UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA

CASE NO. 1:20-cv-23564-MGC

DAVID WILLIAMS and CAROLL ANGLADE, THOMAS MATTHEWS, MARTIZA ANGELES, and HOWARD CLARK, *individually and on behalf of all others similarly situated*,

Plaintiffs,

v.

RECKITT BENCKISER LLC and RB HEALTH (US) LLC,

Defendants.

DEFENDANTS' MOTION TO STRIKE THE SUBMISSIONS OF THEODORE H. FRANK AND TRUTH IN ADVERTISING, INC.

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A week away from the August 17, 2021, Final Approval Hearing there is not a single bona fide objection to the proposed Class Action Settlement ("Settlement") between Plaintiffs and Defendants Reckitt Benckiser LLC and RB Health (US) LLC ("RB Health"). Dkt. No. 52. There are, instead, two submissions by uninjured interest groups who have asked this Court to reject the Settlement to further their own policy goals. The interest groups behind these submissions have no Article III standing, and as a result the law requires this Court to disregard these objections on jurisdictional grounds.

The first submission is by the Center for Class Action Fairness ("CCAF"), filed in the name of one of its litigation attorneys, Theodore H. Frank. Dkt. No. 75 at 2 ("CCAF Brief"). To object to the Settlement, Mr. Frank must have Article III standing. The record confirms that he does not. Mr. Frank claims he purchased Neuriva in February 2021, submitted a claim form, and so insists he is a class member and has standing as such. Dkt. No. 75-1 at ¶¶ 4-6 ("Frank Decl."). But a review of the papers CCAF submitted confirms that Mr. Frank has no standing at all: Any "injury" he suffered is entirely self-inflicted. The only rational conclusion to be drawn from the timing and nature of Mr. Frank's Neuriva purchase—given his admission that his entire law practice is devoted to filing objections to class settlements—is that he bought Neuriva for the sole purpose of attempting to object to the Settlement. Courts repeatedly hold that trap purchases like Mr. Frank's, designed to manufacture an injury and bring a resulting claim, do not give rise to Article III standing. Likewise, as to the Settlement's injunctive relief component, Mr. Frank has expressly disavowed any future intent to purchase Neuriva. *Id.* at ¶ 7. So, Mr. Frank could not possibly be affected by any change to the products' labeling. Settled law confirms without future purchase intent there is no Article III standing to seek injunctive relief.

Even if Mr. Frank had Article III standing to object (he does not), he does not satisfy

a related requirement necessary to maintain objector standing, that he is an "aggrieved class member." Mr. Frank's chief complaints concerning the Settlement are that the injunctive relief is inadequate and that Plaintiffs' counsel's fee award is too substantial. But to be an "aggrieved class member" the changes to the settlement sought by the objector must actually benefit that objector. Mr. Frank has already told the Court that he won't buy Neuriva in the future, so the injunctive relief aspects of the Settlement have no bearing on him. Similarly, under the plain terms of the Settlement, Mr. Frank is entitled to a complete refund for the $21.95 he spent to purchase Neuriva. Plaintiffs' attorneys' fees are untethered from the pool of funds available to the class for refunds under the Settlement, so adjusting the fee structure would not affect Mr. Frank's entitlement to monetary relief.

Regardless, even if the Court were to consider CCAF's submission on the merits, it provides no basis to reject the Settlement. The bulk of CCAF's substantive critique concerning Neuriva purports to attack the science that underlies the products' labeling. But Mr. Frank and CCAF's other counsel are lawyers, not doctors or scientists. They are not competent or qualified to opine on the clinical studies that support Neuriva's marketing. The only evidence before the Court on that point is from Dr. Gary W. Small, a board-certified M.D. in psychiatry with a specialty in cognitive medicine, whose testimony establishes the validity of the science regarding Neuriva's principal ingredients. *See* Dkt. No. 62-1 ("Small Decl."). As explained in Dr. Small's Supplemental Declaration, attached as Exhibit A ("Small Suppl. Decl."), Mr. Frank and his lawyers are, quite simply, wrong in their assertions that criticize the clinical studies of Neuriva's active ingredients—errors that are perhaps to be expected when lawyers unqualified to offer expert opinion purport to act as such on matters they know nothing about. This is an independent basis to disregard that aspect of the CCAF submission under both Rule 702 and *Daubert*.

The second submission is by the interest group Truth in Advertising, Inc. ("TINA"), an organization likewise opposed to the Settlement on philosophical grounds. Dkt. No. 83 ("TINA Brief"). TINA does not even purport to be a class member or otherwise claim standing, so its submission can be disregarded on that basis alone. Indeed, TINA filed a very similar brief in *Collins v. Quincy Bioscience, LLC,* No. 19-cv-22864, Dkt No. 168 (Oct. 28, 2020) (S.D. Fla.) making many of the same arguments it makes now. This Court ultimately approved the settlement in *Collins*, in a Final Judgement and Order that—correctly—did not take into account TINA's submission. *Collins v. Quincy Bioscience, LLC,* No. 19-cv-22864, Dkt. No. 200 (Nov. 18, 2020). The Court should do the same thing here.

For these reasons, RB asks the Court to disregard the CCAF and TINA submissions and give them no consideration in its assessment of whether the Settlement should be finally approved.[1]

I. THE COURT SHOULD DISREGARD THE CCAF SUBMISSION

A. Mr. Frank Does Not Have Article III Standing to Object to the Settlement.

As the United States Supreme Court recently held, *all* class members must have Article III standing; that is, they each must have suffered some cognizable injury. *TransUnion LLC v. Ramirez*, 141 S.Ct. 2190, 2208 (2021) ("Every class member must have Article III standing in order to recover individual damages. 'Article III does not give federal courts the power to order relief to any uninjured plaintiff, class action or not.'") (quoting *Tyson Foods, Inc. v. Bouaphakeo*, 577 U.S. 442, 466 (2016) (Roberts, C. J., concurring)). Article III standing

[1] Because the CCAF and TINA Briefs are properly disregarded on Article III grounds, RB Health focuses this brief on that issue along with related procedural considerations. The CCAF and TINA Briefs nonetheless both address the Settlement's injunctive relief component. Dkt. No. 75 at 4-24; 83 at 3-12. While RB Health maintains that neither CCAF nor TINA should be heard on that issue (or any other) pertaining to the Settlement, to ensure that the Court's concerns expressed in its April 26, 2021 Order (Dkt. No. 58) and its more recent August 5, 2021 Order (Dkt. No. 84) are addressed, RB Health intends to further brief the adequacy of the Settlement's injunctive relief in its forthcoming August 16 submission called for by the Court's August 5 Order.

requirements likewise apply to objectors seeking to challenge a class settlement, and without such standing their objections must be disregarded. *See Association for Disabled Americans, Inc. v. Amoco Oil Co.*, 211 F.R.D. 457, 475 (S.D. Fla. 2002) ("*As a matter of law*, Objectors' failure to show a concrete, particular injury-in-fact that is actual or imminent and not merely conjectural *requires that their objections be overruled for lack of standing*.") (internal citations omitted) (emphasis added); *see also Keil v. Lopez*, 862 F.3d 685, 699 (8th Cir. 2017) ("[A] class member appealing a settlement still must show that she satisfies the standing requirements of Article III.") (internal quotation marks and citation omitted); *In re Hydroxycut Mktg. & Sales Pracs. Litig.*, 2013 WL 5275618, at *2 (S.D. Cal. Sept. 17, 2013) ("The party seeking to invoke the Court's jurisdiction—in this case, the Objectors—has the burden of establishing standing.") (*citing Steel Co. v. Citizens for a Better Environment*, 523 U.S. 83, 103-04 (1998)).

Thus, even where an objector "technically qualifie[s]…for membership in the class," unless she has Article III standing her objection may not be heard. *See In re First Capital Holdings Corp. Financial Products Securities Litig.*, 33 F.3d 29, 30 (9th Cir. 1994) (dismissing appeal of putative class member and objector to settlement challenging attorneys' fees paid under the settlement for lack of Article III standing). And as illustrated in *First Capital*, the refusal to hear the objection of an individual or group who lacks standing is not discretionary—without Article III standing the court simply has no jurisdiction to entertain the objector's complaints. *Id.* ("We dismiss this appeal because [the objector] lacks standing. The power of federal courts to hear cases is always subject to the constraints set forth in Article III of the Constitution."); *accord Association for Disabled Americans, Inc.*, 211 F.R.D. at 474 ("The Objector organizations also lack standing to appear in this case under Article III of the Constitution."); *id.* at 475 (noting that "as a matter of law" the court is "require[d]" to disregard objectors who lack standing).

In order to maintain standing, the party seeking to invoke the Court's jurisdiction must affirmatively demonstrate: "(i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant;

and (iii) that the injury would likely be redressed by judicial relief." *TransUnion*, 141 S.Ct. at 2203. As is relevant here, Article III standing limits are imposed to ensure that participation in cases and controversies is limited to those who have a "'personal stake' in the case," and to prevent federal courts from acting as "a roving commission to publicly opine on every legal question." *Id.*

Accordingly, Article III is not satisfied by "self-inflicted" injuries, which includes those a party voluntarily incurs out of a desire to participate in litigation. *Muransky v. Godiva Chocolatier, Inc.*, 979 F.3d 917, 931 (11th Cir. 2020) (en banc) (citing *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 416 (2013)) (parties "cannot manufacture standing merely by inflicting harm on themselves"). "To hold otherwise would allow 'an enterprising plaintiff . . . to secure a lower standard for Article III standing.'" *Tsao v. Captiva MVP Rest. Partners, LLC*, 986 F.3d 1332, 1345 (11th Cir. 2021) (internal citations omitted). And any doubts about the existence of Article III standing are resolved *against* the party seeking to invoke the court's jurisdiction. *See Elend v. Basham*, 471 F.3d 1199, 1206 (11th Cir. 2006) (a court "should not speculate concerning the existence of standing" and "[i]f the plaintiff fails to meet [his] burden, [then the] court lacks the power to create jurisdiction by embellishing a deficient allegation of injury").

There is a well-developed body of law concerning the prohibition on "self-inflicted" injuries in cases like this one—putative class actions regarding alleged deceptive product labeling. Courts consistently hold that when a person buys a product with a full awareness of the alleged misleading nature of its labeling, and does so merely to sustain a claim, that purchase is a "self-inflicted" injury that does not satisfy Article III standing requirements. *See Wasser v. All Market, Inc.*, 329 F.R.D. 464, 471 (S.D. Fla. 2018) (any purchase made by plaintiff of product with knowledge of the alleged deceptiveness of its labeling would be a "self-inflicted" injury not supporting Article III standing) ("The Plaintiffs 'cannot manufacture standing by choosing' not to purchase a product because of allegedly deceptive labeling, when the Plaintiffs actually know the truth underlying that labeling and thus cannot be deceived by

it in the future.") (quoting *Clapper*, 568 U.S. at 402)); *Red v. General Mills, Inc.*, 2015 WL 9484398, at **4-5 (C.D. Cal. Dec. 29, 2015) (dismissing putative class action on Article III standing grounds where plaintiff's purchase of allegedly deceptive product made with knowledge of product's purported harmfulness) ("Plaintiff knew that [an ingredient in the product was] unhealthy, knew that food products sold in California contain [that ingredient], and knew that she could (or should be able to) look at the ingredients on the label to determine whether or not that particular product contained [the ingredient]."); *Guttmann v. Nissin Foods (USA) Co. Inc.*, 2015 WL 4881073 at *2 (N.D. Cal., Aug. 14, 2015) ("This order finds [serial class action plaintiff] Guttmann was keenly aware of the alleged injury he might suffer by eating Nissin's noodles, and he knew he could have avoided any such injury."); *see also Debernardis v. IQ Formulations*, LLC, 942 F.3d 1076, 1088 (11th Cir. 2019) (finding plaintiffs alleged sufficient facts to establish they suffered an injury in fact where "they would not have purchased had they known" defendant's dietary supplements were defective); *accord Tsao*, 986 F.3d at 1345 (time and costs incurred in preventing identity theft, when risk of such theft was non-imminent and speculative, was self-inflicted injury not supporting standing) ("[Plaintiff] cannot conjure standing here by inflicting injuries on himself to avoid an insubstantial, non-imminent risk of identity theft.").

CCAF's objection to the Settlement fails to meet these standards. The record shows that Mr. Frank purchased Neuriva out of a desire to object, such that any money he spent on the product is a "self-inflicted injury" that does not satisfy Article III standing.

As detailed in his Declaration, Mr. Frank is a CCAF lawyer who has spent the last decade monitoring federal court dockets in search of class settlements where he perceives some strategic value in objections that might further the CCAF's "mission." *See* Frank Decl. ¶¶ 12-13 ("I founded the non-profit CCAF . . . . CCAF's mission is to litigate on behalf of class members against unfair class action procedures and settlements."). Mr. Frank explains that the CCAF's decisions about the settlements it chooses to object to are tactical, informed, and systematic. *Id.* at ¶ 25 ("[CCAF and Mr. Frank] are confronted with many more

opportunities to object (or appeal erroneous settlement approvals) than we have resources to use, and make painful decisions several times a year picking and choosing which cases to pursue, and even which issues to pursue within the case."). Mr. Frank, as his declaration boasts, *see* Frank Decl. ¶¶ 13-15, has some renown in this regard. Thus, one court within the Eleventh Circuit—in the context of rejecting an objection Mr. Frank had filed—described him as "being in the business of objecting to class settlements," and found that his ideological approach "is not motivated to serve the interests of the class." *In re: Equifax Inc. Customer Data Breach Litig.*, 2020 WL 256132, at *42 (N.D. Ga., Mar. 17, 2020) (reversed in part on other grounds *In re: Equifax Inc. Customer Data Breach Litig.*, 999 F.3d 1247 (11th Cir. 2021)); *see also Fruitstone v. Spartan Race, Inc.*, 2021 WL 2012362, at *5 (M.D. Fla. May 20, 2021) (Bloom, J.) (overruling objection brought by objector represented by Mr. Frank). Against this backdrop, it is borderline fantastical to read Mr. Frank's Declaration and conclude his Neuriva purchase was made in ignorance of this lawsuit, or that he was deceived by the product's label into making that purchase. *See Elend*, 471 F.3d at 1206 (burden to show standing not met where court must speculate about the alleged harm).

The timing of Mr. Frank's purchase further proves that it was made solely to "manufacture standing." *Wasser*, 329 F.R.D. at 471. The instant action is one of three lawsuits challenging the labeling of Neuriva, filed over a period from June 19, 2020, to September 9, 2020. Dkt. No. 52-1 at 5-6. The fact of a pending class settlement was made public on January 7, 2021, when the Parties submitted their Notice of Settlement stating their intent "to settle the litigated claims in this case on a class-wide basis." Dkt. No. 47. Mr. Frank's $21.95 Neuriva purchase was made on February 4, 2021, three weeks *after* this Notice. Frank Decl. ¶ 4. The three short paragraphs describing this purchase, *id.* ¶¶ 4-6, do not purport to establish any deception suffered by Mr. Frank from his Neuriva purchase—apparently the only time he ever bought the product—and reads instead as what it is: A chronology of the steps Mr. Frank took, once aware of a potential settlement to which he might object, to gin up a claim that might allow him to later interfere with that Settlement in furtherance of non-party

CCAF's policy interests. That purchase is therefore a "self-inflicted injury" that cannot provide Article III standing. *Red*, 2015 WL 9484398, at **4-5; *Wasser*, 329 F.R.D. at 471; *Guttmann*, 2015 WL 4881073 at *2. At a minimum, the declaration fails to carry Mr. Frank's affirmative burden of proving that the purchase was legitimate such that the money he spent was not a self-inflicted injury. *Trichell v. Midland Credit Mgmt., Inc.*, 964 F.3d 990, 996 (11th Cir. 2020) ("The party invoking the jurisdiction of a federal court bears the burden of establishing [Article III standing] to the extent required at each stage of the litigation."). [2]

Mr. Frank's standing deficiencies are particularly acute as it pertains to injunctive relief. Federal courts in Florida—consistent with Circuit law elsewhere—hold that to maintain standing for injunctive relief to challenge a deceptively labeled product, there must be some intent to purchase that product in the future. *See Snyder v. Green Roads of Florida, LLC*, 430 F. Supp. 3d 1297, 1304 (S.D. Fla. 2020) ("Plaintiffs allegations make clear that they will not purchase more of Defendant's products so long as the labelling does not meet their standards. Accordingly, Plaintiffs lack standing to assert a claim for injunctive relief."); *Marty v. Anheuser-Busch Co., LLC*, 43 F. Supp. 3d 1333, 1351-52 (S.D. Fla. 2014) ("Because there are no allegations in the Amended Complaint that the plaintiffs would purchase [the mislabeled product] in the future, the undersigned finds that the plaintiffs have failed to plead a real and immediate threat of future injury and thus have failed to plead standing to seek injunctive relief.") (internal citation and quotation omitted); *Wasser*, 329 F.R.D. at 471 (same); *see also Lanovaz v. Twinings N. Am.*, 726 Fed. App'x 590, 591 (9th Cir. 2018) ("[T]he wrong [plaintiff] alleged was her purchase of [the defendant's] products with misleading labels. As she does not intend to purchase [defendant's] products in the future, it is unlikely that she will again

[2] Moreover, as discussed in Section I.B, *infra*, under the terms of the Settlement Mr. Frank would be entitled to a full refund for his sole Neuriva purchase. Again, the application of ordinary Article III injury standards would dictate that, with this form of relief available to him, Mr. Frank has no standing under Article III. *See Hardy v. Bed Bath & Beyond, Inc.*, 2018 WL 1272687, at *2 (S.D. Fla. Mar. 9, 2018) ("Hardy could have received a full refund, [so] the only injury she actually alleges was essentially mooted."); *Hamilton v. Gen. Mills, Inc.*, 2016 WL 4060310, at *5 (D. Or. July 27, 2016) (finding plaintiff "failed to establish an injury in fact" in light of company's refund offer).

be wronged in a similar way.") (affirming summary judgment as to standing on claim for injunctive relief due to lack of future purchase intent; statement that plaintiff would "consider" future purchases insufficient to support standing).

Here, Mr. Frank's Declaration unequivocally disclaims standing for injunctive relief, by admitting he will not purchase Neuriva in the future. Mr. Frank states: "I currently have no plans to purchase any Neuriva Product in the future. The injunctive relief provides me no benefit." Frank Decl. ¶ 7. This statement legally bars him from any claim to seek injunctive relief and, as it pertains to CCAF's submission, to modify the injunctive relief agreed to under the Settlement. *Snyder*, 430 F. Supp. 3d at 1304; *Marty*, 43 F. Supp. 3d at 1351-52. Thus, the CCAF Brief's lengthy diatribe about the supposed inadequacies in the Settlement's injunctive relief[3] and Neuriva's labeling, CCAF Brief at 4-19, are in furtherance of a client, Mr. Frank, who has already admitted to this Court that he has absolutely no legal interest in how that product will be labeled in the future. *Compare* Frank Decl. ¶ 7 *with Wasser*, 329 F.R.D. at 471 *and Lanovaz*, 726 Fed. App'x at 591. Again, this admitted lack of Article III standing compels this Court to disregard CCAF's objection submitted on his behalf. *First Capital*, 33 F.3d at 30; *Association for Disabled Americans, Inc.*, 211 F.R.D. at 475.

B. Mr. Frank Is Not An "Aggrieved Class Member" As Is Required to Object.

Even if a potential class member demonstrates he has Article III standing (Frank has not done so), the objector must still be an "aggrieved class member" for the Court to consider the objection. *First Capital*, 33 F.3d at 30. In practical terms, this means that "the objecting class member must be 'aggrieved' by [the settlement provision]," she is objecting to. *Glasser v. Volkswagen of Am., Inc.*, 645 F.3d 1084, 1088 (9th Cir. 2011). Or, stated affirmatively: "If modifying [the settlement provision] would not actually benefit the objecting class member, the class member lacks standing because his challenge to the [settlement provision] cannot result in redressing any injury." *Id.*; *see also Low v. Trump University, LLC*, 246 F. Supp. 3d

[3] As noted in Footnote 1, RB still intends to separately address in its forthcoming August 16, 2021, filing why CCAF's complaints are also substantively wrong and to further explain how the revised labeling provides meaningful relief to the class.

1295, 1306 (S.D. Cal. 2017) (objector did not have aggrieved class member status to object to settlement's opt-out provisions, where modification of that term would not benefit her). Thus, this Court has in the past correctly stricken proposed objections where the putative objector has not met this "aggrieved class member" requirement. *See Collins v. Quincy Bioscience, LLC*, 2020 WL 7135528, *5 (S.D. Fla. Nov. 16, 2020) (noting that an objector carries the "burden" to "demonstrate that he is an 'aggrieved class member'" and striking objection).

Here, the CCAF Brief raises two objections to the Settlement on Mr. Frank's behalf: (1) that the injunctive relief provision is inadequate, and (2) that Plaintiffs' counsel's fee request might overcompensate them. CCAF Brief at 4-24, 25-29. But Mr. Frank is not "aggrieved," as the law requires, by potential changes to either of these aspects of the Settlement.

As to the injunctive relief component, as discussed in Section I.A, *supra*, Mr. Frank has already disclaimed any legal interest in how Neuriva is labeled by stating under oath that he does not intend to buy it in the future. Frank Decl. ¶ 7. So, a change to how Neuriva is labeled "would not actually benefit [Mr. Frank]." *Glasser*, 645 F.3d at 1088; *see also Broomfield v. Craft Brew Alliance, Inc.*, 2020 WL 1972505, at *20 (N.D. Cal. Feb. 5, 2020) (objector was not an "aggrieved class member" in objecting to household cap on refunds where objector would not be eligible for more money regardless of the cap). Because Mr. Frank has sworn before this Court he will not buy Neuriva again—apparently content with just the one purchase made to manufacture an attempted objection—nothing about RB Health's conduct or decisions about how to label that product could possibly affect him. *See Custom LED, LLC v. eBay, Inc.*, 2014 WL 2916871, at *6 (N.D. Cal. Jun. 24, 2014) ("One must be an aggrieved class member to object to a class action settlement; to be an aggrieved class member, an individual must fall within the class definition and also must have been injured by the defendant's conduct.").

The same thing is true for Mr. Frank's objection to the Settlement's attorneys' fees provisions: Nothing about any of the requested modifications to those terms would have any

bearing on Mr. Frank's recovery. CCAF Brief at 25-29. Mr. Frank's claim was, according to his Declaration, submitted with his proof of purchase showing that he paid $21.95 for Neuriva. Frank Decl. ¶¶ 4-5. Under the terms of the Settlement he is entitled to a refund of that entire amount. Dkt. No. 52-1 at 11, Settlement ¶ IV.B.2.a. (claims submitted with proof of purchase entitle class members of refunds of purchase amount up to $32.50). The attorneys' fees provisions of the Settlement do not bear on the availability of that refund to Mr. Frank, as those fees are paid by RB Health separately, not deducted from the Settlement's Monetary Relief fund. *Id.* at 14, Settlement ¶ V.A ("The amount finally approved by the Court shall be the sole responsibility of, and will solely be paid by the Settling Defendants above and beyond any relief provided to the Settlement Class."); *see Brown v. Hain Celestial Grp., Inc.*, 2016 WL 631880, at *10 (N.D. Cal. Feb. 17, 2016) (objector lacked standing to challenge monetary relief element of settlement because objector has not showed how he was aggrieved by this element or how he would actually benefit from changing this part of the settlement). Thus, Mr. Frank is not an "aggrieved class member" as to this aspect of the Settlement. *Glasser*, 645 F.3d at 1088-859 (objector not an aggrieved class member because not harmed by the attorneys' fees term).[4]

II. CCAF'S LAWYERS ARE NOT QUALIFIED TO ADDRESS THE SCIENCE CONCERNING NEURIVA AND THEIR ASSERTIONS ARE WRONG

On May 24, 2021, in response to this Court's Order RB Health filed its Supplemental Brief Regarding Injunctive Relief, Dkt. No. 62, which was accompanied by the Declaration of Gary W. Small. Dr. Small is an M.D. and UCLA Professor who is an expert in the field of cognitive decline and the medical treatment of those and related mental health conditions. *See*

[4] RB Health expects Mr. Frank may respond at that he is "aggrieved" by the Settlement's fee structure because it constitutes a "constructive common fund" and this structure affords an objector standing to complain as to the fees. CCAF Brief at 25. But even in cases where there is an (alleged) "constructive common fund" Article III standing must still be met with non-speculative facts. *Glasser*, 645 F.3d at 1088. The combined force of the Settlement's structure and Mr. Frank's otherwise inadequate allegations of standing do not rise beyond that non-speculative level here as to how any changes to the Settlement's fees provisions would bear on availability of relief to the class.

Small Decl. at 24-25. The Small Declaration contained a study-by-study analysis of the clinical studies relied on by RB Health to substantiate Neuriva's labeling claims. Small Declaration at 28-39. Dr. Small ultimately concluded that these studies "support[] the promotional and implied claims that individuals who take Neurofactor and PS, the ingredients in Neuriva, experience a noticeable improvement in cognitive function including focus, concentration, memory, learning, reasoning, and accuracy." *Id.* at 39.

A substantial amount of the CCAF Brief purports to address this testimony and argues that the clinical studies supporting Neuriva's labeling are not valid and that Dr. Small's testimony is otherwise undermined by scientific studies CCAF's lawyers have identified. CCAF Brief at 8-19. This critique by CCAF is incurably flawed from an evidentiary perspective: CCAF's lawyers are purporting to testify on matters of expert science that they are not qualified to speak to. But even if the Court were to look past this defect, CCAF's lawyers are also wrong on the science, as Dr. Small's Supplemental Declaration explains. *See generally* Exhibit A.

A. CCAF'S Lawyers Are Not Qualified Offer Expert Scientific Testimony and So the Scientific Critique in CCAF's Brief Should Be Stricken Under Rule 702 and *Daubert*.

The CCAF Brief criticizes at length the studies that Dr. Small concluded were reliable and support Neuriva's labeling claims. CCAF Brief at 10-19. Throughout this entire discussion, there is no citation to any evidence or testimony from a non-lawyer declarant. So, the only conclusion the Court can draw is that the entire critique is merely the opinion of CCAF's lawyers, including Mr. Frank. But as CCAF's lawyers, they cannot purport to testify in this fashion at all. *See Putnam v. Head*, 268 F.3d 1223, 1246 (11th Cir. 2001) (stating that lawyers should not provide testimony in cases in which they are also advocates because "the roles of an advocate and a witness are inconsistent," citing Model Rules of Professional Responsibility).

More pointedly, Mr. Frank (as well as his CCAF co-counsel M. Frank Bednarz) are utterly unqualified to opine on matters of science that the CCAF Brief purports to critique.

This entire aspect of the CCAF Brief is an improper attempt to sidestep the requirements of Federal Rule of Evidence 702 and *Daubert*, which allows only witnesses "qualified as an expert by knowledge, skill, experience, training, or education" to offer expert testimony. Fed. R. Evid. 702; *see also Rink v. Cheinova, Inc.*, 400 F.3d 1286, 1292 (11th Cir. 2005) (in evaluating expert testimony district courts must engage in a "rigorous inquiry to determine whether the expert is qualified to testify competently regarding the matters he intends to address"). Moreover, in the context of class certification, the Eleventh Circuit mandates that the district court "conduct a *Daubert*-like critique of [a] proffered expert's qualifications." *Sher v. Ratheyon Co.*, 419 Fed. App'x 887, 890 (11th Cir. 2011) (reversing class certification decision as error where district court did not scrutinize proffered expert testimony).

There is no attempt made to qualify either Mr. Frank or Mr. Bednarz on matters of neurological science or medicine, and no indication in the record that either one has even the slightest knowledge, training, or expertise in those areas. Thus, pages 10-19 of the CCAF Brief should be treated for what it is: The armchair critique of lawyers who are unqualified to speak to the scientific issues under consideration, which should be excluded from this Court's analysis under Rule 702 and *Daubert*. *See Lopez v. Allstate Fire & Cas. Ins. Co.*, 2015 WL 5584898, at *5 (S.D. Fla. Sept. 23, 2015) ("A lawyer with extensive experience in a particular area of law is not necessarily qualified to provide expert testimony on proper internal processes of the particular industry the lawyer represents.") (collecting cases); *Medina v. Louisville Ladder, Inc.*, 496 F. Supp. 2d 1324, 1327 (M.D. Fla. 2007) (disqualifying expert who had "no material background in warnings related to consumer products in general or [the product at issue] in particular," had "never written any articles on the subject of warnings," and had never been "court-qualified as an expert regarding the specific subject of warning adequacy"). This flaw provides an additional ground for the Court to strike this aspect of the CCAF Brief in full. *Sher*, 419 Fed. App'x at 890-91 (error to base class certification decision on untested proffered expert testimony).

The absence of proper qualifications by Mr. Frank or other CCAF lawyers is further

illustrated by how the CCAF Brief merely borrows from pre-existing allegations in the Amended and Consolidated Complaint. *See* CCAF Brief at 8 (citing 10 allegations from the Amended and Consolidated Complaint regarding purportedly faulty studies and ingredients' in ability to cross the blood-brain barrier). This critique is borrowed even for the purposes of this case, as many of the same assertions were made in the *Collins* matter. *See Collins v. Quincy Bioscience,* No. 19-cv-22864, Dkt No. 1 ("Complaint") at ¶ 4 (July 11, 2019) ("[T]he fact that Prevagen cannot affect the brain is further supported because the protein derivatives the apoaequorin is rapidly digested into are unable to cross the blood brain barrier, so they can never reach the brain to affect it to begin with."), ¶¶ 5-6; Dkt No. 15 ("Amended Complaint") at ¶¶ 4-5, 9-10, 52 (Sept. 11, 2019); *Collins v. Quincy Bioscience*, No. 19-cv-22864, Dkt No. 168 ("*Collins* TINA Brief") at 1-2 (Oct. 28, 2020) ("Quincy's representations about Prevagen are contradicted by the results of Quincy's clinical trial and are thus materially deceptive.").[5]

Regardless, as discussed below, the CCAF Brief's analysis of the science is also substantively wrong.

B. The CCAF Brief's Scientific Critique is Erroneous.

The crux of the argument asserted in the CCAF Brief attacking the science supporting Neuriva's principal ingredients is that the ingredient claims are not substantiated because the science supporting the claims run afoul to the FDA's "Guidance for Industry: Substantiation for Dietary Supplement Claims Made Under Section 403 (r) (6) of the Federal Food, Drug, and Cosmetic Act" ("FDA Guidance")[6]. This assertion, however, is wrong on two major fronts. First, the FDA Guidance provides non-binding recommendations.

> FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless

[5] TINA does the same in its Brief here, falling back on allegations already made in this case. TINA Brief at 6 (attacking Neuriva's claim that it is "backed by real science," citing the Amended and Consolidated Complaint at ¶ 6, which also attacks Neuriva's statements regarding being "backed by science").

[6] Attached as Exhibit A to Declaration of M. Frank Bednarz ("Bednarz Decl."). *See* Dkt. No. 77-1.

> specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

Id. at 2.

Second, the science supporting Neuriva's ingredient claims provide more than sufficient substantiation under the FDA's recommended guidelines. *See* Small Supp. Decl. at 1-2. The FDA adopted the FTC's substantiation standard of "competent and reliable scientific science" for claims regarding the benefits and safety of dietary supplements. FDA Guidance at 3. As discussed in detail below and in Dr. Small's Supplemental Declaration, Neuriva's ingredient claims are substantiated by several peer-reviewed and published clinical studies utilizing "randomized, double-blind, placebo-controlled test designs," the "gold standard" for studies of safety and efficacy of clinical interventions. Small Supp. Decl. at 4; *see* FDA Guidance at 6; Small Decl. at 9-16. These kinds of studies remain the most convincing research design in which randomly assigning the intervention can eliminate the influence of unknown or immeasurable confounding variables such as placebo effects that may otherwise lead to biased and incorrect estimate of treatment effects. *See* Small Supp. Decl. at 4. Also, randomization eliminates confounding by baseline variables and blinding eliminates confounding by co-interventions, thus eliminating the possibility that the observed effects of intervention are due to differential use of other treatments. *See id.*

Such well-designed clinical studies have shown that individuals who take WCCE and PS experience a noticeable improvement in cognitive function. *See id.* at 1-2. Similarly, clinical studies have also shown that supplementation with SOD decreases stress and fatigue. *See id*. at 2.

1. Ingredient Studies can Substantiate Ingredient Claims.

The CCAF Brief also takes issue with the fact that the Neuriva ingredient claims are supported by clinical studies regarding those very ingredients, rather than studies of the products themselves or studies involving a combination of ingredients. However, studies regarding individual ingredients are regularly used to support claims relating to dietary

supplement products. *See id*. at 3. For instance, there is significant scientific evidence connecting memory to caffeine consumption. *See id*. There is no debate regarding the ability of caffeine, an active ingredient in many dietary supplements, to bolster memory, specifically working memory. *See id*. Similarly, there is ample scientific support for the claims relating to the active ingredients (WCCE, PS and SOD) in Neuriva as detailed in Defendants' Supplemental Brief Regarding Injunctive Relief and as further validated by Dr. Small's Declaration and Supplemental Declaration.

Moreover, the FDA Guidance indicates that an ingredient study can be used as substantiation for an ingredient claim. "We recommend that the studies being used as substantiation for dietary supplement claims identify a specific dietary supplement ***or ingredient*** . . ." (emphasis added). *See* Small Supp. Decl. at 3-4; FDA Guidance at 5. The CCAF Brief erroneously asserts that the FDA has made clear that testing is only relevant and reliable if the product as a whole is tested which is contradictory to the FDA Guidance. *See* Small Supp. Decl. at 3-4. The CCAF Brief references Example 5 in the FDA Guidance as its basis for invalidating the clinical studies supporting the Neuriva ingredient claims. However, Example 5 is distinguishable and inapplicable here because the revised claims on Neuriva labeling do not refer to the products themselves, but instead to the products' ingredients. And the clinical studies at issue specifically support Neuriva's ingredient claims. *See id*. at 4.

Again, the FDA Guidance provides recommendations and are not binding rules or regulations. Notwithstanding, the clinical studies supporting Neuriva's ingredient claims more than satisfy the recommended substantiation standard provided under the FDA Guidance, as validated by Dr. Small. *See id*. at 3.

2. Well-Designed Pilot Studies Can Provide Statistically Significant Results.

Although some of the studies supporting the Neuriva ingredient claims are referenced as a "pilot study", that does not diminish the results or conclusions reached in those studies, as explained in Dr. Small's Supplemental Declaration. *See id*. at 4-5. First, the term "pilot study" may be defined differently by one journal versus another journal based on a number

of potential factors, including sample size. *See id.* Therefore, a study may be arbitrarily referenced as a pilot study according to a particular journal's parameters in how it determines and defines what constitutes a pilot study. *See id*.

Second, nearly all of the scientific evidence supporting the Neuriva ingredient claims, including the pilot studies, are peer-reviewed and published studies involving randomized, double-blind, placebo-controlled test designs, the gold standard for intervention studies. *See id*.; FDA Guidance at 7.

Third, a study involving a large sample may be statistically significant, but this does not necessarily mean that its results are clinically meaningful. *See id*. at 4-5. For example, a study involving thousands of subjects may show a statistically significant result but lead to minimal differences (*e.g.*, just a few percentage points) between outcomes of the active treatment and placebo treatment groups. *See id*. at 5. Meanwhile, when multiple pilot studies involving randomized, double-blind, placebo-controlled test designs all reach similar statistically significant results, they can in the aggregate be viewed as not only statistically significant but also clinically meaningful. *See id*. at 4-5.

3. Research Supporting Neuriva Ingredient Claims Include Clinical Studies Involving All Age Groups.

The CCAF Brief also attempts to invalidate some of the studies because they were performed on healthy young adults while the products are intended for the elderly with cognitive impairment. However, there is nothing referenced in the CCAF Brief or in the Neuriva ingredient claims to indicate that Neuriva is intended solely for the elderly with cognitive impairment. *See id.* Rather, the Neuriva ingredient claims state generally that the ingredients help with cognitive function. *See id.*

Moreover, many of the studies supporting the Neuriva ingredient claims were indeed performed on elderly adults with mild cognitive impairment in addition to studies involving healthy young adults. *See id*. Accordingly, the fact that the clinical studies regarding WCCE and PS involve all age groups, both young and old, as well as both healthy adults and those

with mild cognitive impairment provides further credibility to the significance of the results reached in those studies regarding the cognitive benefits of treatment with WCCE and PS. *See id.*

The CCAF Brief also erroneously asserts that because one of the studies was conducted in Japan on elderly Japanese subjects, that fact alone invalidates or diminishes the test results. That bald assertion is completed unsupported. *See id*. at 9. The fact that a study was conducted in Japan does not, in of itself, invalidate or affect the significance of the test results. *See id*. Rather, what is critical in determining the credibility and reliability of a clinical study is to evaluate the study's design, implementation, and quality. *See id.* Indeed, the FDA Guidance provides that "[f]oreign research could be sufficient to substantiate a claim as long as the design and implementation of the foreign research are scientifically sound. . . ." FDA Guidance at 6. Here, the foreign study at issue (Kato-Kataoka *et al*, 2010), was a randomized double-blind, placebo-controlled clinical trial, *i.e.*, the gold standard. *See* Small Supp. Decl. at 9.

4. WCCE Increases BDNF Which Crosses the Blood-Brain Barrier

Another unsupported assertion made in the CCAF Brief is that Neuriva cannot work because its "natural ingredients" are food, which gets digested into constituent parts before they enter one's bloodstream. However, an ingredient does not necessarily have to cross the blood-brain barrier to be effective. *See id*. at 6. There are many effective supplements and medicines whose active ingredients do not cross the blood-brain barrier, but instead the ingredients are absorbed into the body through the digestive tract. *See id*. Also, the mechanism of action of WCCE is tightly linked to an increase in levels of BDNF, an important neuroprotein involved in cognitive function and the most prevalent growth factor in the central nervous system. *See id*. at 6. Research indicates that WCCE increases BDNF levels. *See id*. BDNF is a neurotrophin critical for the survival, growth, and maintenance of neurons, and is involved in learning, memory and in emotional and cognitive function. *See id*. It plays

an important role in supporting neurogenesis, which is the growth and development of neurons in the brain. *See id*.

Accordingly, although WCCE may not cross the blood-brain barrier, research shows that BDNF does. *See id*. Therefore, individuals who supplement with WCCE will have increased levels of BDNF which crosses the blood-brain barrier and improves cognitive function. *See id*.

5. Clinical Studies of WCCE (Neurofactor)

As detailed in Dr. Small's Declaration and Supplemental Declaration, the clinical studies below, which involve similar dosage formulations in Neuriva, substantiate the ingredient claim that WCCE improves cognitive function. *See* Small Decl. at 31-35; *see* Small Supp. Decl. at 6-9. Dr. Small describes the design, results and conclusions reached in those studies, and explains why the unqualified lay opinions offered by Mr. Frank as to each of the studies are unsupported and specious. *See* Small Supp. Decl. at 6-9.

a. Robinson Study (2019)

This peer-reviewed and published study involved a randomized double-blinded, placebo-controlled test performed on 71 adults with mild memory impairment.[7] *See id.* at 6. The results demonstrated more than just the potential for WCCE to provide cognitive benefits. *See id*. at 6-7. Rather, in as little as seven days, significant reductions in reaction times were observed for groups supplemented with both 100 mg and 200 mg of WCCE versus placebo. *See id*. at 7. These effects were observed for the entire 28-day study period. Specifically, the WCCE groups demonstrated a 41% and 32% reduction in reaction time compared to a 12% decrease in the placebo group after 28 days compared to baseline. *See id*. These results suggest that WCCE has a significant impact on reaction time in as little as seven days and these benefits persist throughout a 28-day period. *See id*. Overall, the reductions in

[7] Robinson J, Hunter J, Reyes-Izquierdo T, et al., *Cognitive short- and long-term effects of coffee cherry extract in older adults with mild cognitive decline, Aging, Neuropsychology, and Cognition*, 2019 Dec 12; 1-17, attached as Exhibit 2 to Dkt. No. 62 ("Defendants' Supplemental Brief").

reaction time suggest that, during periods of cognitive challenge, WCCE supports motor response and executive function (performance); reduces mental fatigue; and benefits attention, motivation, and alertness. *See id.*

b. Robinson Study (2021)

The only criticism asserted in the CCAF Brief regarding this study is that it is a pilot study. Yet, this is another peer-reviewed and published study involving a randomized, double-blind, placebo cross-over design in which researchers compared 100 mg of WCCE to placebo and found levels of BDNF increased within 90 minutes, and several relevant brain regions showed increased activation on MRI.[8] *See id*. Compared to placebo, BDNF led to significantly better results on key mental performance tasks and also revealed that BDNF crosses the blood-brain barrier. *See id.* As Dr. Small explains, these results suggest that WCCE[9] is associated with decreased reaction time and may protect against cognitive errors on robust tasks of working memory (i.e., n-back) and response inhibition (i.e., go/no-go). *See id*. Furthermore, these behavioral results are concomitant with distinct neuro-functional changes within key neural structures involved in decision-making and attention. *See id*. Decreased reaction time is associated with better mental focus and concentration abilities. *See id*.

c. Reed Study (2019)

In this study, researchers conducted a block-randomized, double-blind, placebo-controlled, cross-over study in 30 healthy adults who took 100 mg or 300 mg doses of

[8] Robinson J, Yanes J, Reid M, *Neurophysiological Effects of Whole Coffee Cherry Extract in Older Adults with Subjective Cognitive Impairment: A Randomized, Double-Blind, Placebo-Controlled, Cross-Over Pilot Study*, antioxidants, 2021 Jan 20;149-172, attached as Exhibit 3 to Defendants' Supplemental Brief.

[9] The CCAF Brief attempts to distinguish Neurofactor from WCCE as another attempt to invalidate the studies. However, Neurofactor is merely the trade name for the WCCE used in Neuriva. Neurofactor is WCCE. Also, the CCAF Brief references a purported document submitted by FutureCeuticals to the FDA, but that document is not attached to the Bednarz Declaration as indicated in the CCAF Brief. Regardless, based on its description in the CCAF Brief, this purported document does not seem to discuss or have any bearing on the science relating to the ingredient claim that WCCE improves cognitive function.

WCCE in a ready-to-drink format.[10] *See id*. at 7-8. This format was compared with a placebo drink and a drink with 75 mg of caffeine (positive control). *See id*. at 8. Contrary to the assertions in the CCAF Brief, this study positively demonstrated that WCCE improved cognitive function. *See id*. In fact, the study results showed positive effects from ingesting 100 mg of WCCE: self-reported alertness increased (p=0.041) and self-reported mental fatigue decreased (p=0.034) after study volunteers completed a series of fatiguing cognitive tasks. *See id*. Similar results were observed after ingestion of 300 mg of WCCE for self-reported mental fatigue (p=0.032) and self-reported alertness (p=0.04). *See id*. Mental fatigue is a symptom that has been linked to impaired accuracy and impaired concentration on cognitive testing. *See id*.

d. Reyes-Izquierdo Studies (2013a; 2013b)

Both of the Reyes-Izquierdo studies showed that participants administered with 100 mg of WCCE had significant increases in BDNF levels.[11] *See id*. at 8-9. The first study showed increases in plasma BDNF levels by 148% compared to baseline while the second study, conducted to confirm and further investigate this effect, similarly resulted in an increase of plasma BDNF by 91% compared to placebo. *See id*. at 8. As Dr. Small explains, BDNF is an important neuroprotein involved in cognitive function and is the most prevalent growth factor in the central nervous system. *See id*. Increased levels of BDNF leads to significantly better results on key mental performance tasks. *See id*. at 9.

[10] Reed, R.A., Mitchell, E.S., Saunders, C et al, *Acute Low and Moderate Doses of a Caffeine-Free Polyphenol-Rich Coffeeberry Extract Improve Feelings of Alertness and Fatigue Resulting from the Performance of Fatiguing Cognitive Tasks*. J Cogn Enhanc 3, 193–206 (2019) attached as Exhibit 4 to Defendants' Supplemental Brief.

[11] Reyes-Izquierdo T, Nemzer B, Shu C, Huynh, L, Argumedo R, Keller R, & Pietrzkowski Z., *Modulatory effect of coffee fruit extract on plasma levels of brain-derived neurotrophic factor in healthy subjects.* British Journal of Nutrition, 2013 110(3), 420-425, attached as Exhibit 5 to Defendants' Supplemental Brief; Reyes-Izquierdo T, Argumedo R, Shu C, Nemzer B, Pietrzkowski Z. *Stimulatory Effect of Whole Coffee Fruit Concentrate Powder on Plasma Levels of Total and Exosomal Brain-Derived Neurotrophic Factor in Healthy Subjects: An Acute Within-Subject Clinical Study.* Food and Nutrition Sciences, 2013, 4, 984-990, attached as Exhibit 6 to Defendants' Supplemental Brief.

6. Clinical Studies of Phosphatidylserine (PS)

Similarly, several studies and articles have revealed that soybean-derived PS is beneficial for cognitive function in humans of various age groups. *See id*. at 9-10.

a. Kato-Kataoka Study (2010)

The CCAF Brief includes two errant statements relating to this study. *See id*. at 9. First, as Dr. Small clarifies, the fact that this study was conducted in Japan does not, in of itself, necessarily affect the significance of the test results, particularly given that this study was a double-blind, placebo-controlled clinical trial.[12] *See id*. Second, the PS group did in fact demonstrate a significant influence of PS on cognitive function and greater accuracy of responses on neuropsychological testing following 6 months of administration versus baseline. *See id.* at 9-10. Moreover, at the 3-month post-treatment follow-up, there was a significant difference on neuropsychological testing between the PS and placebo groups including cognitive improvements in delayed verbal recall, a sensitive memory measure. *See id.*

b. Yong Study (2011)

This study randomized 120 young adults into two groups: one receiving 250 ml of milk and the other receiving 250 ml of milk with 100 mg of PS per day for 40 days.[13] *See id*. at 10. The group receiving PS showed significant ($p<0.05$) improvements in several measures of cognitive performance, including directed memory, associative learning, free memory of images, recognition of meaningless figures, and portrait-features linked to memory. *See id*. at 10. As Dr. Small makes clear, the PS group receiving 100 mg of PS with 250 ml of milk does not invalidate the results of this study, particularly given that both the placebo and PS groups received equal amounts of milk at baseline. *See id*.

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[12] Kato-Kataoka, A, Sakai, M, Ebina, R, Nonaka, C, Asano, T, & Miyamori, T (2010). *Soybean-derived phosphatidylserine improves memory function of the elderly Japanese subjects with memory complaints.* J. Clin Biochem Nutr, 47(3), 246-255 attached as Exhibit 9 to Defendants' Supplemental Brief.

[13] T. Yong, et al, *Research on Human Memory Enhancement by Phosphatidylserine Fortified Milk.* Chongqing Medicine 40(30) (2011), attached as Exhibit 10 to Defendants' Supplemental Brief.

c. Crook (1998)

Review articles can serve as helpful resources in identifying and summarizing scientific evidence, as affirmed by Dr. Small. *See id*. at 9. This article summarizes the clinical study performed by Crook and associates in 1997 demonstrating that soybean-derived PS (100 mg/day and 300 mg/day for 3 weeks or 12 weeks) improved memory functions, such as memorizing names and faces, in elderly people with age-associated memory impairment.[14]

7. Clinical Studies on Melon Concentrate (SuperOxide Dismutase)

A growing body of evidence demonstrates that a daily intake of melon juice concentrate rich in SOD may have a positive effect on several signs and symptoms of stress and fatigue.[15] *See id*. at 10-11. These studies suggest that melon concentrate (with 140 IU SOD) supplementation is an effective and natural way to reduce stress and fatigue, supporting the SOD ingredient claims in Neuriva De-Stress. *See id*.

Unable (and unqualified) to refute the SOD study results, Mr. Frank is relegated to attacking the research as pilot studies. *See id*. at 10. But again, Mr. Frank's lay opinion is without merit and based on false assertions. The mere reference to a clinical trial as a pilot study does not invalidate the statistical significance of that study for a myriad of reasons, as Dr. Small explains, particularly when multiple pilot studies involving randomized, double blind, placebo-controlled tests reach similar results and conclusions as is the case with the clinical studies supporting the SOD ingredient claims. *See id.* at 10-11.

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[14] Crook TH., *Treatment of Age-Related Cognitive Decline: Effects of Phosphatidylserine, in Anti-Aging Medical Therapeutics*, Vol II, edited by R.M. Klatz, Health Quest Publications, Chicago, 1998, 20-29, attached as Exhibit 8 to Defendants' Supplemental Brief.

[15] M. Milesi, et al., *Effect of an oral supplementation with a proprietary melon juice concentrate (Extramel) on stress and fatigue in healthy people: a pilot, double-blind, placebo-controlled clinical trial.* Nutrition Journal, 8:40 (2009), attached as Exhibit 11 to Defendants' Supplemental Brief ("Milesi Study"); J. Carillon, et al., *Dietary Supplementation with a Superoxide Dismutase-Melon Concentrate Reduces Stress, Physical and Mental Fatigue in Healthy People: A Randomised, Double-Blind, Placebo-Controlled Trial*. Nutrients Journal (2014), 6, 2348-2359, attached as Exhibit 12 to Defendants' Supplemental Brief ("Carillon Study").

8. None of the Purported "Negative" Studies Cited in the CCAF Brief Are Relevant or Applicable to the Neuriva Ingredient Claims.

The CCAF Brief cites to purported "negative" studies on PS and alleges that they were not taken into consideration as part of the totality of the scientific evidence. However, three of the four studies cited in the CCAF Brief examine qualified health claims relating to disease like dementia.[16] *See id*. at 11. The Neuriva ingredient claims are not qualified health claims, but rather structure/function claims. *See id*. Therefore, the studies cited in the CCAF Brief relating to qualified health claims are wholly inapplicable and should not be considered in the totality of the scientific evidence relating to PS structure/function claims. *See id*.

The one non-qualified health claim study referenced in the CCAF Brief[17] should also not be considered in examining Neuriva's PS ingredient claim. *See id*. First, the dosage of PS administered to the test subjects in that study vary significantly from the dosage of PS contained in Neuriva, therefore the study is inapplicable. *See id*. Further, the study itself concedes that it suffered from a number of issues which may have influenced the results of the study including: (1) sampling error, (2) sensitivity of the cognitive tests to detect treatment effects, defined as the test-retest reliability, (3) inadequate sample size; and (4) presence of other phospholipids in the capsules administered to the test subjects. *See id*. This final issue is critical as the authors admit that the presence of three other phospholipids including, phosphatidylcholine, phosphatidylethano-lamine and phosphatidylinositol may have influenced the treatment effect of the Soy-PS. *See id*.

III. TINA IS AN ADMITTED NON-OBJECTOR WHOSE SUBMISSION HOLDS NO BEARING ON THIS COURT'S FINAL APPROVAL OF THE SETTLEMENT

Last, there is the Brief submitted by TINA, who likewise object to both the injunctive relief and attorneys' fees component of the Settlement. TINA Brief at 3-14. As noted in its accompanying Motion for Leave, TINA does not claim to have objector status and instead is appearing because of the group's own policy interests. Dkt. No. 74 at 2-3. But as explained

[16] *See* Exhibits C, E and G to Bednarz Decl.
[17] *See* Exhibit F to Bednarz Decl.

by Judge Gold in *Association for Disabled Americans*, simply because an interest group claims some generalized policy interest in the matters at issue in the settlement, does *not* give such groups Article III standing to object. 211 F.R.D. at 474 ("Because neither objecting organization is a member of the class or has asserted objections on behalf of a specific class member, each lacks standing to challenge the settlement. . . . Objectors' claimed mandate to represent disabled persons does not obviate the need to satisfy Article III's standing requirements.").

Even if the Court were to overlook the standing problems, it bears noting that TINA submitted a similar brief in *Collins*, where it likewise complained about the nature of the injunctive relief agreed to and the purported excessiveness of the potential attorneys' fees for class counsel. *See Collins v. Quincy Biosciences*, No. 19-cv-22864, Dkt. No. 168 at 7-13 (Oct. 28, 2020). Yet, this Court proceeded to approve the settlement in *Collins* without speaking to or otherwise crediting TINA's filing. *Collins v. Quincy Bioscience, LLC,* No. 19-cv-22864, Dkt. No. 200 (Nov. 18, 2020). The same result is appropriate here—particularly given the noted similarities between the *Quincy* settlement and the Settlement reached in this case. *See* Dkt. No. 62 at 15.

IV. CONCLUSION

The process for objections to the Settlement have concluded. When Article III standing requirements are accounted for, not one legitimate Neuriva purchaser or consumer has objected to the Settlement. This demonstrates that the Settlement reached is fair and reasonable. *Allapattah Servs., Inc. v. Exxon Corp.*, 2006 WL 1132371, at *12 (S.D. Fla. Apr. 7, 2006) (citing *Wal-Mart Stores, Inc. v. Visa U.S.A. Inc.*, 396 F.3d 96, 118 (2d Cir. 2005)) (granting final approval of settlement and rejecting objections as "patently frivolous") ("If only a small number of objections are received, that fact can be viewed as indicative of the adequacy of the

settlement."); *In re Newbridge Networks Securities Litigation*, Fed. Sec. L. Rep. (CCH) P 90319, 1998 WL 765724, at *2 (D.D.C. 1998) ("The absence of objections … give[s] rise to a strong inference of satisfaction among the class members."); *Zakskorn v. American Honda Motor Co., Inc.*, 2015 WL 3622990, at *9 (E.D. Cal. 2015) ("Given the very small number of objections, less than 0.0005 percent of the class, and the low number of opt-outs, 0.0247 percent of the total potential class, the overall reaction of the class has been positive. This factor too weighs in favor of approval.") (citing *Churchill Village, L.L.C. v. General Electric*, 361 F.3d 566, 577 (9th Cir. 2004) (affirming approval of a class action settlement where 90,000 class members received notice, and 45 objections and 500 opt outs were received)).

This Court should disregard the CCAF Brief and TINA Brief, and proceed to grant Final Approval of the Settlement.[18]

Dated: August 10, 2021

Respectfully Submitted,

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[18] While RB Health maintains that the Settlement is fair and reasonable as currently structured, and warrants Final Approval, it notes for the Court that it has engaged the Settlement's Notice Administrator, Angeion, to develop and implement a Supplemental Notice plan. *See* Exhibit B, Supplemental Declaration of Steven Weisbrot ¶¶ 6-13. This Supplemental Notice plan will direct additional social media notice to channels that Mr. Weisbrot has determined have the greatest likelihood of additional "conversions," i.e., will result in the filing of additional claims. *Id.* ¶ 8.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on August 10, 2021, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF.

/s/ Lori P. Lustrin
Lori P. Lustrin

EXHIBIT A

SUPPLEMENTAL DECLARATION OF DR. GARY W. SMALL

I. Introduction

In my Declaration, submitted on May 21, 2021 ("Declaration"), I provided my assessment of certain ingredient claims made for the Neuriva dietary supplements (Neuriva Original, Neuriva Plus and Neuriva De-Stress) in the context of the totality of scientific evidence available regarding the product ingredients. There, I provided a background on cognitive health and the Neuriva ingredients, as well as a summary of the scientific evidence supporting the benefits of those ingredients.

I have reviewed the Objection of Theodore H. Frank ("Frank Objection") and the lay opinions contained therein criticizing the science and clinical studies supporting the Neuriva ingredient claims. In this Supplement Declaration, I will address the specific issues raised in the Frank Objection and further discuss the totality of scientific evidence supporting the Neuriva ingredient claims.

II. Scientific Support for the Ingredients in Neuriva

Scientific research supports the promotional and implied claims that individuals who take Whole Coffee Cherry Extract (WCCE) and Phosphatidylserine (PS), the ingredients in Neuriva, experience a noticeable improvement in cognitive function including focus, concentration, memory, learning, reasoning, and accuracy. These ingredients, at doses that are included in the formulation, were shown in clinical studies to increase BDNF and help with mental focus, accuracy memory, learning and concentration which contribute to reasoning and accuracy.

Studies show that WCCE in healthy individuals increases brain-derived neurotrophic factor (BDNF; Reyes-Izquierdo et al, 2013a; 2013b), which increases neurotransmission (Ng

et al, 2019) and supports development and growth of dendritic connections in the brain (Yamada et al, 2002). It is also involved in neuronal maturation during development (Grande et al, 2010; Kowianski et al, 2018), as well as memory and learning (Grande et al, 2010). Research demonstrating the cognitive benefits of WCCE has been performed on healthy adults (Reed et al, 2018; Reyes-Izquierdo et al, 2013a; 2013b) as well as those with mild cognitive impairments (Robinson et al, 2019; Robinson et al, 2021).

PS is a major component of brain tissue that mostly resides in the plasma membrane, which is a membrane of lipids (i.e., fats) and proteins that form the external boundary of the cytoplasm or material comprising the living part of a cell (Mozzi et al, 2003). PS plays an essential role in keeping nerve cell membranes healthy and in forming myelin, the insulating sheath surrounding many nerve fibers (Glade and Smith 2015). These PS functions are associated with normal memory formation and learning. PS also plays an important role in maintaining accuracy in mental tasks, and human studies suggest that its level decreases with age (Kato-Kataoka et al, 2010). Soybean-derived PS has been shown to improve cognitive performance in both healthy young adults (Yong et al, 2011) and those with mild cognitive impairments (Crook et al, 1991a; 1998b; Kato-Kataoka et al, 2010).

The other active ingredient in Neuriva De-Stress, melon concentrate contains a potent antioxidant, SuperOxide Dismutase ("SOD"). SOD is one of the main antioxidant enzymes found in living cells and organisms. Clinical studies have shown that melon concentrate containing high levels of SOD showed a protective effect against DNA damage resulting from oxidative stress. (Milesi et al, 2009). Clinical studies have shown that supplementation with melon concentrate containing high levels of SOD decreases stress and fatigue.

III. Frank Objection

Based on my review of Mr. Frank's Objection and Declaration, as submitted to the court, I understand that Mr. Frank is an attorney and purported class member of the Neuriva class settlement. He is not a physician, scientist or expert in aging and memory or in the diagnosis and treatment of age-related cognitive decline. Therefore, the opinions stated in the Frank Objection are Mr. Frank's lay opinions regarding the totality of scientific evidence supporting the Neuriva ingredient claims. I will address those opinions here.

A. Use of Ingredient Studies to Support Ingredient Claims

The Frank Objection first takes issue with the fact that the Neuriva ingredient claims are supported by clinical studies regarding those very ingredients, rather than studies of the products themselves or studies involving a combination of ingredients. However, studies regarding individual ingredients are regularly used to support claims relating to dietary supplement products. For instance, there is significant scientific evidence connecting memory to caffeine consumption. There is no debate regarding the ability of caffeine, an active ingredient in many dietary supplements, to bolster memory, specifically working memory. Similarly, there is ample scientific support for the claims relating to the active ingredients (WCCE, PS and SOD) in Neuriva.

Moreover, the FDA guidance that the Frank Objection cites does indicate that an ingredient study can be used as substantiation for an ingredient claim. "We recommend that the studies being used as substantiation for dietary supplement claims identify a specific dietary supplement **or ingredient** . . ."[1] The Frank Objection refers to Example 5 in the FDA guidance as a basis for invalidating the clinical studies supporting the Neuriva ingredient

[1] *See* Exhibit A to Frank Bednarz Declaration at page 5.

claims. However, Example 5 is distinguishable and inapplicable here because the revised claims on Neuriva labeling do not refer to the products themselves, rather to the products' ingredients. And the clinical studies at issue support Neuriva's ingredient claims and not the products themselves.

B. Pilot Studies

Further, although some of the studies supporting the Neuriva ingredient claims are referenced as a "pilot study", that does not diminish the results or conclusions reached in those studies for a number of reasons. First, the term "pilot study" may be defined differently by one journal versus another journal, and is usually defined as such because of a relatively small sample size. Therefore, a study may be arbitrarily referenced as a pilot study according to a particular journal's parameters in how it determines and defines what constitutes a pilot study.

Second, nearly all of the scientific evidence supporting the Neuriva ingredient claims, including the pilot studies, are all peer reviewed and published studies involving randomized, double-blind, placebo-controlled test designs, which is the gold standard for studies of safety and efficacy of clinical interventions. These kinds of studies remain the most convincing research design in which randomly assigning the intervention can eliminate the influence of unknown or immeasurable confounding variables such as placebo effects that may otherwise lead to biased and incorrect estimate of treatment effects. Also, randomization eliminates confounding by baseline variables and blinding eliminates confounding by co-interventions, thus eliminating the possibility that the observed effects of intervention are due to differential use of other treatments. The advantage of trial over an observational study is the ability to demonstrate causality.

Third, a study involving a large sample may be statistically significant, but this does

not necessarily mean that its results are clinically meaningful. For example, a study involving thousands of subjects may show a statistically significant result but lead to minimal differences (e.g., just a few percentage points) between outcomes of the active treatment and placebo treatment groups. Meanwhile, when multiple pilot studies involving randomized, double-blind, placebo-controlled test designs all reach similar statistically significant results, they can in the aggregate be viewed as not only statistically significant but also clinically meaningful.

C. Study Populations

The Frank Objection also attempts to invalidate some of the studies because they were performed on healthy young adults while the products are intended for the elderly with cognitive impairment. However, there is nothing referenced in the Frank Objection or in the Neuriva ingredient claims to indicate that Neuriva is intended solely for the elderly with cognitive impairment. Rather, the Neuriva ingredient claims state generally that the ingredients help with cognitive function.

Moreover, many of the studies supporting the Neuriva ingredient claims were indeed performed on elderly adults with mild cognitive impairment. (Robinson et al, 2019; Robinson et al, 2021; Crook et al, 1991a; 1998b; Kato-Kataoka et al, 2010), in addition to studies involving healthy young adults. Accordingly, the fact that the clinical studies regarding WCCE and PS involve all age groups, both young and old, as well as both healthy adults and those with mild cognitive impairment provides further credibility to the significance of the results reached in those studies regarding the cognitive benefits of treatment with WCCE and PS.

D. Blood Brain Barrier

Finally, the Frank Objection asserts that Neuriva cannot work because its "natural

ingredients" are food, which gets digested into constituent parts before they enter one's bloodstream. However, an ingredient does not necessarily have to cross the blood brain barrier to be effective. There are many effective supplements and medicines whose active ingredients do not cross the blood brain barrier, but instead the ingredients are absorbed into the body through the digestive tract. Also, the mechanism of action of WCCE is tightly linked to an increase in levels of BDNF, an important neuroprotein involved in cognitive function and the most prevalent growth factor in the central nervous system (Autry and Monteggia 2012). Research indicates that WCCE increases BDNF levels. (Robinson et al, 2021; Reyes-Izquierdo et al, 2013a; 2013b). BDNF is a neurotrophin critical for the survival, growth, and maintenance of neurons, and is involved in learning, memory and in emotional and cognitive function (Loprinzi and Frith. 2019). It plays an important role in supporting neurogenesis, which is the growth and development of neurons in the brain (Henry et al, 2007). Investigators (Aimone et al, 2014) have demonstrated the importance of neurogenesis to memory and learning and its role in the adult hippocampus.

Although WCCE may not cross the blood brain barrier, research shows that BDNF does. (Robinson et al, 2021; Reyes-Izquierdo et al; 2012a; 2013b). Therefore, individuals who supplement with WCCE will have increased levels of BDNF which crosses the blood brain barrier and improves cognitive function.

IV. Clinical Studies of WCCE (Neurofactor)

Robinson Study (2019)

This peer reviewed and published study involved a randomized double-blinded, placebo-controlled test performed on 71 adults with mild memory impairment. (Robinson et al, 2019). The results demonstrated more than just the potential for WCCE to provide cognitive benefits.

Rather, in as little as seven days, significant reductions in reaction times were observed for groups supplemented with both 100 mg and 200 mg of WCCE versus placebo. These effects were observed for the entire 28-day study period. Specifically, the WCCE groups demonstrated a 41% and 32% reduction in reaction time compared to a 12% decrease in the placebo group at after 28 days compared to baseline. These results suggest that WCCE has a significant impact on reaction time in as little as seven days and these benefits persist throughout a 28-day period. Overall, the reductions in reaction time suggest that, during periods of cognitive challenge, WCCE supports motor response and executive function (performance); reduces mental fatigue; and benefits attention, motivation, focus, and alertness.

Robinson Study (2021)

The only criticism asserted in the Frank Objection regarding this study is that it is a pilot study. Yet, this is another peer reviewed and published study involving randomized, double-blind, placebo cross-over design. In this clinical study, researchers compared 100 mg of WCCE to placebo and found levels of BDNF increased within 90 minutes, and several relevant brain regions showed increased activation on MRI. Compared to placebo, BDNF led to significantly better results on key mental performance tasks. This study also revealed that BDNF crosses the blood-brain barrier. These results suggest that WCCE is associated with decreased reaction time and may protect against cognitive errors on robust tasks of working memory (i.e., n-back) and response inhibition (i.e., go/no-go). Furthermore, these behavioral results are concomitant with distinct neuro-functional changes within key neural structures involved in decision-making and attention. Decreased reaction time is associated with better mental focus and concentration abilities.

Reed Study (2019)

Reed and associates (2018) conducted a block-randomized, double-blind, placebo-controlled, cross-over study in 30 healthy adults who took 100 mg or 300 mg doses of WCCE in a ready-to-drink format. This format was compared with a placebo drink and a drink with 75 mg of caffeine (positive control). Contrary to the lay opinions in the Frank Objection, this study demonstrated that WCCE improved cognitive function. In fact, the study results showed positive effects from ingesting 100 mg of WCCE: self-reported alertness increased ($p=0.041$) and self-reported mental fatigue decreased ($p=0.034$) after study volunteers completed a series of fatiguing cognitive tasks. Similar results were observed after ingestion of 300 mg of WCCE for self-reported mental fatigue ($p= 0.032$) and self-reported alertness ($p=0.04$) (Reed et al, 2018). Mental fatigue is a symptom that has been linked to impaired accuracy and impaired concentration on cognitive testing (Sievertsen et al, 2016; Hancock and McNaughton, 1986).

Reyes-Izquierdo Studies (2013a; 2013b)

Both of the Reyes-Izquierdo studies showed that participants administered with 100 mg of WCCE had significant increases in BDNF levels. The first study showed increases in plasma BDNF levels by 148% compared to baseline (Reyes-Izquierdo et al, 2013a) while the second study, conducted to confirm and further investigate this effect, similarly resulted in an increase of plasma BDNF by 91% compared to placebo (Reyes-Izquierdo et al, 2013b). As detailed in my Declaration and above, BDNF is an important neuroprotein involved in cognitive function and is the most prevalent growth factor in the central nervous system. BDNF, which can be detected via blood samples, is critical for the survival, growth, and maintenance of neurons, and is involved in learning, memory, emotions, and overall cognitive function. It also increases neurotransmission (Ng et al, 2019) and supports

development and growth of dendritic connections in the brain (Yamada et al, 2002). It is also involved in neuronal maturation during development (Grande et al, 2010; Kowianski et al, 2018), as well as memory and learning (Grande et al, 2010). As discussed in my declarations, increased levels of BDNF does leads to significantly better results on key mental performance tasks (Robinson et al, 2021).

V. Clinical Studies of Phosphatidylserine (PS)

Several studies have revealed that soybean-derived PS is beneficial for cognitive function in humans of various age groups.

Crook (1998)

Review articles can serve as helpful resources in identifying and summarizing scientific evidence. The Crook (1998) article does just that. It summarizes the clinical study performed by Crook and associates in 1997 demonstrating that soybean-derived PS (100 mg/day and 300 mg/day for 3 weeks or 12 weeks) improved memory functions, such as memorizing names and faces, in elderly people with age-associated memory impairment. Cognitive benefits were seen at both doses examined (Crook 1998).

Kato-Kataoka Study (2010)

The Frank Objection includes two errant statements relating to this study. First, the fact that this study was conducted in Japan does not, in of itself, affect the significance of the test results. What is critical is the study's design, implementation and quality. This study was a double-blind, placebo-controlled clinical trial of 78 elderly subjects with mild cognitive impairment. So, this study utilized the gold standard for an intervention study. Second, the PS group did in fact demonstrate a significant influence of soybean-derived PS on cognitive function and greater accuracy of responses on neuropsychological testing following 6 months

of administration versus baseline. Moreover, at the 3-month post-treatment follow-up, there was a significant difference on neuropsychological testing between the PS and placebo groups (Kato-Kataoka et al, 2010). Cognitive improvements were observed in delayed verbal recall, a sensitive memory measure.

Yong Study (2011)

This study randomized 120 young adults into two groups: one receiving 250 ml of milk and the other receiving 250 ml of milk with 100 mg of PS per day for 40 days. The investigators reported that PS led to significant ($p<0.05$) improvements in several measures of cognitive performance, including directed memory, associative learning, free memory of images, recognition of meaningless figures, and portrait-features linked to memory (Yong et al, 2011). These mental skills assist with everyday memory challenges, such as recalling names and faces. The fact that the PS group received 100 mg of PS with 250 ml of milk does not invalidate the results of this study, particularly given that both the placebo and PS groups received equal amounts of milk at baseline.

VI. Clinical Studies on Melon Concentrate (SuperOxide Dismutase)

A growing body of evidence demonstrates that a daily intake of melon juice concentrate rich in SOD may have a positive effect on several signs and symptoms of stress and fatigue. (Milesi et al, 2009; Carillon et al, 2014). These studies suggest that melon concentrate (with 140 IU SOD) supplementation is an effective and natural way to reduce stress and fatigue, supporting the SOD ingredient claims in Neuriva De-Stress.

The only relevant objection proffered by Mr. Frank regarding the SOD studies is that they are referenced as pilot studies. The mere reference to a clinical trial as a pilot study does not invalidate the statistical significance of that that study for a myriad of reasons, as discussed above.

That is particularly true when multiple pilot studies involving randomized, double blind, placebo-controlled tests reach similar results and conclusions as is the case with the clinical studies supporting the SOD ingredient claims.

VII. The Qualified Health Claim Studies Cited in Frank's Objection

The Frank Objection cites to purported "negative" studies on PS. However, three of the four studies examine qualified health claims, for instance relating to dementia. The Neuriva ingredient claims are not qualified health claims, but rather structure/function claims. Therefore, those studies are not applicable and should not be considered in the totality of the scientific evidence relating to PS ingredient claims.

The one non-qualified health claim study referenced in the Frank Objection should also not be considered in examining Neuriva's PS ingredient claim. (Jorissen et al, 2000). First, the dosage of PS administered to the test subjects in that study vary significantly from the dosage of PS contained in Neuriva, therefore the study is inapplicable. Further, the study itself concedes that it suffered from a number of issues which may have influenced the results of the study including: (1) sampling error, (2) sensitivity of the cognitive tests to detect treatment effects, defined as the test-retest reliability, (3) inadequate sample size; and (4) presence of other phospholipids in the capsules administered to the test subjects. Regarding this last critical issue, the authors admit that the presence of three other phospholipids including: phosphatidylcholine, phosphatidylethanolamine and phosphatidylinositol may have influenced the treatment effect of the Soy-PS.

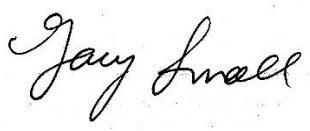
VIII. Conclusions

Despite the misguided lay opinions expressed in the Frank Objection, the totality of the scientific evidence supports Neuriva's ingredient claims that individuals who take Neurofactor and PS, experience a noticeable improvement in cognitive function including

focus, concentration, memory, learning, reasoning, and accuracy. These ingredients were shown in clinical studies, utilizing the gold standard for intervention tests, to increase BDNF and help with mental focus, accuracy memory, learning and concentration which contribute to reasoning and accuracy. Meanwhile, clinical studies have shown that supplementation with melon concentrate containing high levels of SOD decreases stress and fatigue.

I declare under penalty of perjury under the laws of the State of New Jersey that the foregoing is true and correct and of my personal knowledge.

Executed this __7th___ day of August, 2021, at 11:00 AM, Weehawken, NJ_____.



Gary W. Small, M.D.

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EXHIBIT B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
MIAMI DIVISION

DAVID WILLIAMS, CAROLL ANGLADE, THOMAS MATTHEWS, MARITZA ANGELES, and HOWARD CLARK, *individually, and on behalf of other similarly situated individuals,*

Plaintiffs,

v.

RECKITT BENCKISER LLC and RB HEALTH (US) LLC,

Defendants.

CASE NO. 1:20-cv-23564-MGC

SUPPLEMENTAL DECLARATION OF STEVEN WEISBROT, ESQ. OF ANGEION GROUP REGARDING THE SUPPLEMENTAL NOTICE PROGRAM

I, Steven Weisbrot, Esq., declare under penalty of perjury as follows:

1. I am the President and Chief Innovation Officer at the class action notice and claims administration firm Angeion Group, LLC ("Angeion"). I am fully familiar with the facts contained herein based upon my personal knowledge.

2. My credentials were previously reported in my Declaration filed with *Plaintiffs' Unopposed Motion for Preliminary Approval of Class Settlement and Certification of the Settlement Class* (Dkt. No. 52-3).

3. In my previous Declaration, I described in detail the proposed Notice Program, which included a combination of social media, paid search, and programmatic display advertising. In addition to these methods, the Notice Program in this matter also provided for the creation of a dedicated website as well as toll-free telephone support to further inform Settlement Class Members of their rights and options under the Settlement.

4. The purpose of this Supplemental Declaration is to provide the Court with additional information regarding the notice measures that will be implemented in this matter to supplement the Notice Program. The additional notice measures described in this Declaration were based on (1) the independent analysis of the data collected in this case concerning the Notice Program thus far that was performed by my team and I, (2) an assessment of what form of supplemental notice would be mostly likely to stimulate additional claims, and (3) mine and my team's expertise and experience in designing and implementing notice programs for class actions, including supplemental notice programs like the one described herein.

5. It is important to note that the notice efforts described herein are in addition to (not in lieu of) the notice efforts described in my previous Declaration and are designed to use the modes of advertising which proved to be most impactful during the initial Notice Program. The Supplemental Notice program described here is being undertaken voluntarily and is not otherwise required by the Settlement agreed to between the Parties or the existing Notice Plan that is a component of that Settlement.

ADDITIONAL SOCIAL MEDIA NOTICE

6. In addition to the notice efforts described in my previous Declaration, we will now implement a Supplemental Notice program consisting of a second social media campaign to provide additional notice to Settlement Class Members.

7. As described in my initial Declaration, the existing Notice Program consisted of multiple forms of Notice: (1) media notice; (2) social media notice; and (3) a paid search campaign. *See* Dkt. No. 52-3 at 7-11. To determine the form of supplemental notice most likely to be effective, we analyzed the data already collected from the existing Notice Program as to each of these forms of notice to design a Supplemental Notice that we believe would lead to increased claims. In reviewing the data already collected, my team and I considered specifically those forms or notice in the existing Notice Plan that had generated to a high conversion rate, with the goal of designing the Supplemental Notice that would be likely to increase the claims filing rate by using targeted notice that capitalized on our assessment of that data.

8. Following a review of the notice data from the original notice campaign, it was determined social media advertising, especially advertising on Facebook and displayed on a desktop rather than a mobile device, was the most effective form of notice in creating conversions i.e. causing class members to file claims. So, we designed the Supplemental Notice plan to focus primarily on serving Facebook ads on desktops, i.e., deploying the supplemental notice in the setting most likely to generate additional claims.

REDESIGN OF ADVERTISEMENT

9. The Supplemental Notice includes additional measures to further increase the likelihood of generating additional claims. In implementation of notice plans there is a phenomenon known as viewer fatigue, sometimes called "banner blindness." Viewer fatigue or banner blindness suggests that if a particular format of banner advertisement is seen initially and not acted upon or ignored, it is more likely that an identically-presented banner advertisement will be similarly ignored on repeat viewings. I am aware of this phenomenon through my experience in designing and implementing notice programs.

10. So, the Supplemental Notice plan contains an additional element intended to mitigate the effects of banner blindness and to garner the attention of Settlement Class Members who saw but did not necessarily act upon the prior Notice. Angeion will redesign the Facebook ads, focusing on new attention-grabbing visuals and advertising copy. A copy of the re-designed advertisement is attached to this Declaration as Exhibit A.

11. We believe that a simple redesign of the ad, coupled with the purchase of additional display Facebook placements will increase the number of claims.

12. The Supplemental Notice plan calls for these re-designed advertisements to be deployed such that they will deliver an estimated 1.1 million additional paid media impressions in the channel that the existing Notice Plan data suggests is likely to have the highest conversion rate. Again, these are in addition to the impressions already implemented via the initial Notice Plan.

13. The Supplemental Notice plan will be implemented throughout the remainder of the claims period, which runs through October 1, 2021, based on the currently scheduled August 17, 2021, date of the Final Approval Hearing (i.e. 45 days after Final Approval).

CONCLUSION

14. In my professional opinion, the Notice Program has already provided full and proper notice to Settlement Class Members. The Supplemental Notice program described above is being implemented by Angeion at the request of the Parties to increase claims filing rates by coupling a strategic redesign of the Facebook ads, and utilizing the highest converting media formats from the initial program. I hereby declare under penalty of perjury that the foregoing is true and correct.

Dated: August 9, 2021

STEVEN WEISBROT, ESQ.

Exhibit A

Angeion Group
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You could get money from a class action settlement if you bought Neuriva products between January 1, 2019 and April 23, 2021 in the United States.

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Williams, et al. v. Reckitt Benckiser, et al
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