BLOOD HURST & O'REARDON, LLP
TIMOTHY G. BLOOD (CA 149343)
LESLIE E. HURST (CA 178432)
THOMAS J. O'REARDON II (CA 247952)
701 B Street, Suite 1700
San Diego, CA 92101
Telephone: 619/338-1100
619/338-1101 (fax)
tblood@bholaw.com
lhurst@bholaw.com
toreardon@bholaw.com

Attorneys for Plaintiffs and the Class

[Additional counsel appear on signature page.]

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF OHIO

DINO RIKOS, TRACEY BURNS, and LEO JARZEMBROWSKI, On Behalf of Themselves, All Others Similarly Situated and the General Public,

Plaintiffs,

v.

THE PROCTER & GAMBLE COMPANY,

Defendant.

Case No. 11-CV-00226-TSB

CLASS ACTION

PLAINTIFFS' MOTION FOR PRELIMINARY APPROVAL OF CLASS ACTION SETTLEMENT

Judge: Hon. Timothy S. Black
Courtroom: 815
Date Filed: September 21, 2010

Pursuant to Fed. R. Civ. P. 23, Plaintiffs Dino Rikos, Tracey Burns, and Leo Jarzembowski, move for entry of an order consistent with the terms of the parties' Stipulation of Settlement and Exhibits attached thereto (a copy of which is attached as Exhibit 1 to the concurrently filed Declaration of Timothy G. Blood):

(1) certifying a nationwide Settlement Class for settlement purposes only;

(2) preliminarily approving the settlement, including the attached Stipulation of Settlement and all exhibits thereto;

(3) approving the Class Notice Program and the authorization to disseminate the Class Notice to the Settlement Class;

(4) appointing the Settlement Administrator;

(5) setting a date and procedures for a Final Approval Hearing on the proposed settlement;

(6) setting forth procedures and deadlines for Settlement Class Members to file objections to the proposed settlement and appear at the Final Approval Hearing;

(8) setting forth procedures and deadlines for Settlement Class Members to request exclusion from the Settlement Class;

(10) naming Class Representatives, Dino Rikos, Tracey Burns, and Leo Jarzembowski;

(11) appointing as Class Counsel, Timothy G. Blood and Thomas J. O'Reardon II of Blood Hurst and O'Reardon LLP; and

(13) issuing related relief pursuant to the Stipulation of Settlement.

A proposed Preliminary Approval Order is attached as Exhibit 2 to the Declaration of Timothy G. Blood. Counsel for the parties have conferred and Defendant The Procter & Gamble Company ("P&G" or "Defendant") does not oppose this Motion.

Dated: September 29, 2017

BLOOD HURST & O'REARDON, LLP
TIMOTHY G. BLOOD (CA 149343)
LESLIE E. HURST (CA 178432)
THOMAS J. O'REARDON II (CA 247952)

By: *s/ Timothy G. Blood*
TIMOTHY G. BLOOD

701 B Street, Suite 1700
San Diego, CA 92101
Tel: 619/338-1100
619/338-1101 (fax)
tblood@bholaw.com
lhurst@bholaw.com
toreardon@bholaw.com

Attorneys for Plaintiffs and the Class

FUTSCHER LAW PLLC
DAVID A. FUTSCHER
913 N. Oak Drive
Villa Hills, KY 41017
Tel: 859/912-2394
david@futscherlaw.com

NICHOLAS & TOMASEVIC, LLP
CRAIG M. NICHOLAS (178444)
ALEX M. TOMASEVIC (245598)
225 Broadway, 19th Floor
San Diego, CA 92101
Tel: 619/325-0492
619/325-0496 (fax)
cnicholas@nicholaslaw.org
atomasevic@nicholaslaw.org

MORGAN & MORGAN, P.A.
RACHEL L. SOFFIN
One Tampa City Center
201 N. Franklin St., 7th Floor
Tampa, FL 33602
Tel: 813/223-5505
813/223-5402 (fax)
rsoffin@forthepeople.com

O'BRIEN LAW FIRM, PC
EDWARD K. O'BRIEN
One Sundial Avenue, 5th Floor
Manchester, NH 03103
Tel: 603/668-0600
603/672-3815 (fax)
eobrien@ekoblaw.com

SAMUEL ISSACHAROFF
40 Washington Square South
New York, NY 10012
Tel: 212/998-6580
sil3@nyu.edu

BONNETT, FAIRBOURN, FRIEDMAN
& BALINT, P.C.
ANDREW S. FRIEDMAN
ELAINE A. RYAN
PATRICIA N. SYVERSON (203111)
2325 E. Camelback Road, Suite 300
Phoenix, AZ 85016
Tel: 602/274-1100

602/798-5860 (fax)
afriedman@bffb.com
eryan@bffb.com
psyverson@bffb.com
Additional Attorneys for Plaintiffs

S.D. OHIO CIV. R. 7.2(a)(3) MEMORANDUM SUMMARY

Pursuant to S.D. Ohio Civ. R. 7.2(a)(3) and this Court's Civil Procedures, plaintiffs Dino Rikos, Tracey Burns and Leo Jarzembowski ("Plaintiffs") respectfully submit this summary regarding their over length memorandum in support of the joint motion for preliminary approval of class action settlement.

The Parties seek preliminary approval of a nationwide class action settlement. The proposed settlement has been reached after seven years of litigation that included extensive motion practice before this Court, the Sixth Circuit and the U.S. Supreme Court, fact and expert discovery involving hundreds of thousands of pages of documents, subpoenas to more than 30 third-parties, 19 depositions and 21 expert reports, and protracted settlement negotiations with three different mediators before and after rulings on class certification. The proposed settlement is fair, reasonable and adequate and readily meets the standards for preliminary approval. Likewise, the Class Notice Program satisfies due process and should be approved.

Section I (pages 1-2) is a brief introduction that summarizes the primary reasons why the proposed settlement should receive preliminary approval, including outlining the relief to be provided and the Class Notice to be disseminated to the Settlement Class.

Section II (pages 2-6) sets forth the general history of the litigation, including the substantial motion practice and party, third-party and expert discovery.

Section III (pages 6-11) discusses the terms of the Stipulation of Settlement. Specifically, P&G will provide up to $15 million in cash refunds, plus at least $5 million and up to $10 million in Digestive Health Improvement Contributions that will directly benefit the Settlement Class. To obtain the cash payments, Settlement Class Members need only return a simple Claim Form. The Claim Form, which features pictures of the Align packaging, only requires Claimants to provide their contact information and check one of three boxes that identify their purchases. No proof of purchase is required. P&G will separately pay all notice and settlement administration expenses and awards of Plaintiffs' Counsel's attorneys' fees and costs, and Class Representative service awards. P&G will agree to refrain from making the

"clinically proven" five symptom relief advertising claims absent new supporting clinical data or analysis, or a change in the product formula. The Class Notice Program, which was designed by a vastly experienced third-party settlement administrator that exceeds the Federal Judicial Center's guidelines, and includes multiple print and online components to reach the Settlement Class.

Section IV (pages 11-20) discusses application of the requirements of preliminary settlement approval. If "the proposed settlement appears to be the product of serious, informed, non-collusive negotiation, 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," then the court should direct notice be given to class members of a formal fairness hearing. *In re Polyurethane Foam Antitrust Litig*., MDL No. 2196, 2012 U.S. Dist. LEXIS 192151, at *14 (N.D. Ohio Jan. 23, 2012). The Settlement is well within the range of possible approval as a fair, reasonable, and adequate resolution between the Parties, and should be preliminarily approved.

Section V (pages 20-26) sets forth and applies Rule 23's certification requirements to the Settlement Class. With one exception, the proposed Settlement Class is identical to the one certified by this Court and affirmed by the Sixth Circuit: the Settlement Class is nationwide. There is little question that the proposed nationwide Settlement Class meets the requirements of Rules 23(a) and (b)(3). *See In re Sears, Roebuck & Co. Front-Loading Washer Prods. Liab. Litig*., No. 06 C 7023, 2016 U.S. Dist. LEXIS 25290, at *30 (N.D. Ill. Feb. 29, 2016) (citing *Amchem*, 521 U.S. at 620).

Section VI (pages 26-29) discusses why the Class Notice Program should be approved. The Class Notice fully satisfies the "content" requirements by disclosing the essential terms of the Stipulation of Settlement, Settlement Class Members' rights and options, and other essential terms. Further, the methods of disseminating the Class Notice satisfy all due process requirements.

Section VII (page 29) discusses why the Court should appoint the Plaintiffs as the representatives of the Settlement Class and why Mr. Blood and Mr. O'Reardon should be appointed Class Counsel pursuant to Fed. R. Civ. Proc. 23(g).

Finally, Section VIII (pages 29-30) sets forth the proposed timing for settlement-related events, including the Final Approval Hearing and objection and opt-out deadlines.

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MEMORANDUM IN SUPPORT

I. INTRODUCTION

After seven years of heavy litigation and shortly before trial was to begin, the Parties reached a proposed settlement of this class action, as memorialized in the concurrently filed Stipulation of Settlement.[1] Settlement was reached after months of negotiations assisted by a well-regarded mediator. The Parties now request that the Court preliminarily approve the Settlement and authorize the proposed Class Notice be sent to the Settlement Class.

As detailed below, under the Settlement P&G will pay up to about $30 million in settlement benefits. This includes up to $15 million in cash payments where Settlement Class Members are eligible to receive refunds of up to $49.26. P&G will also make payments ranging from $5 million to $10 million in the form of intellectual property, research and education grants, and/or product donations to research or education institution working to improve digestive health. Defendant will also pay Notice and Claim Administration Expenses and Attorneys' Fees and Expenses, which are approximately $5 million, collectively. P&G must also abide by injunctive relief that prohibits making the "clinically proven" five symptom relief claims, absent new supporting clinical data or analysis, or a change in product formula.

The Settlement Class covers the same time period and is otherwise the same as the previously certified class affirmed by the Sixth Circuit, with the exception that it is expanded to include those who purchased Align in the United States and its territories. The Settlement Class is defined as: All persons who purchased Align within the United States and its territories, other than solely for purposes of resale, from March 1, 2009 to June 6, 2016. Excluded from the Settlement Class are: (i) Defendant and its officers, directors, and employees; (ii) any person who files a valid and timely Request for Exclusion; and (iii) judicial officers and their immediate family members and associated court staff assigned to the case.

[1] All capitalized terms herein have the same meaning as set forth in the Stipulation of Settlement (hereinafter "Settlement," "Settlement Agreement," or "SA").

The proposed Class Notice meets the Federal Rule of Civil Procedure 23(c)(2)(B) "most practicable under the circumstances" standard and exceeds the minimum notice guideline set by the Federal Judicial Center.[2] The notice will target Settlement Class Members through various Internet channels and publications as set forth in the attached media plan. *See* Declaration of Carla Peak on Settlement Notice Plan ("Peak Decl."), ¶¶4, 14-29, Exhibit 1. Notice also will be posted to various websites, including a website established especially for this Settlement. The Notice and Claim Administration Expenses will be paid by P&G separate and apart from any other consideration paid under the Settlement.

The proposed Settlement readily meets the standard for preliminary approval. Thus, the Court should enter the proposed preliminary approval order that, among other things: (1) preliminarily approves the terms of the Settlement; (2) approves the form, method and plan of Class Notice; (3) certifies the Settlement Class for settlement purposes and appoints Class Counsel and Class Representatives; and (4) schedules a Final Approval Hearing and related dates at which the request for final approval of the proposed Settlement and entry of the judgment will be considered.

II. HISTORY OF THE LITIGATION

The Settlement was reached after seven years of hard-fought litigation that included an appeal to the Sixth Circuit and petition for certiorari to the United States Supreme Court, extensive investigation and discovery, work with expert witnesses, including preparation of expert reports for class certification and trial, and months of negotiations, including mediations with three separate mediators. These efforts are detailed in the concurrently filed Declaration of Timothy G. Blood ("Blood Decl.").

A. The Litigation

This case concerns P&G's labeling and advertising of its over-the-counter probiotic supplement, Align. Third Amended Class Action Complaint ("3AC"), ¶1. Align is promoted as helping to build and maintain a healthy digestive system, restore natural digestive balance,

[2] All references to "Rule" or "Rules" herein are to the Federal Rules of Civil Procedure unless specifically stated otherwise.

and protect against occasional digestive upsets. *Id*. at ¶¶1, 2, 4-5, 14-15, 23-30. Plaintiffs allege and were ready to prove at trial that Align does not deliver the claimed digestive health benefits. *Id*. at ¶¶20-22, 32-37. They were prepared to present evidence that the independent studies, some of P&G's own studies, and high quality meta-analyses of clinical studies confirm that Align does not provide the advertised health benefits. *Id*. at ¶¶3, 31, 38-41. Likewise, P&G is represented by teams of experienced attorneys who vigorously defended the marketing and advertising of Align.

On September 21, 2010, Plaintiff Dino Rikos filed a class action complaint challenging Align's labeling and advertising. Blood Decl., ¶5. The complaint was filed in the United States District Court for the Southern District of California on behalf of Plaintiff Rikos and all other consumers who purchased P&G's Align branded products and captioned *Dino Rikos v. The Procter & Gamble Company*, No. 3:10-cv-01974-BEN(CAB). The complaint included claims for violation of California's Consumers Legal Remedies Act ("CLRA"), Civ. Code §§1750, *et seq*., Unfair Competition Law ("UCL"), Bus. & Prof. Code §§17200, *et seq*., and for breach of express warranty. Blood Decl., ¶5. The complaint was amended on October 27, 2010, to add a request for actual and punitive damages under the CLRA. *Id*., ¶6.

Upon P&G's motion to transfer venue pursuant to 28 U.S.C. §1404, on April 13, 2011, the Action was transferred to the Southern District of Ohio and renumbered Case No. 1:11-cv-00226-TSB. Blood Decl., ¶¶7-8. P&G moved to dismiss Rikos' complaint and, after full briefing and consideration, the federal district court in Ohio upheld all of Rikos' claims, dismissing only his request for injunctive relief. ECF No. 28. In accordance with the order, on October 20, 2011, Plaintiff Rikos filed a complaint for injunctive and declaratory relief against P&G arising out of the same facts and circumstances in the Superior Court of the State of California, County of San Diego captioned *Dino Rikos v. The Procter & Gamble Company*, No. 27-2011-00099818-CU-BT-CTL. Blood Decl., ¶9.

On August 17, 2012, Plaintiff Rikos filed a Second Amended Class Action Complaint that added Tracey Burns and Leo Jarzembowski as named plaintiffs and proposed class representatives. Plaintiffs alleged five single-state classes consisting of consumers who

purchased Align in California, Florida, Illinois, New Hampshire, and North Carolina. SAC, ¶44. Claims for violations of each of these states' consumer protection and false advertising laws were also added. *Id*. at ¶¶75-117.

On November 30, 2012, P&G moved for partial judgment on the pleadings pursuant to Rule 12(c), and moved to dismiss under Rule 12(h)(3). Blood Decl., ¶14. The Court granted the motion as to certain claims, but left intact Plaintiffs' core claims under each state's false advertising and consumer protection statutes. ECF No. 94.

After extensive fact and expert discovery, on January 13, 2014, Plaintiffs moved to certify five classes pursuant to Rules 23(a) and 23(b)(3), and to appoint Plaintiff Dino Rikos as class representative of California and Illinois classes, Plaintiff Tracey Burns as class representative of Florida and North Carolina classes, and Plaintiff Leo Jarzembowski as class representative of a New Hampshire class. Plaintiffs also moved to appoint Plaintiffs' Counsel Timothy G. Blood as class counsel. On June 19, 2014, the Court granted certification of five single-state classes, including the requested class representatives and class counsel. ECF No. 140.

Defendant appealed the certification order to the United States Court of Appeals for the Sixth Circuit, which affirmed the order granting class certification and thereafter denied Defendant's petition for rehearing *en banc*. *See Rikos v. P&G*, 799 F.3d 497 (6th Cir. Ohio Aug. 20, 2015) ("Rikos"). Defendant then petitioned the Supreme Court for *writ of certiorari*. Plaintiffs opposed the petition, which the Supreme Court denied. Blood Decl., ¶¶17-19.

Plaintiffs' Counsel obtained and analyzed voluminous discovery produced by P&G and third parties, conducted an independent investigation, and consulted with experts to analyze and supplement the discovery produced. The written discovery Plaintiffs served on P&G included comprehensive interrogatories and requests for production. *Id*. at ¶23. Counsel also negotiated confidentiality and ESI protocols. *Id*. at ¶25. As part of this discovery, Plaintiffs' Counsel obtained, reviewed and analyzed approximately 752,341 pages of hard-copy and electronic documents produced by P&G and an additional 20,280 pages of documents produced in response to over 30 subpoenas served by Plaintiffs on third-parties involved in

advertising and marketing Align, retailers selling Align, and scientists who conducted research on Align. *Id*. at ¶¶24, 27-31. Plaintiffs' Counsel also responded to P&G's discovery requests to the three named Plaintiffs, which included the collection and production of responsive documents. *Id*. at ¶33.

The parties deposed 19 witnesses, including P&G's scientists and marketing personnel involved in Align, third-party scientists, and two of P&G's primary scientific experts. *Id*. at ¶¶30-32. In addition to written discovery directed at Plaintiffs, P&G deposed each of the Plaintiffs, and one of Plaintiffs' scientific experts. In total, for class certification and trial, the Parties exchanged twenty-one expert reports from fourteen retained experts on issues relating to advertising and marketing, gastroenterology, microbiology, biostatistics, FDA regulations, and damages. *Id*. at ¶¶34-37. Plaintiffs' experts did extensive work on this case, including a meta-analysis of the clinical data.

B. Settlement Negotiations

One year after this Action was filed, on September 19, 2011, the Parties participated in an all-day mediation with Mark D. Petersen of Farella Braun + Martel LLP. Blood Decl., ¶40. By this time Defendant had moved the Action to Ohio, answered the complaint, and unsuccessfully challenged the complaint (except for Plaintiff Rikos' request for injunctive relief, which was dismissed). No settlement was reached. *Id*.

On April 10, 2013 a second mediation was attempted with mediator David P. Kamp in Cincinnati, Ohio. *Id*. at ¶41. Following the April 2013 mediation session, Mr. Kamp met with the parties separately in Cincinnati and San Diego. *Id*.

On March 13, 2017, the Parties participated in an all-day mediation in San Francisco, California, which was conducted by the third mediator retained for this Action, Antonino Piazza. Although no settlement was reached, the Parties appeared closer to a potential resolution. *Id*. at ¶42. After two more months of hard-fought arm's length negotiations, a settlement in principle was reached on May 1, 2017. *Id*. Over the last four months, the Parties continued detailed negotiations on all aspects of the Settlement Agreement and its exhibits. *Id*. at ¶43.

Ultimately, the settlement process was driven by the uncertainty caused by passages in the Sixth Circuit opinion which, although seemingly contrary to established substantive state law, created a significant amount of risk. Viewed in light of the possible meaning of the Sixth Circuit opinion, the Settlement represents an excellent result. It is also limited in scope, so that more recent purchasers can challenge P&G over Align's current advertising. Likewise, one can seek to curtail the allegedly false and misleading advertising without interference from this Settlement.

III. SETTLEMENT TERMS

The following is a summary of the terms of the Settlement.

A. The Settlement Class

The Settlement Class is the same as the class the Court certified on June 19, 2014, except it is expanded to include all Align purchasers in the United States and its territories between March 2009 and June 2016. *Compare* SA at §II.A., ¶34 *with Rikos v. P&G*, No. 1:11-cv-226, ECF No. 140 (6/19/2014 Order Certifying Class Action) ("Class Cert. Order") at 1. Excluded from the Settlement Class are: (i) Defendant and its officers, directors, and employees; (ii) any person who files a valid and timely Request for Exclusion; and (iii) judicial officers and their immediate family members and associated court staff assigned to the case. SA, §II.A. The proposed Class Representatives are also the same as previously appointed by the Court: Dino Rikos, Tracey Burns, and Leo Jarzembowski. Class Cert. Order at 1.

B. The Settlement Relief

Under the Settlement, P&G will provide the following benefits to Settlement Class Members:

1. Cash Refunds

Under the Settlement, Settlement Class Members may receive a Cash Refund of up to $49.26 for three purchases of Align. For purchases made between March 1, 2009 and October 31, 2009, Settlement Class Members may receive a refund of up to $31.76 for two purchases of Align. This was the period during which P&G expressly advertised Align's health benefits

to be "clinically proven". This equates to $15.88 for each purchase or 50% of the average weighted retail price of Align during that time period. SA, §IV.A.2.a.1. For purchases made between November 1, 2009 and June 6, 2016, Settlement Class Members may receive one refund of $17.50, which is 50% of the average weighted retail price of Align during this time period. SA, §IV.A.2.a.2. P&G will pay out up to $15,000,000 in Cash Refunds. SA, §IV.A.2.c.

To obtain the cash payment, Settlement Class Members need only return a simple Claim Form. The Claim Form, which features pictures of the Align packaging, only requires Claimants to provide their contact information and to check one of three boxes that identify their purchases. SA, Ex. 3 (Claim Form). No proof of purchase is required. Claimants need only attest that the purchase information is true and accurate. *Id*. Claim Forms will be available for downloading at the Settlement Website and Class Counsels' website, and can be mailed or emailed upon request. SA, §V.2. Claim Forms may be submitted online through the Settlement Website or via U.S. mail to the Settlement Administrator. SA, §IV.A.2.b.

The Settlement Administrator will determine whether Claim Forms submitted by Settlement Class Members are complete and timely, and will make final decisions on whether a valid Claim for payment is made, and the amount of such payment, subject to agreement of Class Counsel and P&G's Counsel. SA, §§IV.A.2.b., V.1. For any Claims found to be deficient, the Settlement Administrator will seek to remedy the deficiency. SA, §V.4. Claimants will be mailed either a check or a letter explaining any denial within 60 days of the Effective Date of the Settlement. SA, §V.5. Denied claims may be appealed to the Settlement Administrator. SA, §V.6.

2. Digestive Health Improvement Contributions

In addition to Cash Refunds, P&G will contribute a minimum of $5,000,000 and up to $10,000,000 worth of Digestive Health Improvement Contributions ("DHIC"). The DHIC are in addition to and do not reduce the $15,000,000 available for Cash Refunds. SA, §IV.4.A.1.b.

P&G will contribute $5,000,000 worth of guaranteed, up-front, non-reversionary DHIC. DHIC will be in the form of: (1) intellectual property and/or know-how; (2) research and/or education grant(s); and/or (3) product donations to research and/or educational

institutions and/or programs working to improve digestive health. SA, §IV.4.A.1.a. All contributions are subject to prior review and approval by Class Counsel. *Id*. Contributions will directly benefit the Settlement Class by targeting U.S. consumers who suffer from Irritable Bowel Syndrome ("IBS"), or who regularly seek assistance and care for their digestive health. SA, §IV.4.A.1.a. The value of intellectual property and know-how contributions will be supported by an independent third-party appraiser qualified in valuing intellectual property and know-how. SA, §IV.6.a. Grants will be valued at the dollar amount actually paid by P&G. SA, §IV.6.b. Product donations will be valued at the price P&G sells the products to wholesalers and/or distributors. SA, §IV.6.c.

If eligible Claims are below $10,000,000, P&G will contribute Additional DHIC so that the total aggregate contributions to the Settlement Class (including Cash Refunds and all DHIC) will reach $15,000,000. SA, §IV.A.3.a. If the aggregate amount of eligible Claims exceeds $15,000,000, P&G will contribute additional DHIC up to a maximum of $25,000,000 total value (including Cash Refunds and all DHIC) to the Settlement Class. SA, §IV.A.3.b.

3. Injunctive Relief

The Settlement prohibits P&G from making the "clinically proven" five symptom relief claims, absent new supporting clinical data or analysis, or change in product formula. SA, §IV.B. "New supporting clinical data or analysis" means competent and reliable scientific evidence that was not originally relied on by P&G to support these claims, which were made on the Align packaging and sold to consumers from approximately March 1, 2009 through October 31, 2009. *Id*. The limited scope of the injunctive relief allows any consumer (or government agency) to sue to enjoin P&G from advertising that Align has the advertised health benefits.

4. Notice and Claim Administration Expenses

All Notice and Claim Administration Expenses will be paid by P&G separate and apart from any other consideration paid under the Settlement. SA, §VI.A.1. This includes all notice expenses, the costs of administering the Class Notice Program, and the costs of processing and distributing all Cash Refunds to authorized Claimants. SA, §II.A.19. Plaintiffs estimate the

Notice and Claim Administration Expenses will be in excess of $500,000. Blood Decl., ¶44.

5. Attorneys' Fees and Expenses

Class Counsel, on behalf of all Plaintiffs' Counsel, will apply for an award of Attorneys' Fees and Expenses not to exceed $4,500,000. SA, §IX.A. Class Counsel will distribute and allocate the Attorneys' Fees and Expenses among the firms that comprise Plaintiffs' Counsel. P&G agrees not to oppose an application for these amounts. P&G will pay Attorneys' Fees and Expenses separately and in addition to the Settlement benefits to Settlement Class Members. SA, §IX.A. None of the Settlement benefits for Settlement Class Members will be reduced to pay attorneys' fees or to reimburse expenses of Class Counsel.

Class Counsel may also petition the Court for service awards of up to $2,500 for each Class Representative for their time invested in connection with the Action and willingness to serve as Class Representatives. The Court-approved service awards will be paid by P&G separate and apart from the other payment obligations in the Settlement Agreement. SA, §IX.C.

C. Release and Waiver

In consideration for the Settlement, the Settlement Class Members will be subject to the following release and waiver of rights:

> [W]ith the exception of claims for personal injury, all claims, demands, actions, suits, and/or causes of action that have been brought or could have been brought, are currently pending or were pending, or are ever brought in the future, by any Settlement Class Member against P&G or any Released Party, in any forum in the United States and its territories, whether known or unknown, asserted or unasserted, under or pursuant to any statute, regulation, common law or equity, that relate in any way, directly or indirectly, to facts, acts, events, transactions, occurrences, courses of conduct, representations, omissions, circumstances or other matters related to or referenced in any claim raised (including, but not limited to, any claim that was raised against any Released Party) in this Action, including damages, costs, expenses, penalties, and attorneys' fees.

SA, §§II.A.28, VIII.

This Release does not include claims for personal injury and does not extend to purchases made outside of the Class Period. SA, §II.A.28. The Release will also be made available at the Settlement Website.

D. The Class Notice Program

The Parties have developed a Class Notice Program with the help of the Settlement Administrator KCC LLC ("KCC"), a firm that specializes in developing class action notice plans. SA, §VI.A.1.

Class Notice will be provided to Settlement Class Members primarily through publication, including online banner advertisements. SA, §VI.C.1. This is because Align was sold over the counter at retail stores, and P&G does not have contact information for Settlement Class Members. Use of the Internet also maximizes the dollars spent to contact the Settlement Class. Internet publication through the use of hyperlinked online banner advertisements has the further advantage of immediately linking the reader to the Settlement Website and the Claim Form. The details of the Class Notice Program, including the methodology underlying its design, are further explained in the Peak Declaration and the Class Notice Program prepared by KCC, which is attached as Exhibit 1 to the Peak Declaration.

The Publication Notice provides Settlement Class Members with information regarding the Settlement and informs them about their rights. SA, §VI.C.1. It contains general descriptions of the lawsuit, Settlement Class Members' legal rights, and the Settlement's relief, including how a Claim may be filed. The Publication Notice also directs Settlement Class Members to a neutral website dedicated to the Settlement (www.AlignSettlement.com), which will contain the Claim Form, the detailed Long-form Class Notice, Court orders, Settlement-related deadlines, and other documents and information. Settlement Class Members may also obtain a copy of the Claim Form by calling the Settlement Administrator toll-free or by writing to the Settlement Administrator. The Publication Notice and Internet banner ads will appear in a variety of places selected based on market research evaluating the demographics of consumers who purchase Align. SA, §VI.C.1; Peak Decl., ¶¶15-27, Ex. 1 (Class Notice Program). The Publication Notice is attached to the Stipulation of Settlement as Exhibit 4.

KCC designed the paid media portion of the Class Notice Program to target Settlement Class Members on the websites they are currently browsing and through dedicated advertising on specific web properties. This includes online banner advertisements across multiple devices, including desktop, tablet, and mobile devices. The banner ads will allow visitors to self-identify as potential Settlement Class Members and "click" on a banner that will link them directly to the official Settlement Website. *See* Peak Decl., ¶23, Exs. 1 (the Class Notice Program) and 2 (Internet banner ad exemplars).

Complementing the Publication Notice and Internet banner ads is the detailed Long-form Class Notice. SA, §§VI.B.3, VI.C.2. The Long-form Class Notice contains detailed information about the lawsuit, the Settlement benefits, the Release and how to opt-out, as well as how to object and exercise other rights under the Settlement Agreement. The Long-form Class Notice will be available on the Settlement Website and by request to the Settlement Administrator. *Id*. at §§VI.B.1., VI.C.2. The Long-form Class Notice is attached to the Stipulation of Settlement as Exhibit 5.

Website Notice through the Settlement Website will include the Long-form Class Notice, along with a copy of the Settlement Agreement and its exhibits, any preliminary approval order, the Claim Form, the Third Amended Class Action Complaint, the motions for preliminary and final settlement approval, answers to frequently asked questions, the toll-free hotline number maintained by the Settlement Administrator for this Settlement, and Settlement-related deadlines. SA, §VI.B.3.

IV. THE SETTLEMENT MERITS PRELIMINARY APPROVAL

Settlements of class actions are strongly favored. As a matter of express public policy, "[t]he law favors settlement, particularly in class actions and other complex cases where substantial judicial resources can be conserved by avoiding formal litigation." Rubenstein, Newberg on Class Actions ("Newberg"), §13:44 (5th ed. 2015); *see also UAW v. GMC*, 497 F.3d 615, 632 (6th Cir. 2007) (noting "the federal policy favoring settlement of class actions"); *Waggoner v. U.S. Bancorp*, No. 5:14-cv-1626, 2016 U.S. Dist. LEXIS 179843, at *9 (N.D.

Ohio Dec. 29, 2016) (there is a "strong public interest in encouraging settlement of complex litigation and class action suits").

Rule 23(e) sets forth a two-step process in which the Court first determines whether a proposed class action settlement deserves preliminary approval and then, after notice is given to class members, whether final approval is warranted. *In re Inter-Op Hip Prosthesis Liab. Litig.*, 204 F.R.D. 359, 379 (N.D. Ohio 2001); *Reed v. Rhodes*, 869 F. Supp. 1274, 1278 (N.D. Ohio 1994).

At preliminary approval, "[the Court] is not obligated to, nor could it reasonably, undertake a full and complete fairness review." *In re Inter-Op*, 204 F.R.D. at 379. Instead it must "conduct a threshold examination [of] the overall fairness and adequacy of the settlement in light of the likely outcome and the cost of continued litigation." *Id.* The preliminary fairness assessment "is not to be turned into a trial or rehearsal for trial on the merits," for "it is the very uncertainty of outcome in litigation and avoidance of wasteful and expensive litigation that induce consensual settlements." *Id.* at 379; Manual for Complex Litigation §21.632 (4th ed. 2004) (the "Manual") (preliminary approval stage is an "initial evaluation" of the fairness of the proposed settlement); *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, No. 1:01-CV-9000, 2001 U.S. Dist. LEXIS 26714, at *16-20 (N.D. Ohio Oct. 19, 2001).

The "court's role in evaluating a private consensual agreement must be limited to the extent necessary to reach a reasoned judgment that the agreement is not the product of fraud or overreaching by, or collusion between, the negotiating parties, and that the settlement, taken as a whole, is fair, reasonable and adequate to all concerned." *Clark Equipment Co. v. International Union, Allied Industrial Workers*, 803 F.2d 878, 880 (6th Cir. 1986). A settlement "warrants preliminary approval if it is within the range of what ultimately could be considered fair, reasonable, and adequate—a determination left to the sound discretion of the Court." *Bowling v. Pfizer*, 144 F. Supp. 3d 945, 952 (S.D. Ohio 2015).

If "the proposed settlement appears to be the product of serious, informed, non-collusive negotiation, 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," then the court should direct notice be given to class members of a formal fairness hearing. *In re Polyurethane Foam Antitrust Litig*., MDL No. 2196, 2012 U.S. Dist. LEXIS 192151, at *14 (N.D. Ohio Jan. 23, 2012); *Brent v. Midland Funding, LLC*, No. 3:11-cv-1332, 2011 U.S. Dist. LEXIS 98763, at *17 (N.D. Ohio Sept. 1, 2011) (noting that "[t]he Court granted the motion for preliminary approval" after "finding that the proposed settlement was within the range of fairness and reasonableness"); *In re Telectronics Pacing Sys*., 137 F. Supp. 2d 985, 1015 (S.D. Ohio 2001) (same).

The Sixth Circuit has articulated seven factors to use in evaluating the fairness of a class action settlement: (1) the risk of fraud or collusion; (2) the complexity, expense and likely duration of the litigation; (3) the amount of discovery completed; (4) the likelihood of success on the merits; (5) the opinions of class counsel and class representatives; (6) the reaction of absent class members; and (7) the public interest in the settlement. *UAW*, 497 F.3d at 631. These factors must all be considered as a whole to determine whether a proposed settlement is fair, adequate, and reasonable. *Bowling*, 143 F.R.D. at 151; *Thompson v. Midwest Foundation Independent Physicians Asso*., 124 F.R.D. 154, 157 (S.D. Ohio Dec. 4, 1988) ("A class action settlement cannot be measured precisely against any particular set of factors, however, and the court may be guided by other factors, the relevancy of which will vary from case to case."). At the preliminary approval stage, only certain of the Sixth Circuit's factors are relevant to the fairness inquiry. *Smith v. Ajax Magnethermic Corp*., No. 4:02CV0980, 2007 U.S. Dist. LEXIS 85551, at *15 (N.D. Ohio Nov. 7, 2007) (at preliminary approval, analyzing the strength of plaintiffs' case, the risk, expense, complexity, and likely duration of litigation, the amount offered in settlement, and the experience and views of counsel); *see also In re Skechers Toning Shoe Prods. Liab. Litig*., No. 13-md-2308, 2012 U.S. Dist. LEXIS 113641, at *20-21 (W.D. Ky. Aug. 13, 2012).

The Stipulation of Settlement is well within the range of possible approval as a fair, reasonable, and adequate resolution between the Parties, and should be preliminarily approved. All of the relevant factors set forth by the Sixth Circuit for evaluating the fairness of a settlement at the final stage weigh in favor of preliminary approval now, and there can be no

doubt that the Settlement was reached in a procedurally fair manner given the ongoing guidance and assistance of mediator Antonio Piazza. For these reasons, the Stipulation of Settlement merits preliminary approval.

A. The Settlement Is the Product of Good Faith, Informed, and Arm's-Length Negotiations Conducted Before a Respected Mediator Following Seven Years of Protracted Litigation

In evaluating a proposed class action settlement, the district court must make sure the terms are reasonable and the settlement is not the product of fraud, overreaching, or collusion. *Priddy v. Edelman*, 883 F.2d 438, 447 (6th Cir. 1989). "Where the proposed settlement was preceded by a lengthy period of adversarial litigation involving substantial discovery, a court is likely to conclude that settlement negotiations occurred at arms-length." Newberg, §13:14; *In re Inter-Op Hip Prosthesis Liab. Litig.*, 204 F.R.D. at 350-51 ("when a settlement is the result of extensive negotiations by experienced counsel, the Court should presume it is fair.").

1. There Is No Fraud or Collusion

This Settlement was reached after numerous complex and contentious arms-length negotiations—assisted by three third-party mediators—over the course of seven years and as trial approached. Blood Decl., ¶39; *see, e.g., Enter. Energy Corp. v. Columbia Gas Transmission Corp.*, 137 F.R.D. 240, 244 (S.D. Ohio 1991) (approving settlement reached "[a]fter almost six months of concerted negotiations").

The fact that experienced mediators were heavily involved in the negotiation of the Settlement demonstrates it is anything but collusive. *Gascho v. Global Fitness Holdings, LLC*, 822 F.3d 269, 277 (6th Cir. 2016) ("parties' two-and-a-half years of litigation, extensive discovery, ongoing settlement negotiations, and formal mediation session all weighed against the possibility of fraud or collusion"); *Waggoner*, 2016 U.S. Dist. LEXIS 179843, at *8 (finding no risk of fraud or collusion where "the settlement was the result of arms-length negotiations between parties that were represented by able counsel, after considerable discovery and an involved mediation before an experienced mediator"); *Dudenhoeffer v. Fifth Third Bancorp*, No. 1:08-CV-538-SSB, 2016 U.S. Dist. LEXIS 187041, at *8 (S.D. Ohio July 11, 2016) (same).

In addition, hard-fought litigation over the course of seven years was the driving force behind this Settlement. This involved substantial motion practice, an appeal to the Sixth Circuit followed by denial of a petition for *writ of certiorari* from the Supreme Court, extensive discovery, work up of expert reports and trial preparation.

At this preliminary stage the Court must only decide whether there are "substantial grounds to doubt the preliminary fairness … of the proposed settlement agreement," it does not need to decide whether proposed service awards and attorneys' fees will be approved. *In re Inter-Op Hip Prosthesis Liab. Litig.*, 204 F.R.D. at 352. Nevertheless, the proposed Attorneys' Fees and Expenses were negotiated after the Parties agreed on the principal terms of the Settlement and with the assistance of the mediator. Blood Decl., ¶42. Neither the fees nor service awards will reduce the benefits available to the Settlement Class.

No fraud or collusion that attends this Settlement. Thus, this factor supports preliminary approval.

2. Extensive Discovery Was Conducted by Both Parties and Contributed to This Settlement

As shown above, this Settlement was reached after the Parties conducted substantial fact and expert discovery on all relevant issues. Blood Decl., ¶¶22, 34.

Accordingly, the Settlement was conceived from informed negotiations by experienced counsel. "[W]hen significant discovery has been completed, the Court should defer to the judgment of experienced trial counsel who has evaluated the strength of his case." *Bronson v. Bd. of Educ. of City Sch. Dist. of City of Cincinnati*, 604 F. Supp. 68, 73 (S.D. Ohio 1984); *Gascho*, 822 F.3d at 277 (affirming settlement approval where "[d]iscovery was 'extensive,' including the service of multiple sets of interrogatories, the production of over 400,000 documents, and over ten depositions").

B. The Settlement Provides Substantial Benefits to Settlement Class Members and Serves an Important Public Interest

In evaluating the fairness of the consideration offered in the Settlement, it is not the role of the Court to second-guess the negotiated resolution of the parties. "[T]he court's

intrusion upon what is otherwise a private consensual agreement negotiated between the parties to a [class-action] lawsuit must be limited to the extent necessary to reach a reasoned judgment that the agreement is not the product of fraud or overreaching by, or collusion between, the negotiating parties, and that the settlement, taken as a whole, is fair, reasonable and adequate to all concerned." *Vassalle v. Midland Funding, LLC*, No. 3:11-cv-00096, 2014 U.S. Dist. LEXIS 146543, at *18 (N.D. Ohio Oct. 14, 2014).

This is because settlements are "a product of compromise efforts by adversaries[] [and] [u]sually neither side will attain all its goals in such a settlement." *In re Ford Motor Co. Spark Plug & Three Valve Engine Prods. Liab. Litig.*, No. 1:12-MD-2316, 2016 U.S. Dist. LEXIS 188074, at *15 (N.D. Ohio Jan. 26, 2016); *Bronson*, 604 F. Supp. at 78; *City of Detroit v. Grinnell Corp.*, 495 F.2d 448, 455 n.2 (2d Cir. 1974) ("there is no reason, at least in theory, why a satisfactory settlement could not amount to a hundredth or even a thousandth part of a single percent of the potential recovery."), abrogated on other grounds by *Goldberger v. Integrated Res., Inc.*, 209 F.3d 43, 49-50 (2d Cir. 2000).

The settlement taken as a whole, rather than the individual component parts, must be examined for overall fairness. *Granada Invest., Inc. v. DWG Corp.*, 962 F.2d 1203, 1206 (6th Cir. 1992). The possibility "that the settlement could have been better … does not mean the settlement presented was not fair, reasonable or adequate[.]"*In re Polyurethane Foam Antitrust Litig.*, 168 F. Supp. 3d 985, 1001 (N.D. Ohio 2016). Because "[s]ettlement is the offspring of compromise; the question … is not whether the final product could be prettier, smarter or snazzier, but whether it is fair, adequate and free from collusion." *Id.* The benefits provided by this Settlement are excellent.

The Settlement provides substantial benefits to the Settlement Class. First, Settlement Class Members may apply for a Cash Refund of up to $49.26 for three purchases of Align. SA, §§IV.A.2.a.1 and 2. The individual refund awards represent 50% of the average weighted retail price of Align during the respective time periods. *Id.* P&G will pay up to $15,000,000 in Cash Refunds. SA, §IV.A.2.c.

Second, P&G will contribute at least $5,000,000 in Digestive Health Improvement Contributions to support digestive health research and education. *Id*. at §IV.4.A.1.a. These contributions will directly benefit Settlement Class Members that suffer from IBS, or who regularly seek assistance and care for their digestive health. All Settlement Class Members will benefit from this relief considering that the only reason to purchase Align is for its advertised digestive health benefits.

Third, the Settlement ensures P&G will not promote the health benefits of Align as being "clinically proven" absent new supporting clinical data or analysis, or a change in product formula. *Id*. at §IV.B.

The combined value of the Cash Refunds, DHIC payments, Notice and Claim Administration Expenses and Attorneys' Fees and Expenses is at least $20 million and may exceed $30 million.

Additionally, the Settlement's public benefit supports preliminary approval. *See Redington v. Goodyear Tire & Rubber Co*., No. 5:07-cv-1999, 2008 U.S. Dist. LEXIS 64639, at *53 (N.D. Ohio Aug. 22, 2008). In addition to the relief provided, the Settlement is in the public's interest because it "would avoid prolonged litigation, resulting in the conservation of both the parties' resources and the Court's resources." *Moore v. Aerotek, Inc*., No. 2:15-cv-2701, 2017 U.S. Dist. LEXIS 102621, at *18 (S.D. Ohio June 30, 2017); *In re Telectronics Pacing Sys., Inc*., 137 F. Supp. 2d at 1025 (finding the settlement was in the public interest because, *inter alia*, "it frees … the valuable judicial resources of this Court").

Based upon the foregoing, these factors weigh in favor of preliminary approval of the proposed Settlement.

C. The Risk, Expense, Complexity, and Likely Duration of Further Litigation Support Preliminary Approval

The risk, expense, complexity and duration of litigation are significant factors considered in evaluating the reasonableness of a settlement. *Lonardo v. Travelers Indem. Co*., 706 F. Supp. 2d 766, 781 (N.D. Ohio 2010) (approving settlement where the case "was a hard-fought legal battle from the filing of the complaint … to the final settlement conference" and

explaining that "[b]ased on the Court's intimate knowledge of these proceedings, there is no reason to believe that either party would litigate the remainder of the case less vigorously"). Although Plaintiffs have an unflagging belief in the strength of their claims against P&G, Plaintiffs must balance this against the considerable risks and duration of continuing litigation.

The most significant risk arises from passages in the Sixth Circuit's opinion affirming class certification. The Sixth Circuit's opinion suggests that if Plaintiffs fail to prove Align is ineffective for everyone or, conversely Defendant sufficiently shows Align works for anyone, then the entire class loses. The Sixth Circuit opinion states that, "[i]f Align in fact is proven scientifically to work for some individuals, Plaintiffs will lose on the merits" and the "straightforward impact of [] evidence [that Align might work for some sub-populations] is simply that it may prevent Plaintiffs from succeeding on the merits." *Rikos*, 799 F.3d at 520, 523. It continues, stating "an inability of the plaintiff class to prove [that Align does not work for anyone] would not result in individual questions predominating. Instead, a failure of proof on th[is] issue … would end the case" and "there is only one reason to buy Align: its digestive health benefits. And whether or not Align works as promised for *anyone*—the issue here—is a scientific question that will not turn on the individual behavior of consumers; if Align is shown to work, even for only certain individuals, then presumably Plaintiffs lose." *Id*. at 521-22.

The Sixth Circuit goes on to state that "the district court may choose to revisit the issue of class certification rather than dismiss the case if assessment of the fully developed evidence presented by both parties suggests Align actually works for some subpopulations" and "[i]f later evidence disproves Plaintiffs' contentions that common issues predominate, the district court may consider at that point whether to modify or decertify the class." *Id*. at 520.

Factually, Plaintiffs believe the facts show that they win, although there is an element of proving a negative (showing that Align cannot work for anyone, no matter how unique). Plaintiffs also contend that despite the language in the Sixth Circuit opinion, it cannot reflect an accurate interpretation of the opinion since that interpretation would have the effect of altering state substantive law. The consumer protection laws asserted are strict liability laws that use a reasonable person standard to determine falsity, rather than a common law fraud

standard that requires a showing that each class member was misled and the product did not work. If these unqualified advertising claims are untrue or misleading to the reasonable person, including because Align does not work for many people, rather than every conceivable person, then liability attaches and the class is still entitled to recover. *See*, *e.g*., *Lavie v*. *Procter & Gamble Co*., 105 Cal. App. 4th 496, 506-07 (2003) (under the UCL "unless the advertisement targets a particular disadvantaged or vulnerable group, it is judged by the effect it would have on a reasonable consumer"); *Consumer Advocates v*. *Echostar Satellite Corp*., 113 Cal. App. 4th 1351, 1360 (2003) (same standard applies to CLRA); *Latman v*. *Costa Cruise Lines, N.V*., 758 So. 2d 699, 703 (Fla. App. 2000) (FDUTPA applies reasonable consumer standard); *Kitzes v*. *Home Depot, U.S.A*., *Inc*., 374 Ill. App. 3d 1053, 1061 (2007) ("under the Consumer Fraud Act, materiality is tested with a reasonable person standard"); *Mulligan v*. *Choice Mortg*. *Corp*. *USA*, No. 96-596-B, 1998 U.S. Dist. LEXIS 13248, at *34-35 (D. N.H. Aug. 11, 1998) ("New Hampshire courts use an objective standard to determine whether acts or practices are 'unfair or deceptive' in violation of the CPA."); *Ridley v*. *Wendel*, 795 S.E.2d 807, 813 (N.C. Ct. App. 2016) (test is whether defendant's act possessed the tendency or capacity to mislead or create the likelihood of deception to a reasonable person); *Jones v*. *Capitol Broad*. *Co*., 128 N.C. App. 271, 275 (1998) (same).

Nonetheless, the existence of the Sixth Circuit's opinion creates substantial risk for success and, at a minimum, can lead to substantial delay. Plaintiffs do not know how the district court would interpret the opinion or how the Sixth Circuit would interpret its opinion on appeal.

The challenges created by the language in the Sixth Circuit's opinion are in addition to the ordinary risk a case like this poses. The trial would amount to a fierce "battle of the experts," which always presents the potential for confusing jurors.

Settlement will ensure the Settlement Class a fair and reasonable recovery and bring attention to P&G's misleadingly advertised product. The proposed Settlement guarantees a substantial recovery for the Settlement Class now while obviating the need for a lengthy, complex, and uncertain trial and appeal. *Preston v*. *Craig Transp*. *Co*., No. 3:14 CV 1410,

2015 U.S. Dist. LEXIS 183019, at *6 (N.D. Ohio Oct. 29, 2015).

As in *Amos v. PPG Indus*, "[t]he amount and form of this relief balanced against the Plaintiffs' likelihood of success on the merits weighs in favor of approving the Settlement Agreement. In contrast to the uncertainty of litigation, the Settlement Agreement provides immediate certainty to Plaintiffs … [and] [a]fter [seven] years of litigation, this certainty outweighs the risk of proceeding on the merits of Plaintiffs' claims and receiving nothing." No. 2:05-cv-70, 2015 U.S. Dist. LEXIS 106944, at *10 (S.D. Ohio Aug. 13, 2015); *see also UAW*, 497 F.3d at 631 ("The fairness of each settlement turns in large part on the bona fides of the parties' legal dispute.").

D. The Experience and Views of Counsel

"The Sixth Circuit has held that, in the context of approving class action settlements, the Court should defer to the judgment of experienced counsel who has competently evaluated the strength of his proofs." *Smith*, 2007 U.S. Dist. LEXIS 85551, at *14. Class Counsel fully endorses the proposed Settlement as fair, reasonable, and adequate. Blood Decl., ¶39. This opinion is based on Class Counsel's collective and substantial experience litigating dozens of class actions and serving as class counsel for many. *Id*. at ¶¶45-46, Ex.3 (BHO Resume). Experienced counsel's endorsement "is entitled to significant weight, and supports the fairness of the class settlement." *UAW v. GMC*, No. 05-CV-73991-DT, 2006 U.S. Dist. LEXIS 14890, at *18 (E.D. Mich. March 31, 2006); *see also In re Skechers Toning Shoe Prods. Liab. Litig.*, No. 11-md-2308, 2013 U.S. Dist. LEXIS 67441, at *34-35 (W.D. Ky. May 10, 2013) (citing BHO's experience in class action litigation and their views of the settlement before the court).

V. THE CLASS IS PROPERLY EXPANDED TO INCLUDE ALL PURCHASERS NATIONWIDE

When presented with a proposed settlement, a court must determine whether the proposed settlement class satisfies the requirements for class certification under Rule 23. *UAW*, 497 F.3d at 625. This Court previously found these requirements were met and certified five single-state classes (California, Florida, Illinois, New Hampshire, and North Carolina), and appointed Plaintiffs' Counsel, Timothy G. Blood, as class counsel, and Plaintiffs as class

representatives. ECF No. 140. Certification was upheld by the Sixth Circuit Court of Appeals.

The Parties now seek to expand the class to include all those who purchased Align in the United States and its territories. In the litigation context, expanding the scope of the certified class in this way presents issues of manageability of the case at trial. However, no such issues exist here because the expanded scope is done in the context of a settlement class, where there will be no trial. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 620 (1997) ("Confronted 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 be no trial.").

Further, in the settlement context differences in state law do not defeat certification. *Brent*, 2011 U.S. Dist. LEXIS 9876, at *48 ("The Court is satisfied that the speculative possibility that certain class members may have more lucrative claims under state law should not prevent the classwide settlement of this case."); *see also Sullivan v. DB Invs., Inc.*, 667 F.3d 273, 299-302 (3d Cir. 2011) (*en banc*) (explaining that "[a]s long as a sufficient constellation of common issues binds class members together, variations in the sources and application of applicable laws will not foreclose class certification"); *Hanlon v. Chrysler Corp.*, 150 F.3d 1011, 1022-23 (9th Cir 1998) (finding predominance satisfied where class members brought claims under "local variants of a generally homogenous collection of causes which include products liability, breaches of express and implied warranties, [] and lemon laws").

Given that the requirements for a settlement class are generally less onerous than those for a trial class, there is little question that the proposed nationwide Settlement Class meets the requirements of Rules 23(a) and (b)(3). *See In re Sears, Roebuck & Co. Front-Loading Washer Prods. Liab. Litig.*, No. 06 C 7023, 2016 U.S. Dist. LEXIS 25290, at *30 (N.D. Ill. Feb. 29, 2016) (citing *Amchem*, 521 U.S. at 620).

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A. The Settlement Class Satisfies the Requirements of Federal Rule of Civil Procedure 23(a)

Rule 23(a) enumerates four prerequisites for class certification: (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy. The Parties agree that each of these requirements is met for purposes of certifying this Settlement Class.

1. Numerosity

Rule 23(a)(1) requires that a class be "so numerous that joinder of all members is impracticable." While no strict numerical test exists, "thousands" of products sold will satisfy the numerosity requirement. Class Cert. Order at 16. "Between 2009 and 2013, Defendant sold over 9.5 million (9,500,000) packages of Align." *Id*. Accordingly, the numerosity requirement is readily satisfied. *Id*.

2. Commonality

Rule 23(a)(2) requires the existence of "questions of law or fact common to the class." "Commonality is determined by whether the issues raised have the capacity [in] a classwide proceeding to generate common answers apt to drive the resolution of the litigation." Class Cert. Order at 16. "To demonstrate commonality, plaintiffs must show that class members have suffered the same injury." *Id*. "[T]here need be only one common question to certify a class." *Id*. This prerequisite is readily met here. *Id*. at 17. This Court previously found commonality was satisfied stating "[h]ere, determining whether Align provides any digestive health benefit is a common question that will advance this litigation." *Id*. The Sixth Circuit agreed, "the district court correctly found that Plaintiffs have demonstrated that their claims share a common question—whether Align is 'snake oil' and thus does not yield benefits to anyone." *Rikos*, 799 F.3d at 508-09.

3. Typicality

Rule 23(a)(3) "requires that the claims … of the representative parties be typical of the claims … of the class." "A proposed class representative's claim is typical if it arises from the same event or practice or course of conduct that gives rise to the claims of other class members, and [the] claims are based on the same legal theory." Class Cert. Order at 16-17.

"Typical does not mean identical, and the typicality requirement is liberally construed." *Id*. Here, typicality is met because "Plaintiffs and the proposed [C]lass[] assert the same claims that arise from the same course of conduct—Defendant's representations about the digestive health benefits of Align." *Id*. at 19. This Court explained, "Defendant advertised to all that the proprietary probiotic bacteria in Align provides proven digestive health benefits.… For each member within the proposed [C]lass[] to recover under the claims at issue, each must prove the same elements as the Plaintiffs." *Id*. at 19; *Rikos*, 799 F.3d at 509 ("the district court did not abuse its discretion in finding that the claims or defenses of the representative parties are typical of the claims or defenses of the class.").

4. Adequacy of Representation

Rule 23(a)(4) "requires the Court to determine whether the representative parties will fairly and adequately protect the interests of the class." This requires "a two pronged inquiry." Class Cert. Order at 19. The representatives must have common interests with unnamed class members and must vigorously prosecute their interests through qualified counsel. *Id*.

Here, the interests of Plaintiffs and members of the Settlement Class are fully aligned and there are no conflicts of interest, disabling or otherwise. Each of them purchased Align and was subject to the same allegedly false advertising and suffered the same injuries. *Id*. at 20-24. Further, Plaintiffs retained qualified counsel with significant experience prosecuting large consumer rights class actions, including class actions against manufacturers of digestive health "probiotic" products. *Id*. at 24; *see also* Blood Decl., ¶¶45-46, Ex. 3 (BHO Resume). Any doubt on this score is dispelled by the vigorous way Plaintiffs' Counsel litigated this case for seven years. Accordingly, the adequacy requirement is met.

B. The Rule 23(b)(3) Requirements Are Satisfied

Certification is warranted under Rule 23(b)(3) because "the questions of law or fact common to class members predominate over any questions affecting only individual members," and "a class action is superior to other available methods for fairly and efficiently" settling the controversy. This case satisfies the predominance and superiority requirements.

1. Common Issues of Law and Fact Predominate

"Predominance is a test readily met in certain cases alleging consumer or securities fraud …." Class Cert. Order at 25. "This requirement is satisfied when the questions common to the class are at the heart of the litigation." *Id*. "The predominance inquiry trains on the legal or factual questions that qualify each class member's case as a genuine controversy." *Id*. at 26. "[T]he fact that a defense may arise and may affect class members differently does not compel a finding that individual issues predominate over common ones." *Id*. "The requirement demands only predominance of common questions, not exclusivity or unanimity of them." *Id*.

"An issue central to the validity of each one of the claims in a class action, if it can be resolved in one stroke, can justify class treatment." *Id*. at 25-26. Thus, "[w]hen common questions present a significant aspect of the case and they can be resolved for all members of the class in a single adjudication, there is clear justification for handling the dispute on a representative rather than on an individual basis." *Hanlon*, 150 F.3d at 1022.

This Court previously found predominance is met explaining:

> Here, the predominating common issues shared by Plaintiffs and each class member are whether Defendant represented through its advertising and labeling that Align promotes digestive health and whether the advertising message is truthful or not deceptive. The resolution of these questions does not rise or fall on the individualized conduct of class members, but on Defendant's conduct and the objective medical science about whether Align works. These questions are binary: either the advertising message was made or it was not, and the digestive health claim is either true or not. Accordingly, it is "patently true" that proof that certain representations were made and, whether made truly or falsely, [can] be established without resort to the testimony of individual class members.

Class Cert. Order at 26 (emphasis omitted).

With respect to damages the Court explained that "[c]ommon issues may predominate when liability can be determined on a class-wide basis, even when there are some individualized damage issues." *Id*. at 30. The Court held, where, as here, "damages could be measured on a classwide basis, predominance is readily met." *Id*. "Align has no value other than its advertised purpose. It is a capsule filled with bacteria and inert ingredients. If, as alleged, the bacteria does nothing then the capsule is worthless and [P]laintiffs and the [C]lass

[M]embers are entitled to a return of the purchase price paid under both damage and restitution theories." *Id*. (emphasis omitted). The Sixth Circuit Court of Appeal affirmed this Court's ruling holding "the district court did not abuse its discretion in determining that common issues will predominate over individual issues in resolving the key merits issue of this case—whether Align promotes digestive health for anyone." *Rikos*, 799 F.3d at 524. Thus, as before, common issues predominate for Rule 23(b)(3) purposes.

2. Class Treatment Is Superior in this Case

Rule 23(b)(3) "sets forth the factors to determine whether a class action is superior to other available methods for the fair and efficient adjudication of the controversy." Class Cert. Order at 36. "These factors include: (i) the class members' interest in individually controlling separate actions; (ii) the extent and nature of any litigation concerning the controversy already begun by or against class members; (iii) the desirability or undesirability of concentrating the litigation of the claims in the particular forum; and (iv) the likely difficulties in managing a class action." *Id*.

This Court previously found that Rule 23(b)(3)'s "superiority factors weigh in favor of certification here" because "[t]he value of the claims of individual class members is too small to justify individual litigation" and "class members are not likely to file individual actions—[where] the cost of litigation would dwarf any potential recovery." *Id*. at 37. Accordingly, "[i]t is far more efficient to litigate this action in one case, rather than many [.]" *Id*. Here, "[t]here simply is no other available method of adjudication." *Id*.

Manageability concerns, moreover, while "by [] far, the most critical concern in determining whether a class action is a superior means of adjudication," Newberg §4:72, are irrelevant in the settlement context. *See Amchem*, 521 U.S. at 620 ("Confronted 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 be no trial."). In particular, because the Class is proposed for settlement, manageability concerns presented by variances in state law do not defeat a finding of superiority. The court in *Sullivan* explained, "[b]ecause we are presented with a settlement class certification, we are not as

concerned with formulating some prediction as to how variances in state law would play out at trial, for the proposal is that there be no trial. As such, we simply need not inquire whether the varying state treatments of [the] claims at issue would present the type of insuperable obstacles or intractable management problems pertinent to certification of a litigation class." 667 F.3d at 303-04. Simply put, state law variations are largely "irrelevant to certification of a settlement class." *In re Warfarin Sodium Antitrust Litig*., 391 F.3d 516, 529 (3d Cir. 2004).

Because the class action device provides the superior means to effectively and efficiently resolve this controversy, and as the other requirements of Rule 23 are each satisfied, certification of the Settlement Class is appropriate.

VI. THE CLASS NOTICE PROGRAM SHOULD BE APPROVED

Class notice must meet the requirements of both Rule 23(c)(2) and 23(e). Rule 23(c)(2) requires the Court to "direct to class members the best notice that is practicable under the circumstances, including individual notice to all members who can be identified through reasonable effort," although actual notice is not required. *Amchem*, 521 U.S. at 617; *Reppert v. Marvin Lumber & Cedar Co*., 359 F.3d 53, 56 (1st Cir. 2004); *Silber v. Mabon*, 18 F.3d 1449, 1454 (9th Cir. 1994). The best practicable notice is that which is "reasonably calculated, under all the circumstances, to apprise interested parties of the pendency of the action and afford them an opportunity to object." *Mullane v. Cent. Hanover Bank & Trust Co*., 339 U.S. 306, 314 (1950). Rule 23(e)(1) requires that before a proposed settlement is considered for final approval, the Court "must direct notice in a reasonable manner to all class members who would be bound by the proposal."

The threshold requirement concerning the sufficiency of class notice is whether the means employed to distribute the notice is reasonably calculated to apprise the class of the pendency of the action, of the proposed settlement, and of the class members' rights to opt out or object. *UAW*, 497 F.3d at 629-30. "[N]otice is adequate if it may be understood by the average class member." Newberg, §11:53, at 167.

The Manual sets forth several elements of the "proper" content of notice. If these requirements are met, notice satisfies Rules 23(c)(2) and 23(e), and due process, and binds all members of the Class. The notice must:

1. Describe the essential terms of the settlement;
2. Disclose any special benefits or incentives to the class representatives;
3. Provide information regarding attorneys' fees;
4. Indicate the time and place of the hearing to consider approval of the settlement, and the method for objection to and/or opting out of the settlement;
5. Explain the procedures for allocating and distributing settlement funds; and
6. Prominently display the address of class counsel and the procedure for making inquiries.

Manual, ¶30.212.

The proposed "Class Notice", which includes the Short-Form Notice, Long-Form Notice, online banner advertisements, social media advertisements, print publications in four national publications, and Website Notice, satisfies these content requirements. *See* SA, Exs. 4 (Short Form Notice) and 5 (Long Form Notice); Peak Decl., Exs. 1-2 (the Class Notice Program and online banner ads). The forms of Class Notice are written in simple, straightforward language and include: (1) basic information about the lawsuit; (2) a description of the benefits provided by the Settlement; (3) an explanation of how Settlement Class Members can obtain Settlement benefits; (4) an explanation of how Settlement Class Members can exercise their right to opt-out or object to the Settlement; (5) an explanation that any claims against P&G that could have been litigated in this Action will be released if the Settlement Class Member does not opt out from the Settlement; (6) the name of Class Counsel and information regarding proposed Attorneys' Fees and Expenses, and Plaintiffs' incentive awards; (7) the Final Approval Hearing date; (8) an explanation of eligibility for appearing at the Final Approval Hearing; and (9) the Settlement Website and a toll-free number where additional information can be obtained. SA, Exs. 4-5. Class Notice also informs Settlement Class Members that Plaintiffs' final approval brief and request for Attorneys' Fees and

Expenses will be filed prior to the objection deadline. *See In re Mercury Interactive Corp. Sec. Litig.*, 618 F.3d 988, 993-94 (9th Cir. 2010).

Collectively, the forms of Class Notice provide Settlement Class Members with sufficient information to make an informed and intelligent decision about the Settlement. As such, the Class Notice satisfies the content requirements of Rule 23. *See In re Compact Disc. Minimum Advertised Price Antitrust Litig.*, 216 F.R.D. 197, 203 (D. Me. 2003) ("notice must describe fairly, accurately and neutrally the claims and parties in the litigation … entitled to participate, including the right to exclude themselves from the class"); *see also Skilstaf, Inc. v. CVS Caremark Corp.*, 669 F.3d 1005 (9th Cir. 2012) (upheld order enforcing judgment and settlement agreement in prior related action against plaintiff finding plaintiff's due process rights were not violated where plaintiff was provided full notice of the release and covenant not to sue and rejected opt out opportunity).

Additionally, the proposed dissemination of the Class Notice satisfies all due process requirements. These are small dollar, over-the-counter retail purchases, and there is no way to reasonably identify individual Settlement Class Members. Because P&G does not sell Align directly to consumers, it does not have mailing addresses or other contact information for the members of the Settlement Class. Therefore, the Class Notice Program consists of publishing the Class Notice in targeted print and online sources that direct Settlement Class Members to various methods of obtaining the Claim Form. Peak Decl., ¶¶14-29.

Class Notice is designed to reach 80% of proposed Settlement Class Members at least 2.5 times. *Id.* at 11. This will be accomplished by publishing notice in four magazines (Cooking Light, Men's Health, People and Woman's Day) commonly read by the target audience (probiotic customers aged 25 years and older), paid placement on Top Class Actions' website and its opt-in email newsletter to over 610,000 subscribers, as well as via paid media Internet banner ads widely disseminated on Facebook, Google and Yahoo, reaching over 90% of Internet users with an estimated 205 million impressions. *Id.* at 12-21. Additionally, Class Notice will be available on the Settlement Website and will be provided to Class Members who request it via the toll-free number established for this Settlement. *Id.* at 22.

Pursuant to the Settlement Agreement, section VI.B.4, KCC will provide notice of the proposed Settlement in accordance with CAFA, 28 U.S.C. §1715(b), to appropriate state and federal government officials.

VII. CLASS REPRESENTATIVES AND CLASS COUNSEL SHOULD BE APPOINTED

The Parties also request that the Court reaffirm designation of Plaintiffs Dino Rikos, Tracey Burns, and Leo Jarzembowski as Class Representatives for the Settlement Class. The Court previously appointed each as representatives of the Class. Class Cert. Order at 19-24.

Additionally, Rule 23(g)(1) requires the Court to appoint class counsel to represent the interests of the Class. The Parties request that Timothy G. Blood's appointment as Class Counsel be reaffirmed and that Thomas J. O'Reardon, II also be appointed Class Counsel for the Settlement Class. Class Cert. Order at 25. As set forth above, Mr. Blood and Mr. O'Reardon and their law firm Blood, Hurst & O'Reardon, LLP are experienced and well equipped to vigorously, competently and efficiently represent the proposed Settlement Class. Mr. O'Reardon, along with Mr. Blood, have litigated this matter from the start. Blood Decl., ¶¶45-46, Ex. 3.

VIII. THE PROPOSED SCHEDULE OF EVENTS

The key Settlement-related dates, such as the time to disseminate Class Notice or to opt-out or object, are based on when preliminary approval of the Settlement is granted, and when the Final Approval Hearing is scheduled. The Settlement-related dates calculated in accordance with the provisions of the Settlement are:

DATE	EVENT
Dissemination of Class Notice	Within 30 calendar days from entry of the Preliminary Approval Order
Briefs in support of final approval and for award of attorneys' fees	No later than 45 days prior to the Final Approval Hearing
Deadlines for objections, opt-outs, and notices to appear	30 days before date first set by Court for Final Approval Hearing
Briefs in response to objections and in further support of final approval and attorneys' fees	No later than 7 days prior to the Final Approval Hearing
First day Final Approval Hearing can be set	No earlier than 105 days after entry of Preliminary Approval Order

Accordingly, the Parties request that the Court schedule the Final Approval Hearing one hundred five (105) days after entry of its order granting preliminary approval, or as soon thereafter as the Court's schedule permits.

IX. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that the Motion for Preliminary Approval be granted and the Court enter an order: (i) granting preliminary approval of the proposed class action Settlement Agreement; (ii) certifying the Settlement Class; (iii) appointing Plaintiffs Dino Rikos, Tracey Burns, and Leo Jarzembowski as Class Representatives; (iv) appointing Timothy G. Blood and Thomas J. O'Reardon II as Class Counsel; (v) approving the Class Notice Program; (vi) appointing KCC LLC as the Settlement Administrator; and (vii) scheduling a Final Approval Hearing;

Respectfully Submitted,

Dated: September 29, 2017

BLOOD HURST & O'REARDON, LLP
TIMOTHY G. BLOOD (CA 149343)
LESLIE E. HURST (CA 178432)
THOMAS J. O'REARDON II (CA 247952)

By: *s/ Timothy G. Blood*
TIMOTHY G. BLOOD

701 B Street, Suite 1700
San Diego, CA 92101
Tel: 619/338-1100
619/338-1101 (fax)
tblood@bholaw.com
lhurst@bholaw.com
toreardon@bholaw.com

Attorneys for Plaintiffs and the Class

FUTSCHER LAW PLLC
DAVID A. FUTSCHER
913 N. Oak Drive
Villa Hills, KY 41017
Tel: 859/912-2394
david@futscherlaw.com

NICHOLAS & TOMASEVIC, LLP
CRAIG M. NICHOLAS (178444)
ALEX M. TOMASEVIC (245598)
225 Broadway, 19th Floor
San Diego, CA 92101
Tel: 619/325-0492
619/325-0496 (fax)
cnicholas@nicholaslaw.org

atomasevic@nicholaslaw.org

MORGAN & MORGAN, P.A.
RACHEL L. SOFFIN
One Tampa City Center
201 N. Franklin St., 7th Floor
Tampa, FL 33602
Tel: 813/223-5505
813/223-5402 (fax)
rsoffin@forthepeople.com

O'BRIEN LAW FIRM, PC
EDWARD K. O'BRIEN
One Sundial Avenue, 5th Floor
Manchester, NH 03103
Tel: 603/668-0600
603/672-3815 (fax)
eobrien@ekoblaw.com

SAMUEL ISSACHAROFF
40 Washington Square South
New York, NY 10012
Tel: 212/998-6580
sil3@nyu.edu

BONNETT, FAIRBOURN, FRIEDMAN & BALINT, P.C.
ANDREW S. FRIEDMAN
ELAINE A. RYAN
PATRICIA N. SYVERSON (203111)
2325 E. Camelback Road, Suite 300
Phoenix, AZ 85016
Tel: 602/274-1100
602/798-5860 (fax)
afriedman@bffb.com
eryan@bffb.com
psyverson@bffb.com

Additional Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2017, I electronically filed the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the e-mail addresses denoted on the Electronic Mail Notice List, and I hereby certify that I have mailed the foregoing document or paper via the United States Postal Service to the non-CM/ECF participants indicated on the Electronic Mail Notice List.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed September 29, 2017.

s/ Timothy G. Blood
TIMOTHY G. BLOOD

BLOOD HURST & O'REARDON, LLP
701 B Street, Suite 1700
San Diego, CA 92101
Tel: 619/338-1100
619/338-1101 (fax)
tblood@bholaw.com