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16

17 **UNITED STATES DISTRICT COURT**
18 **NORTHERN DISTRICT OF CALIFORNIA**
19 **SAN FRANCISCO DIVISION**

20 COLLEEN GALLAGHER, ILANA FARAR,
ANDREA LOPEZ, JOANN CORDARO, and
21 ROSANNE COSGROVE, on behalf of
themselves and all others similarly situated,

22 Plaintiffs,

23 v.

24 BAYER AG, BAYER CORPORATION, and
25 BAYER HEALTHCARE LLC,

26 Defendants.
27
28

Case No. 14-cv-04601-WHO

**NOTICE OF MOTION AND MOTION TO
DISMISS; MEMORANDUM OF POINTS
AND AUTHORITIES IN SUPPORT;
[PROPOSED] ORDER**

[Fed. R. Civ. P. 9(b), 12(b)(1), (12)(b)(6)]

**Second Amended Complaint Filed: March
30, 2015**

Date: June 3, 2015
Time: 2:00 PM
Place: Courtroom 2
Judge: William H. Orrick

NOTICE OF MOTION AND MOTION

TO PLAINTIFFS AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that on June 3, 2015, at 2:00 P.M., in Courtroom 2 of the above-entitled court, located at 450 Golden Gate Avenue, San Francisco, California 94102, Defendants Bayer AG, Bayer Corporation, and Bayer HealthCare LLC will and hereby do move pursuant to Fed. R. Civ. P. 12(b)(1) and 12(b)(6) to dismiss the Second Amended Complaint for lack of subject matter jurisdiction and for failure to state a claim upon which relief may be granted. The motion is based on this notice of motion, the memorandum of points and authorities attached hereto, the previous briefing, and the Court's Order on Defendants' Motion to Dismiss, and all other papers and pleadings on file hereon, and the argument of counsel at the hearing of this motion.

The motion specifically is based on the grounds that: (1) Plaintiffs do not adequately plead that Defendants' proper structure/function claims should be interpreted as disease claims; and (2) Plaintiffs' pleadings do not support their allegations that Defendants' claims are false.

Dated: April 13, 2015

SIDLEY AUSTIN LLP

By: /s/ Jonathan F. Cohn
*Attorney of Record for Defendants Bayer AG,
Bayer Corporation, and Bayer HealthCare LLC*

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3 2014)5, 6
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INTRODUCTION AND SUMMARY OF ARGUMENT

1
2 Plaintiffs' third bite at the apple fares no better than the first two. This Court articulated
3 requirements for Plaintiffs to replead their heart health and immunity claims, but the Second
4 Amended Complaint ("SAC") fails to meet these requirements. *See* Order Granting in Part and
5 Denying in Part Motion to Dismiss ("Order") (Docket No. 54). Accordingly, the Court should
6 dismiss the SAC with prejudice with respect to these claims.¹

7 The Court's Order explained that Plaintiffs' heart and immunity claims were "preempted as
8 'structure/function claims' expressly approved by the FDA," and gave Plaintiffs two paths to try to
9 salvage these claims. Order at 1. Plaintiffs could either: (1) "plead facts showing that [these
10 claims] ha[ve] been linked – *by virtue of specifically identified packaging or marketing* – to
11 treatment or prevention of disease," or (2) "explicitly plead – *with support to scientific evidence* –
12 that Bayer's support heart health and support immunity claims are false as structure/function
13 claims." *Id.* at 11, 13-14 (emphasis added).

14 The SAC does neither. First, the SAC fails to identify any packaging or marketing linking
15 Bayer's claims to the treatment or prevention of disease. Second, although Plaintiffs assert that the
16 "support[s] heart health" and "support[s] immunity" claims are false, *see, e.g.*, SAC at ¶¶ 31, 38,
17 40, 41, 56, 59, 60, they cite no "scientific studies to support those specific . . . claims," Order at
18 13. Like the First Amended Complaint ("FAC"), Plaintiffs cite only articles regarding the
19 prevention or treatment of disease.
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21

22 ¹ The Court did not dismiss Plaintiffs' challenge to Bayer's claim that One A Day multivitamins
23 help "support physical energy" after Plaintiffs conceded in their brief that Bayer made a structure-
24 function claim. *See* Order at 14, Memorandum of Law in Opposition to Defendants' Motion to
25 Dismiss (Docket No. 40) at 8-9, n.45. However, in the SAC, Plaintiffs once again misconstrue
26 Bayer's claim and contend that Bayer claimed that consumers "will experience increased energy,"
27 ¶ 77. There is a critical difference between a "supports energy" claim and an "increased energy"
28 claim. *See Kardovich v. Pfizer*, Case No. 13-CR-7378 (RRM) (VVP), 2015 WL 1506996, at *8
(E.D.N.Y. Mar. 31, 2015) (distinguishing between improving and supporting function: "[The
multivitamin] makes no claim that it *improves* immune function. As its packaging says, it claims
to *support* normal immune function." (emphasis added)). Defendants respectfully request this
Court to clarify that Plaintiffs can proceed only on a challenge to Bayer's actual claim ("support
physical energy"), not on the claim Bayer never made ("experience increased energy").

ARGUMENT

I. Plaintiffs Do Not Link Structure/Function Claims to Disease.

As this Court held: “Any state law claim that would impose a labeling requirement that is in addition to or in conflict with the FDA’s requirements for structure/function claims is preempted.” Order at 8 (citing cases).² The FDA has explicitly characterized statements like “supports heart health” and “supports immunity” as structure/function claims. *Id.* at 9-12. The Court allowed Plaintiffs to amend their pleadings to show that “supports heart health” and “supports immunity” have “been linked – *by virtue of specifically identified packaging or marketing* – to treatment or prevention of disease.” *Id.* at 11 (emphasis added). But Plaintiffs have failed to make this showing.³

A. Heart Health

Plaintiffs do not point to any “specific language on the packaging, websites, or in advertisements of the Supplements that would take the ‘supports heart health’ language and move it towards a disease claim.” *Id.* at 10. Instead, like the FAC, the SAC includes images of Women’s and Men’s One A Day packaging that say nothing about the heart except “Support[s] Hearth Health.” *See* SAC at ¶ 35, Illustration 1, and ¶ 47, Illustration 3 (“Formulated to Support . . . Heart Health” and “With Heart Health Support”).

Plaintiffs assert that Bayer “uses television advertisements to link its One A Day heart health Claims with cardiovascular diseases,” but the only example Plaintiffs provide is for One A Day Men’s 50+. *See* SAC at ¶ 36. It is the same screen image Plaintiffs included in the FAC, and it simply states, “Supports heart and eye health.” *See id.*, Illustration 2. Plaintiffs nonetheless allege:

[T]elevision advertisements for One A Day Men’s 50+ state that the product is “a complete multivitamin designed for men’s health concerns as we age.” During the commercial, the claim “[s]upports heart and eye health” appears prominently on the

² The Order clearly summarized the governing law. In the interest of economy and brevity, Defendants will reference the Order for the relevant law and will not re-argue legal issues or re-cite supporting case law already addressed by this Court. Defendants hereby incorporate their arguments from the prior briefing to dismiss Plaintiffs’ complaint.

³ Furthermore, even if Defendants did make disease claims (and they did not), those claims have not been proven actually false, for the reasons stated in Defendants’ earlier filings. *See* Motion to Dismiss (Docket No. 38) at 9-13.

1 screen while a voice-over mentions that the Supplement is “designed for men’s
2 health concerns as we age.” *As most Americans know, “as you get older, your risk
3 for CHD [Coronary Heart Disease] and heart attack rises.”* The juxtaposition of
the heart health Claim and the voice-over leads a consumer to believe that taking
Bayer One A Day Men’s 50+ will support heart health.

4 *Id.* ¶ 36 (emphasis added) (footnotes omitted).

5 But the italicized sentence on CHD and heart attacks is *not* from any Bayer advertisement.

6 *Bayer never spoke or used those words.* The quote is from a National Heart, Lung and Blood
7 Institute (“NHLBI”) webpage titled “Who Is at Risk for Heart Disease?” Nat’l Heart, Lung and
8 Blood Institute, Health Topics, Coronary Heart Disease Risk Factors,
9 <http://www.nhlbi.nih.gov/health/health-topics/topics/hdw/atrisk> (last visited April 7, 2015).

10 Placing this NHLBI language next to Bayer’s language, Plaintiffs create the illusion that the One A
11 Day advertisement contained that wording. But no One A Day advertisement contained that
12 wording or anything like it. Bayer never made any disease claim. In any event, Plaintiffs have no
13 standing to challenge this advertisement, which pertains only to the Men’s 50+ product. Order at
14 10, n.10 (“the plaintiffs in this suit only purchased the One A Day Women’s Supplement, and there
15 is no evidence that the Women’s Supplement’s advertising contained any [relevant]
16 representation”).

17 Finally, Plaintiffs contend that they “commissioned” a “consumer protection survey” in
18 March 2015, which supposedly showed “that many of Bayer’s consumers will interpret ‘supports
19 heart health’ as a disease-prevention claim.” SAC at ¶¶ 46-48. Plaintiffs have not published the
20 survey, provided it to Defendants, or filed it with the Court. Moreover, regardless of whether
21 consumers understand the distinction between structure-function claims and disease claims, the
22 legal distinction exists, the FDA has spoken, and so has this Court.⁴ *See* Order at 10. Claims
23 which the FDA has determined are structure-function claims do not become disease claims (subject

24 _____
25 ⁴ Even if the Court were to consider the unproduced survey relevant, and it is not, “plaintiffs do not
26 provide the actual studies on which these assertions are based, and thus, these unsupported
27 statements do nothing to support the plausibility of plaintiffs’ claim or the particularity standard
28 required under Rule 9(b).” *Kardovich*, 2015 WL 1506996, at *8 (citing *Padilla v. Costco*, No. 11
C 7686 (JWH), 2012 WL 2397012, at *4 (N.D. Ill. June 21, 2012) (failure to identify, discuss, or
attach scientific studies that demonstrate how representations were fraudulent does not satisfy Rule
9(b))).

1 to different statues and regulations) just because some consumers construe them to relate to
2 diseases.

3 **B. Immunity**

4 Plaintiffs' argument on immunity is similarly flawed. Plaintiffs claim that the "marketing
5 and context in which Bayer makes its immunity Claim link this Claim to the concept of getting sick
6 less often," but Plaintiffs cite nothing to support this conclusory assertion. SAC at ¶ 52; *see also*
7 Order at 4 (holding that the Court is "not required to accept as true allegations that are merely
8 conclusory, unwarranted deductions of fact, or unreasonable inferences") (internal quotations
9 marks and citation omitted). The SAC identifies no specific packaging or marketing materials
10 regarding immunity, except for ones that use the structure-function claims: "support[s] immunity"
11 and "immunity support." SAC at ¶¶ 50, 53, Illustration 4. Plaintiffs also cite their own survey, but
12 as discussed, purported consumer perceptions do not eliminate the FDA-recognized distinction
13 between structure-function claims and disease claims.

14 **II. Plaintiffs' Studies Do Not Support Their Attempt to Plead Actual Falsity.**

15 Plaintiffs likewise fail to "explicitly plead—with support to scientific evidence—that
16 Bayer's "support heart health" and "support immunity" claims are false as structure/function
17 claims." Order at 13-14. Instead, Plaintiffs cite articles discussing scientific evidence on the
18 ingredients' impact on *diseases*. "Simply put, these studies concerning specific medical conditions
19 in no way correlate to, let alone contradict as plaintiffs allege, the unrelated claims made by [the
20 product] about its health benefits." *Kardovich*, 2015 WL 1506996, at *6.

21 **A. Heart Health**

22 Plaintiffs assert that "[s]cientists have examined whether supplements with these vitamins
23 support heart health, and studies have shown that they do not." SAC at ¶ 38. Plaintiffs largely cite
24 the same materials they cited in the FAC, including certain National Institute of Health ("NIH")
25 Factsheets. *See id.*, ¶ 40. Each cited Factsheet contains a subsection titled "*Cardiovascular*
26 *disease*" or "*Coronary heart disease*" which summarizes scientific information regarding the
27 ingredient and its effect on or relationship to cardiovascular disease. *See* Nat'l Inst. of Health,
28 Office of Dietary Supplements, *Health Professional Factsheet: Vitamin B6*; Nat'l Inst. of Health,

1 Office of Dietary Supplements, *Health Professional Factsheet: Vitamin E*; Nat'l Inst. of Health,
 2 Office of Dietary Supplements, *Health Professional Factsheet: Vitamin C*. None shows that
 3 Bayer's structure-function claims are false.

4 Plaintiffs also cite an American Heart Association Nutrition Committee publication on diet
 5 and lifestyle recommendations. SAC at ¶¶ 38, 40. The first sentence of the abstract states that
 6 "[i]mproving diet and lifestyle is a critical component of the American Heart Association's strategy
 7 for *cardiovascular disease reduction* in the general population." American Heart Association
 8 Nutrition Committee, A.H. Lichtenstein *et al.*, *Diet and lifestyle recommendations revision 2006: a*
 9 *scientific statement from the American Heart Association Nutrition Committee*, 114 CIRCULATION
 10 82-96 (2006) ("AHA") (emphasis added). The entire publication focuses on strategies to reduce
 11 the incidence of cardiovascular disease.

12 Plaintiffs do not cite any materials that dispute One A Day's actual structure/function claim.
 13 "[T]he results of studies on particular diseases or conditions do not lend facial plausibility to far
 14 more general health benefit claims." *Kardovich*, 2015 WL 1506996, at *7 (relying on *Eckler v.*
 15 *Wal-Mart Stores, Inc.*, No. 12-cv-727, 2012 WL 5382218, at *7 (S.D. Cal. Nov. 1, 2012)). If
 16 anything, the cited materials confirm that One A Day's ingredients help support heart health. *See*
 17 B6 Factsheet ("Vitamin B6 also plays a role in . . . maintaining normal levels of homocysteine . . .
 18 [and] is involved in . . . hemoglobin formation."); *see also* Motion to Dismiss (Docket No. 38)
 19 (MTD) at 11-12.

20 **B. Immunity**

21 Plaintiffs' immunity allegations also rely on articles and studies dealing with disease.⁵ In

22 ⁵ At ¶¶ 56 and 59 of the SAC, Plaintiffs cite: Nat'l Inst. of Health, Office of Dietary Supplements,
 23 *Health Professional Factsheet: Vitamin C* ("regular intakes of vitamin C at doses of at least 200
 24 mg/day do not reduce the incidence of the common cold in the general population") ("vitamin C
 25 supplementation, usually in combination with other micronutrients, does not affect cancer risk");
 26 J.M. Graat *et al.*, *Effect of Daily Vitamin E and Multivitamin-mineral Supplementation on Acute*
 27 *Respiratory Tract Infections in Elderly Persons: A Randomized Controlled Trial*, 288 JAMA 715-
 28 21 (Aug. 2002); B.A. Liu *et al.*, *Effect of Multivitamin and Mineral Supplementation on Episodes*
of Infection in Nursing Home Residents, 55 J. Am. Geriatr. Soc. 35-42 (Jan. 2007); Salah Gariballa,
Vitamin and Mineral Supplements for Preventing Infections in Older People, 331 B.M.J. 304-05
 (Aug. 2005); Donald V. Veverka *et al.*, *Use of Zinc Supplements to Reduce Upper Respiratory*
Infections in United States Air Force Academy Cadets, 15 Complementary Therapies in Clin.
 Practice 91-95 (May 2009); Nat'l Inst. of Health, Office of Dietary Supplements, *Health*

1 addition, the aforementioned Factsheets confirm the ingredients in One A Day are essential to basic
2 immune function. See Nat'l Inst. of Health, Office of Dietary Supplements, *Health Professional*
3 *Factsheet: Vitamin B6* (“Vitamin B6 is involved in . . . immune function (for example, it promotes
4 lymphocyte and interleukin-2 production)”); Nat'l Inst. of Health, Office of Dietary Supplements,
5 *Health Professional Factsheet: Vitamin C* (“[V]itamin C plays an important role in immune
6 function.”); Nat'l Inst. of Health, Office of Dietary Supplements, *Health Professional Factsheet:*
7 *Vitamin E* (“[v]itamin E is involved in immune function.”); see also MTD at 10-11. Because
8 Plaintiffs have failed to “explicitly plead—with support to scientific evidence—that Bayer’s
9 support heart health and support immunity claims are false as structure/function claims,” Order at
10 13-14, this Court should dismiss those claims.

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21 *Professional Factsheet: Selenium* (discussing whether selenium prevents “[c]ardiovascular
22 disease”); R.M. Douglas et al., *Vitamin C for Preventing and Treating the Common Cold*, 3
23 *Cochrane Database Sys. Rev.* CD000980 (2007); Madeline Simasek et al., *Treatment of the*
24 *Common Cold*, 75 *Am. Family Physician* 515 (2007); E. Villamor et al., *Effects of Vitamin A*
25 *Supplementation on Immune Responses and Correlation with Clin. Outcomes*, 3 *Clin.*
26 *Microbiology Rev.* 446-64 (July 2005) (discussing effect of vitamin A on various diseases);
27 Stephen J. Oppenheimer, *Iron and Its Relation to Immunity and Infectious Disease*, 131 *J. Nutrition*
28 616S (Feb. 2001).

At ¶ 57, Plaintiffs cite: Audrey I. Stephen et al., *A Systematic Review of Multivitamin and*
Multimineral Supplementation for Infection, 19(3) *J. Human Nutrition & Dietetics* 179 (June 2006)
(a meta-analysis of 17 randomized controlled trials found no evidence for “a reduction in episodes
of infection, the number of days of infection, or antibiotic use” in participants supplemented with
multivitamins).

CONCLUSION

For the foregoing reasons, the motion to dismiss should be granted and the case dismissed with prejudice. Plaintiffs are not entitled to a fourth bite at the apple.

Respectfully submitted,

Dated: April 13, 2015

SIDLEY AUSTIN LLP
By: /s/ Jonathan F. Cohn

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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN FRANCISCO DIVISION

COLLEEN GALLAGHER, ILANA FARAR,
ANDREA LOPEZ, JOANN CORDARO, and
ROSANNE COSGROVE, on behalf of
themselves and all others similarly situated,

Plaintiffs,

v.

BAYER AG, BAYER CORPORATION, and
BAYER HEALTHCARE LLC,

Defendants.

Case No. 14-cv-04601-WHO

[PROPOSED] ORDER GRANTING
MOTION TO DISMISS OF BAYER AG,
BAYER CORPORATION, AND BAYER
HEALTHCARE LLC

Having considered the Motion to Dismiss the Second Amended Complaint filed by Bayer AG, Bayer Corporation, and Bayer HealthCare LLC, as well as all the papers and argument provided, the Court GRANTS the motion and orders that Plaintiffs’ Second Amended Complaint shall be dismissed with prejudice, except for the challenge to Bayer’s structure-function claim that One A Day “support[s] . . . physical energy.”

IT IS SO ORDERED.

Date: _____, 2015

The Honorable William H. Orrick
United States District Judge