 17, 2021." *Id.* ¶1.30. As discussed below, the $44 million non-reversionary Settlement is a favorable recovery that falls well within the range of reasonableness and meets all of the approval factors required by FED. R. CIV. P. 23(e) and Second Circuit precedent. Accordingly, the Court should grant preliminary approval of the Settlement and direct that Notice be sent to Settlement Class Members. Plaintiffs further submit that the proposed Settlement Class satisfies all requirements of Rule 23(a) and 23(b)(3), and that the Court should certify the Settlement Class for purposes of effectuating the Settlement.

II. ARGUMENT

A. PRELIMINARY APPROVAL OF THE SETTLEMENT IS WARRANTED

1. Standards for Preliminary Approval of a Proposed Class Action Settlement

Public policy favors compromise and settlement of class actions. *See Wal-Mart Stores, Inc. v. Visa U.S.A., Inc.*, 396 F.3d 96, 116-17 (2d Cir. 2005) ("We are mindful of the strong judicial policy in favor of settlements, particularly in the class action context . . . . The compromise of complex litigation is encouraged by the courts and favored by public policy.") (citation omitted).

Rule 23 requires court approval of any settlement of a class action. A district court's review of a proposed class action settlement is a two-step process. *First*, the court reviews the terms of the proposed settlement to determine whether to send notice to the class. *See* FED. R. CIV. P. 23(e)(1); *see also In re Barclays PLC Sec. Litig.*, 2024 WL 6070023, at *1 (S.D.N.Y. Dec. 5, 2024) (order granting preliminary approval). *Second*, after notice and a hearing, the Court determines whether to grant final approval of the settlement. *See* FED. R. CIV. P. 23(e)(2). A court may grant preliminary approval of a settlement upon a finding that it "will likely be able to" approve the settlement as fair, reasonable, and adequate at the final hearing, and certify the class for purposes of judgment on the proposal. *See* FED. R. CIV. P. 23(e)(1)(B). By this motion, Plaintiffs request that the Court take this first step: preliminary approval of the Settlement.

The crux of a court's preliminary approval evaluation is whether notice should be provided to the class given the *likelihood* that the court will be able to finally approve the settlement, after considering "the four factors outlined in Rule 23(e)(2) holistically." *Moses v. New York Times Co.*, 79 F.4th 235, 243 (2d Cir. 2023); *see also* FED. R. CIV. P. 23(e)(1)(B). Rule 23(e)(2) provides that a court may approve a proposed settlement that would bind class members "only after a hearing and only on finding that it is fair, reasonable, and adequate after considering whether:

(A) class representatives and counsel have adequately represented;

(B) the proposal was negotiated at arm's length;

(C) 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); and

(D) the proposal treats class members equitably relative to each other."

FED. R. CIV. P. 23(e)(2).

Courts in the Second Circuit may also consider the factors enumerated in *City of Detroit v. Grinnell Corp.*, 495 F.2d 448 (2d Cir. 1974), many of which overlap with the Rule 23(e) factors. *See Moses*, 79 F.4th at 243 ("Rule 23(e)(2) does not displace our traditional *Grinnell* factors, which remain a useful framework for considering the substantive fairness of a settlement.").[5] Applying

[5] The *Grinnell* factors are: (1) the complexity, expense and likely duration of the litigation; (2) the reaction of the class to the settlement; (3) the stage of the proceedings and the amount of discovery completed; (4) the risks of establishing liability; (5) the risks of establishing damages; (6) the risks of maintaining the class through the trial; (7)

the standards set forth above, it is respectfully submitted that the Settlement should be preliminarily approved. *See, e.g.*, *Barclays*, 2024 WL 6070023 (granting preliminary approval).

2. Rule 23(e)(2)(A): Adequate Representation

"Determination of adequacy typically entails inquiry as to whether: (1) plaintiff's interests are antagonistic to the interests of other members of the class and (2) plaintiff's attorneys are qualified, experienced and able to conduct the litigation." *In re Payment Card Interchange Fee & Merch. Disc. Antitrust Litig.*, 330 F.R.D. 11, 30 (E.D.N.Y. 2019) (citations omitted). Plaintiffs have vigorously prosecuted this litigation since its inception and will continue to do so throughout the administration of the Settlement to secure and deliver its benefits to the Settlement Class. Pfizer served 71 requests for production of documents upon each Consumer Plaintiff and 73 to 86 requests for production of documents upon each TPP Plaintiff, 16 interrogatories upon each Consumer Plaintiff and 17 to 21 interrogatories upon each TPP Plaintiff, and 41 requests for admission upon each Consumer Plaintiff and 143 requests for admission upon each TPP Plaintiff. Plaintiffs also subpoenaed 7 non-parties (SQA, Express Scripts, Apotex, MedImpact, Walgreens, Roquette, and Caremark) for relevant documents and data. *See* Liaison Counsel Decl. ¶7.

Likewise, Class Counsel diligently prosecuted the Action in a collaborative and efficient manner. Class Counsel developed a deep understanding of the facts of the case and merits of the claims through: (i) a comprehensive investigation; (ii) working with multiple experts in the fields of pharmaceutical pricing and economics, pharmaceutical manufacturing regulations and quality management, and toxicology; (iii) defeating, in part, Defendant's motion to dismiss; (iv) commencing and participating in discovery; and (v) preparing for and participating in mediation

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the 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. *Grinnell*, 495 F.2d at 463, *abrogated on other grounds, Goldberger v. Integrated Res., Inc.*, 209 F.3d 43 (2d Cir. 2000).

at arm's-length with experienced counsel representing Pfizer. Class Counsel reviewed over 250,00 documents totaling approximately 2.11 million pages produced by Pfizer and nonparties. *Id.* Plaintiffs also served 118 requests for production of documents, 7 interrogatories and 95 requests for admission upon Pfizer. *Id.* Class Counsel evaluated the potential risks in the case and negotiated strenuously to secure the $44 million recovery. Accordingly, the Settlement Class has been, and remains, well represented.

3. Rule 23(e)(2)(B): The Settlement Is the Product of Good Faith, Informed, and Arm's-Length Negotiations by Experienced Counsel

"Where the proposed settlement appears to be the product of serious, informed, non-collusive negotiations, has no obvious deficiencies, does not improperly grant preferential treatment to class representatives or segments of the class and falls within the range of possible approval, preliminary approval is granted." *In re NASDAQ Mkt.-Makers Antitrust Litig.*, 176 F.R.D. 99, 102 (S.D.N.Y. 1997). "If a class settlement is reached through arm's-length negotiations between experienced, capable counsel knowledgeable in complex class litigation, the Settlement will enjoy a presumption of fairness." *In re GSE Bonds Antitrust Litig.*, 414 F. Supp. 3d 686, 693 (S.D.N.Y. 2019) (cleaned up). "Further, a mediator's involvement in settlement negotiations can help demonstrate their fairness." *Id.*

The Settlement readily satisfies this standard. As discussed above, by December 2025, when the Parties began exploring resolution, fact and non-party discovery were well underway. In advance of mediation, Defendant produced confidential documents and data regarding the pricing, profits, and quantities of Chantix sold throughout the Class Period, and Plaintiffs conducted independent due diligence, including consultations with experts in pharmaceuticals, cGMP compliance, and toxicology. So informed, the Parties engaged experienced neutral Fouad Kurdi, Esq., and conducted a full-day, in-person mediation on March 11, 2026, ultimately reaching an agreement in principle to resolve the Action for $44,000,000 in non-reversionary cash. The Parties then continued to negotiate the specific terms of the Settlement Agreement over the ensuing weeks before execution. Because the Settlement is the product of arm's-length, mediator-supervised negotiations between experienced counsel following substantial discovery, it is entitled to a "presumption of fairness." *In re GSE Bonds*, 414 F. Supp. 3d at 693.

As noted above, Class Counsel have extensive experience prosecuting complex class actions and have conducted a rigorous investigation. Class Counsel believe that the Settlement is not only fair, reasonable, and adequate, but is a very good result for Plaintiffs and the Settlement Class. This opinion is entitled to "great weight." *See In re NASDAQ Mkt.-Makers Antitrust Litig.*, 187 F.R.D. 465, 474 (S.D.N.Y. 1998) (Courts give "great weight . . . to the recommendations of counsel[.]").

B. RULE 23(e)(2)(C): THE SETTLEMENT PROVIDES SIGNIFICANT AND CERTAIN BENEFITS

1. Despite Strong Claims, Many Risks to Recovery Remained

Rule 23(e)(2)(C)(i) instructs courts to consider the adequacy of a proposed settlement in light of "the costs, risks, and delay of trial and appeal." To determine whether the proposed Settlement is fair, reasonable, and adequate, courts balance the continuing risks of litigation against the benefits afforded to class members through settlement. Although Plaintiffs believe the claims to be strong, they acknowledge that Defendant could advance several substantial arguments that could have reduced, or altogether eliminated, any recovery for the class. Courts in the Second Circuit acknowledge that complex litigation, such as this case, poses a great risk because of the difficulty of proving claims in the face of many existing defenses. *See D'Amato v. Deutsche Bank*, 236 F.3d 78, 86 (2d Cir. 2001). Several such considerations motivated Plaintiffs' decision to resolve their claims.

First, although the Court denied, in part, Pfizer's motion to dismiss, Plaintiffs would have faced significant hurdles at class certification, summary judgment, and at trial in connection with ultimately proving that Pfizer's misleading statements about its compliance with current cGMPs predominated over the entire class such that damages were justified.[6] Indeed, Pfizer strongly maintained that it complied with all regulatory requirements, that it made no misstatements or omissions regarding its cGMP compliance, that no Plaintiffs were injured by the nitrosamines present in Chantix, and that Plaintiffs' claims were otherwise preempted by federal law.

Second, class certification requires a "rigorous analysis" of each element of Rule 23, *In re Initial Pub. Offerings Sec. Litig.*, 471 F.3d 24, 29 (2d Cir. 2006) (quoting *Gen. Tel. Co. of the Southwest v. Falcon*, 457 U.S. 147, 160 (1982)), which Pfizer would have challenged. In addition, Pfizer would be expected to challenge the non-textual requirement that the class is ascertainable. *See In re Petrobras Sec.*, 862 F.3d 250, 264-65 (2d Cir. 2017). While Plaintiffs are confident that they could meet their burden of proving each of these elements by a preponderance of the evidence, the risks of doing so loomed large and weighed heavily in the settlement calculus.

The range of reasonableness factor accommodates "the uncertainties of law and fact in any particular case and the concomitant risks and costs necessarily inherent in taking any litigation to completion . . . ." *Visa*, 396 F.3d at 119 (quoting *Newman v. Stein*, 464 F.2d 689, 693 (2d Cir. 1972)). *See also Moses v. New York Times Co.*, 2026 WL 364231, at *3 (2d Cir. Feb. 10, 2026) (eschewing the need for exact values). "In other words, the question for the Court is not whether the settlement represents the highest recovery possible . . . but whether it represents a reasonable one in light of the many uncertainties the class faces . . . ." *Bodon v. Domino's Pizza, LLC*, 2015

6 At the time of settlement, Plaintiffs also had a pending motion for reconsideration of the dismissal of Plaintiffs' warranty claims.

WL 588656, at *6 (E.D.N.Y. Jan. 16, 2015) (quoting *In re Citigroup Inc. Sec. Litig.*, 965 F.Supp.2d 369 (S.D.N.Y. 2013)). While Class Counsel were ready to prove far greater damages at trial, the recovery provided by the Settlement is a very favorable result for the Settlement Class in the face of the Action's litigation risks, including the possibility that no certified class would be established or that no trial would be held.

2. The Effective Process for Distributing Relief to the Settlement Class

The Settlement Agreement provides for the use of a Settlement Administrator to disseminate notice, establish a settlement website, receive Claim Forms and supporting documentation from Settlement Class Members to determine whether they have submitted a valid claim, and if so, obtain a settlement payment. Consumer Settlement Class Members with valid claims will receive a pro rata distribution from the Fund based on the amount they paid, subject to a cap of 20%, Settlement Agreement ¶2.1, which reflects Class Counsel's best estimation of the percentage amount paid by consumers for Chantix compared to the amount paid by TPPs. If the amount of payments to consumer Settlement Class Members would exceed this cap, the total award will be reduced on a pro rata basis based on the amount paid by each consumer Settlement Class Member so that it will not exceed 20% of the Available Settlement Fund.

Similarly, for third party payor Class Members, after payment of the consumer claims as provided above, the remainder of the Available Settlement Fund shall be distributed to each valid third-party payor Settlement Class Member on a pro rata basis according to the total amount of the qualifying and documented payments. *Id.*

After the Settlement reaches its Effective Date, Settlement Agreement ¶¶1.12, 9.1, and the claims process is completed, Approved Claims of Settlement Class Members will be issued Cash Awards. If there are unclaimed funds after the initial distribution, such unclaimed funds will be redistributed on a pro rata basis to all Settlement Class Members who claimed their payments.

S.A. 2.1 (f). If a secondary distribution is not feasible and there are unclaimed funds, the Parties will discuss a Cy Pres recipient with Court approval. *Id.* at ¶2.1(g).

3. The Settlement Does Not Excessively Compensate Class Counsel

The reasonableness of attorneys' fees will be decided by the Court after Class Counsel files a motion for a Fee and Expense Award. The Settlement does not contemplate any specific award. Class Counsel will be compensated out of the Settlement Fund, under the common fund doctrine, and will not be compensated by Defendants. In connection with Class Counsel's motion for fees and expenses, no more than 33% of the Settlement Fund will be requested, an amount that is within the percentages that courts in the Second Circuit have approved in class actions with comparable recoveries. *See, e.g., Kelwin Inkwel, LLC v. PNC Merch. Servs. Co., L.P.*, 2022 WL 3127633, at *4 (E.D.N.Y. Apr. 12, 2022) ("The fee represents one-third (33.33%) of the $10 million Settlement Amount, which the Court finds to be reasonable and consistent with awards in similar cases in this Circuit."); *In re J.P. Morgan Stable Value Fund ERISA Litig.*, 2019 WL 4734396, at *2 (S.D.N.Y. Sept. 23, 2019) (approving fee of one-third of $75 million settlement); *Cent. States Se. & Sw. Areas Health & Welfare Fund v. Merck-Medco Managed Care, L.L.C.*, 504 F.3d 229, 236 (2d Cir. 2007); (affirming an award of attorney's fees that amounted to 30% of a $42.5 million settlement fund); *In re Barclays PLC Sec. Litig.*, 2025 WL 842939, at *1 (S.D.N.Y. Mar. 18, 2025) (awarding class counsel 29% of the Settlement Fund); *Hurtado v. 183 Food Mkt. Corp.*, 2022 WL 2294074, at *2 (S.D.N.Y. June 24, 2022) (awarding "30% of the total Settlement amount as attorneys' fees, plus [costs]").

C. RULE 23(e)(2)(D): SETTLEMENT CLASS MEMBERS ARE TREATED EQUITABLY RELATED TO ONE ANOTHER

The Settlement does not improperly grant preferential treatment to any Plaintiff or any segment of the Settlement Class. Settlement Class Members that were allegedly harmed and that have an eligible claim pursuant to the plan of allocation, will be compensated on a pro rata basis. *See, e.g.*, *In re Merrill Lynch Tyco Rsch. Sec. Litig.*, 249 F.R.D. 124, 135 (S.D.N.Y. 2008) ("A plan of allocation that calls for the pro rata distribution of settlement proceeds on the basis of investment loss is presumptively reasonable.").

D. THE REMAINING *GRINNELL FACTORS* SUPPORT PRELIMINARY APPROVAL[7]

Factor 3 (the stage of the proceedings and the amount of discovery completed): The fact that the Parties have not completed discovery does not weigh against preliminary approval. *See In re IMAX Sec. Litig.*, 283 F.R.D. 178, 190 (S.D.N.Y. 2012) ("The threshold necessary to render the decisions of counsel sufficiently well informed, however, is not an overly burdensome one to achieve-indeed, formal discovery need not have necessarily been undertaken yet by the parties."). As stated above, prior to agreeing to a settlement, Plaintiffs had thoroughly investigated their claims, including consultation with their experts, and the pleadings were thoroughly vetted through the motion-to-dismiss practice. Thereafter, Pfizer substantially completed its document production, Plaintiffs reviewed over 250,00 documents totaling approximately 2.11 million pages produced by Pfizer and nonparties. Similarly, nearly all Plaintiffs had substantially completed their own document productions and written discovery responses, and they were in the midst of being deposed by Pfizer. As stated above, Plaintiffs also conducted a substantial amount of third party discovery directed to obtain prescription pricing data for their damage model; facts from the Canadian supplier of a generic form of Chantix to seek to establish that it was feasible for Pfizer to have formulated, manufactured, tested, and distributed Chantix without nitrosamine contamination; and the firms that made and supplied Pfizer with a key excipient in Chantix and

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[7] Pursuant to Rule 23(e)(3), there are no other agreements made in connection with the proposed Settlement that need be disclosed.

the auditor Pfizer hired to audit that excipient supplier. Plaintiffs conducted a thorough and informed review of this material and had begun a deposition campaign, including the deposition of a key Pfizer chemist who was responsible for quality control at the company, before participating in the mediation. Accordingly, Plaintiffs entered the Settlement fully informed about the Action's strengths and weaknesses so as to be able to reach a fair, reasonable, and adequate settlement on behalf of the class.

Factor 7 **(the ability of the Defendant to withstand a greater judgment):** "This factor is 'typically relevant only when a settlement is less than what it might otherwise be but for the fact that the defendant's financial circumstances do not permit a greater settlement,'" which is not the case here. *Schutter v. Tarena Int'l, Inc.*, 2024 WL 4118465, at *12 (E.D.N.Y. Sept. 9, 2024) (quoting *In re Namenda*, 462 F. Supp. 3d, 314 (S.D.N.Y. 2020)). Although Pfizer could withstand a greater judgment, "this factor, standing alone, does not suggest the settlement is unfair," especially where, as here, the "other *Grinnell* factors weigh heavily in favor of settlement." *D'Amato*, 236 F.3d at 86; *see also Cavalieri v. Gen. Elec. Co.*, 2009 WL 2426001, at *2 (N.D.N.Y. Aug. 6, 2009) ("The court also notes that although neither party contends that defendants are incapable of withstanding greater judgment, that does not 'indicate that the settlement is unreasonable or inadequate."'); *In re Sony SXRD Rear Projection Television Class Action Litig.*, 2008 WL 1956267, at *8 (S.D.N.Y. May 1, 2008) ("a defendant is not required to 'empty its coffers' before a settlement can be found adequate"). "Courts have recognized that a [defendant's] ability to pay is much less important than the other *Grinnell* factors, especially where the other factors weigh in favor of approving the settlement." *In re Sinus Buster Prods. Consumer Litig.*, 2014 WL 5819921, at *11 (E.D.N.Y. Nov. 10, 2014) (quoting *In re Metlife Demutualization Litig.*, 689 F. Supp. 2d 297, 339 (E.D.N.Y. 2010)). Thus, Defendant's "ability to withstand a greater judgment, standing alone, does not suggest that the settlement is unfair." *Viafara v. MCIZ Corp.*, 2014 WL 1777438, at *7 (S.D.N.Y. May 1, 2014) (citations omitted). Therefore, at worst, this factor is neutral.

III. PRELIMINARY CERTIFICATION OF THE SETTLEMENT CLASS

In preliminarily approving the proposed Settlement, the Court must consider whether it can certify the Settlement Class under FED. R. CIV. P. 23(a) and (b)(3). 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 class is being certified in the context of a settlement, there are no "manageability" concerns that need to be considered. *Amchem Prods. v. Windsor*, 521 U.S. 591, 620 (1997). As shown below, all the requirements of Rule 23 have been satisfied.

A. RULE 23(a)'S REQUIREMENTS ARE READILY MET

1. Numerosity

Numerosity is satisfied when the class is "so numerous that joinder of all members is impracticable." FED. R. CIV. P. 23(a)(1). "[N]umerosity is presumed at a level of 40 members." *Consol. Rail Corp. v. Town of Hyde Park*, 47 F.3d 473, 483 (2d Cir. 1995). Here, the proposed Settlement Class encompasses hundreds of thousands of consumers and hundreds of third-party payors. There is no dispute that many hundreds of thousands of consumers nationwide purchased Chantix, and thousands of third-party payors paid for Chantix during the Class Period. Third Party Payor Plaintiffs' own data show hundreds, if not thousands, of unique patients were prescribed and purchased Chantix under these plaintiffs' health plans alone. Indeed, the 23 Consumer and Third-Party Payor Plaintiffs alone satisfy Rule 23(a)(1). *See, e.g., U.S. Fid. & Guar. Co. v.*

Madison Fin. Corp., 2002 WL 31731020, at *6 (S.D.N.Y. Dec. 4, 2002) ("There is no magic minimum number that establishes numerosity . . . and courts have certified classes with as few as 14 members."). Numerosity is easily satisfied.

2. Commonality

Commonality is satisfied when the claims depend on a common contention, the resolution of which will bring a class-wide resolution of the claims. *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 349-50 (2011). "The Rule does not require all questions of law or fact to be common. Indeed, even a single common question will suffice." *Sykes v. Mel Harris & Assocs.*, LLC, 285 F.R.D. 279, 286 (S.D.N.Y. 2012) (citing *Dukes*, 564 U.S. at 359). Rather, Rule 23(a)(2) simply "requires that there be issues whose resolution will affect all or a significant number of the putative class members." *Johnson v. Nextel Commc'ns Inc.*, 780 F.3d 128, 137 (2d Cir. 2015).

Here, there are common questions of law and fact that will generate common answers apt to drive the resolution of the litigation. Plaintiffs allege that Pfizer uniformly misrepresented its compliance with cGMP when marketing Chantix. Common legal and factual questions include but are not limited to: whether Defendant's varenicline containing drugs ("VCDs") containing nitrosamines or similar contaminants were adulterated or misbranded; whether Defendant violated cGMPs regarding the manufacture of its VCDs; and whether Defendant affirmatively misrepresented or omitted facts regarding its compliance with cGMPs. CAC ¶ 213.

3. Typicality

Typicality "is satisfied when 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." *Marisol A. v. Giuliani*, 126 F.3d 372, 376 (2d Cir. 1997) (internal quotations omitted). "In the Second Circuit, analysis of Rule 23(a)(3)'s typicality requirement often converges with that of commonality." *Zivkovic v. Laura Christy LLC*, 329 F.R.D. 61, 70 (S.D.N.Y. 2018). "When the same unlawful conduct was directed at or affected both the named plaintiffs and the prospective class, typicality is usually met." *Stinson v. City of New York*, 282 F.R.D. 360, 371 (S.D.N.Y. 2012) (citations omitted). Accordingly, typicality "is satisfied when 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." *In re Kind LLC "Healthy & All Natural" Litig.*, 337 F.R.D. 581, 595 (S.D.N.Y. 2021) (citations omitted). The typicality threshold is not a demanding one. *See Ebin v. Kangadis Food Inc.*, 297 F.R.D. 561, 565-66 (S.D.N.Y. 2014) (holding that the typicality requirement was satisfied where "the lead plaintiffs' and other class members' claims ar[o]se out of the same course of conduct by the defendant and [were] based on the same legal theories"). Nor do "differences in the degree of harm suffered, or even in the ability to prove damages, . . . vitiate the typicality of a representative's claims." *In re Nissan Radiator/Transmission Cooler Litig.*, 2013 WL 4080946, at *19 (S.D.N.Y. May 30, 2013) (citing *In re Citigroup Pension Plan ERISA Litig.*, 241 F.R.D. 172, 178 (S.D.N.Y. 2006)).

Typicality is readily met here. Plaintiffs' claims and those of the Settlement Class Members arise from the same course of conduct by Defendant: Plaintiffs allege that Pfizer sold Chantix® contaminated with N-nitroso varenicline—a genotoxic, probable human carcinogen—without disclosing the contamination or complying with current Good Manufacturing Practices, causing Plaintiffs and Settlement Class Members to overpay for the drug. Further, Plaintiffs advance the same legal theories as the class to establish Defendant's liability. *Ebin*, 297 F.R.D. at 565-66. Because the same allegedly unlawful conduct was directed at, or affected, Plaintiffs and Settlement Class Members alike, any minor factual variations among class members or differences in the amount of individual damages do not defeat typicality. Instead, Plaintiffs' claims share the same essential characteristics as the claims of the class they seek to represent, and Rule 23(a)(3) is therefore satisfied.

4. Adequacy

To satisfy the adequacy of representation requirement, plaintiffs must establish that: (1) the "there is no conflict of interest between" the class representatives and other members of the class; and (2) the plaintiffs' counsel is "qualified, experienced, and generally able to conduct the litigation." *Bolanos v. Norwegian Cruise Lines Ltd.*, 212 F.R.D. 144, 156 (S.D.N.Y. Nov. 26, 2002) (citation modified) (citations omitted). "The adequacy requirement exists to ensure that the class representatives will 'have an interest in vigorously pursuing the claims of the class, and . . . have no interests antagonistic to the interests of other class members.'" *Toure v. Cent. Parking Sys.*, 2007 WL 2872455, at *7 (S.D.N.Y. Sept. 28, 2007) (quoting *Penney v. Deutsche Bank AG*, 443 F.3d 253, 268 (2d Cir. 2006)). "[O]nly a conflict that goes to the very subject matter of the litigation will defeat a party's claim of representative status." *Dziennik v. Sealift, Inc.*, 2007 WL 1580080, at *65 (E.D.N.Y. May 29, 2007) (quoting *Martens v. Smith Barney Inc.*, 181 F.R.D. 243, 259 (S.D.N.Y. 1998)).

In this case, Plaintiffs possess the same interests as the proposed Settlement Class members because Plaintiffs and Settlement Class Members were allegedly injured in the same manner based on the same allegedly misleading conduct concerning Chantix. Each Plaintiff and each Settlement Class Member have the exact same interest in recovering the damages to which they are entitled related to their purchases of Chantix.

Further, proposed Class Counsel are qualified, experienced, and have extensive experience in successfully litigating complex class actions such as this. *See* Liaison Counsel Decl. ¶20.

Plaintiffs submit that the class is adequately represented.

B. THE PROPOSED SETTLEMENT CLASS SATISFIES THE REQUIREMENTS OF RULE 23(b)(3)

Rule 23(b)(3) requires that common questions "predominate over any questions affecting only individual members and that a class action is superior to other available methods for the fair and efficient adjudication of the controversy." FED. R. CIV. P. 23(b)(3). These requirements are readily satisfied.

1. Common Questions Predominate

Rule 23(b)(3)'s predominance requirement focuses on whether the Defendant's liability is common enough to be resolved on a class basis, *Wal-Mart*, 564 U.S. at 359, and whether the proposed class is "sufficiently cohesive to warrant adjudication by representation." *Amchem*, 521 U.S. at 623. Class-wide issues predominate where "(1) resolution of any material legal or factual questions . . . can be achieved through generalized proof, and (2) these [common] issues are more substantial than the issues subject only to individualized proof." *In re Petrobras Sec.*, 862 F.3d 250, 270 (2d Cir. 2017) (citations omitted). Predominance does not require that every issue be common; it requires only that common questions predominate over individual ones.

Plaintiffs' claims satisfy this standard because they turn on common questions about Pfizer's uniform conduct—conduct directed at every Settlement Class Member in the same way. Here, Plaintiffs' common questions of fact discussed above will predominate over the case. Each of these common questions will be resolved with evidence common to the class, i.e., Pfizer's manufacturing records, internal communications, regulatory submissions, and corporate knowledge of the nitrosamine contamination, and not through individualized proof from each Plaintiff or Settlement Class Member. For example, the resolution of whether Pfizer affirmatively misrepresented or omitted facts regarding its compliance with cGMPs for one plaintiff can be proven with "generalized proof" common to all plaintiffs. *In re Nassau Cnty. Strip Search Cases*, 461 F.3d 219, 227–28 (2d Cir. 2006).

Damages also flow from a common theory. Plaintiffs allege that they and Settlement Class Members overpaid for Chantix because Pfizer did not disclose that the drug was contaminated with a genotoxic, probable human carcinogen—an injury measurable on a class wide basis through a common overpayment or price-premium methodology.

Because Pfizer's allegedly wrongful conduct was uniform across the class, and because the core liability and damages questions are subject to generalized proof that outweighs any individualized issues, the predominance requirement is satisfied.

2. A Class Action Is a Superior Mechanism

Rule 23(b)(3)'s superiority requirement examines whether "the class action device [is] superior to other methods available for a fair and efficient adjudication of the controversy." *Green v. Wolf Corp.*, 406 F.2d 291, 301 (2d Cir. 1968). Given the settlement context in which this case presents itself to the Court, 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). The lack of a trial also assists the predominance requirement. *See, e.g., In re Am. Int'l Group, Inc. Sec. Litig.*, 689 F.3d 229, 242 (2d Cir. 2012) (class settlement that "eliminates manageability problems" resolved predominance concerns that doomed litigation class).

Courts within the Second Circuit have long acknowledged the propriety of certifying settlement classes. "Certification 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." *IMAX*, 283 F.R.D. at 186.

Furthermore, the class action mechanism is superior to individual actions for numerous reasons. First, "[t]he potential class members are both significant in number and geographically dispersed" and "[t]he interest of the class as a whole in litigating the many common questions substantially outweighs any interest by individual members in bringing and prosecuting separate actions." *Meredith Corp. v. SESAC, LLC*, 87 F. Supp. 3d 650, 661 (S.D.N.Y. 2015) (citation modified) (citation omitted). Second, a class action is superior because the "small recoveries" at stake here likely "do not provide the incentive for any individual to bring a solo action prosecuting his or her rights." *Tart v. Lions Gate Entm't Corp.*, 2015 WL 5945846, at *5 (S.D.N.Y. Oct. 13, 2015) (citation omitted). Finally, a class action will conserve judicial resources because "rather than individually settling [thousands of] lawsuits, the proposed Settlement allows for the named Plaintiff[s], class members, and Defendant to resolve all claims . . . at once." *Id.*

For the foregoing reasons, Plaintiffs respectfully request that the Court preliminarily certify the Settlement Class for purposes of implementing the proposed Settlement.

IV. THE PROPOSED NOTICE PROGRAM SHOULD BE APPROVED

The proposed Notice to the Settlement Class satisfies Rule 23 and the constitutional requirements of due process and should be approved. The Second Circuit has held that the "standard for the adequacy of a settlement notice in a class action under either the Due Process Clause or the Federal Rules is measured by reasonableness." *Wal-Mart Stores,* 396 F.3d at 113. "To comport with due process, the notice provided to absent class members must be 'the best practicable, reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to present their objections.'" *Hecht v. United Collection Bureau, Inc.*, 691 F.3d 218, 224 (2d Cir. 2012) (quoting *Phillips Petroleum v. Shutts*, 472 U.S. 797, 812 (1985)).

Here, the proposed Notice Program and Notice documents (*see* Settlement Agreement, Exs. 1-4) provide for direct mail and email notice to Settlement Class Members for whom such information is available, in conjunction with a robust publication and social media campaign designed to reach Settlement Class Members. Additionally, the Notice Program provides for a settlement website and a toll-free number. The settlement website will provide information to Settlement Class Members, including copies of the settlement documents and relevant pleadings and will allow Settlement Class Members to electronically file claims with the Settlement Administrator. The proposed Notice and Notice Program satisfies due process and the Federal Rules. The multi-faceted combination of direct mail notice, publication notice, and a dedicated settlement website constitute "the best notice that is practicable under the circumstances." FED. R. CIV. P. 23(c)(2)(B). Accordingly, the Notice Program and Notice Documents are in line with notice programs routinely approved in this Circuit. *See In re Vitamin C*, 2012 WL 5289514, at *8 (E.D.N.Y Oct. 23, 2012) ("The notice was also distributed widely, through the internet, print publications, and targeted mailings. The . . . distribution of the class notice was adequate.").

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully request that the Court grant the Motion and enter the proposed Preliminary Approval Order, submitted herewith, which will: (i) preliminarily approve the Settlement on the terms set forth in the Settlement Agreement; (ii) preliminarily certify the Settlement Class and appoint the Class Representatives and Class Counsel, for purposes of the Settlement only; (iii) appoint a Settlement Administrator and Escrow Agent; (iv) approve the form and content of the Class Notice; and (v) set a schedule for the Final Approval Hearing, including an opt-out and objection deadlines and the claim submission deadline; and grant such other and further relief as may be required.

Date: May 26, 2026

Respectfully submitted,

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Class Counsel

CERTIFICATE OF SERVICE

I hereby certify that on May 26, 2026, I caused the foregoing to be electronically filed with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the email addresses denoted on the Electronic Mail Notice List.

/*s*/ Joseph P. Guglielmo
Joseph P. Guglielmo