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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

PAUL RIVA, *et al.*,

Plaintiffs,

v.

PEPSICO, INC.,

Defendant.

No. C-14-2020 EMC

RELATED TO

Lead Member Case C-14-0478 EMC,
Sciortino v. Pepsico

**ORDER GRANTING DEFENDANT’S
MOTION TO DISMISS**

(Docket No. 52)

Pending before the Court is Defendant Pepsico, Inc.’s (“Pepsi’s”) Motion to Dismiss the Amended Complaint of Plaintiffs Riva and Ardagna (collectively “Riva Plaintiffs”). Docket No. 52 (“Motion”). The operative complaint is the First Amended Complaint. Docket No. 51.

I. FACTUAL & PROCEDURAL BACKGROUND

Nine putative class actions were filed against Pepsi. In general, each action originally alleged that certain Pepsi products contain a carcinogen, 4-methylimidazole (“4-Mel”), at levels that were unhealthy, because, among other things, they exceeded the levels which triggered warning labels under California Proposition 65.

Following a contested application, the Court appointed the attorneys for Plaintiffs Hall and Ree as interim lead counsel for consolidated class actions. *Sciortino* ECF, Docket No. 65. Interim lead counsel subsequently elected not to allege any personal injury or medical monitoring claims in their consolidated amended complaint. The Court severed the *Riva* case from the consolidated actions to allow Plaintiffs Riva and Ardagna an opportunity to plead a personal injury claim seeking

1 medical monitoring in their own amended complaint independent of the consolidated complaint.
 2 *Sciortino* ECF, Docket No. 75.

3 According to a study cited in the First Amended Complaint (“FAC”), 4-MeI is “used in the
 4 manufacture of pharmaceuticals, photographic chemicals, dyes and pigments, cleaning and
 5 agricultural chemicals, and rubber.” Docket No. 53-2 at 7.¹ Four-MeI has “been identified as a by-
 6 product of fermentation in foods and has been detected in mainstream and sidestream tobacco
 7 smoke.” *Id.* The 4-MeI compound is generated during the caramelization process of caramel colors,
 8 a color additive used in a wide range of foods and beverages, including beer and some soft drinks,
 9 because of its color, flavor, and other properties. Docket No. 53-3; *see also* FAC ¶ 9.

10 Plaintiffs Riva and Ardagna allege that Pepsi’s Diet Pepsi and Pepsi One beverages
 11 contained 4-MeI at levels that caused them to experience an “increased risk of cancer,” specifically
 12 bronchioloalveolar cancer. FAC ¶ 1. To support the claim of the increased risk of
 13 bronchioloalveolar cancer, the Riva Plaintiffs cite to a report by the National Toxicology Program
 14

15
 16 ¹ The Court **GRANTS** for purposes of the motion to dismiss Pepsi’s request for judicial
 17 notice over three scientific articles that the Riva Plaintiffs specifically relied on in the FAC to
 18 provide factual support for the Riva Plaintiffs’ claims. Docket No. 53-2, Pandya Decl. Ex. A, (“NTP
 19 Study”); Docket No. 53-2, Pandya Decl., Ex. B; Docket No. 53-2, Pandya Decl., Ex. C. The Riva
 20 Plaintiffs do not oppose the request for judicial notice or question the authenticity of the articles.
 21 The documents are publicly-available for download or purchase from the websites of government
 22 entities and organizations that host scientific academic journal articles. Pandya Decl. ¶¶ 2-4. The
 23 Court deems these three articles to be incorporated by reference into the FAC. The incorporation by
 24 reference doctrine allows a court ruling on a Rule 12(b)(6) motion to look beyond the pleadings to
 25 “documents whose contents are alleged in a complaint and whose authenticity no party questions,
 26 but which are not physically attached to the plaintiff’s pleading.” *Davis v. HSBC Bank Nevada,*
 27 *N.A.*, 691 F.3d 1152, 1160 (9th Cir. 2012) (citations omitted). Such documents may be considered
 28 as incorporated by reference, *i.e.*, as “part of the complaint,” without converting the Rule 12(b)(6)
 motion into one for summary judgment. *Id.*; *see also Marder*, 450 F.3d at 448. The contents of
 such documents may be assumed to be true for purposes of deciding a Rule 12(b)(6) motion. *Id.*
 The policy concern that this rule addresses is that a plaintiff with a legally deficient claim might
 otherwise survive a motion to dismiss by selectively omitting references to documents upon which
 he relies to state his claim. *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir. 1998), *superseded by*
statute on other grounds as stated in Abrego v. Dow Chem. Co., 443 F.3d 676, 681–82 (9th Cir.
 2006). Use of such documents does not offend the fairness concerns underlying the rule against
 consideration of extrinsic materials, because a plaintiff who bases his claims on the contents of
 particular documents can “hardly complain” when a defendant refers to the same information in its
 defense. *Davis*, 691 F.3d at 1161. In this case, the three scientific studies are specifically cited to
 and relied upon by the FAC. FAC ¶¶ 10-13; 19-20; 23. They are necessary to the Riva Plaintiffs’
 claims regarding exposure and injury. *Id.* Incorporation by reference is proper. *Davis*, 691 F.3d at
 1160.

1 that found that high levels of exposure to 4-MeI resulted in increased incidences of
2 alveolar/bronchial neoplasms in mice. *Id.* ¶ 11.

3 According to the FAC, the compound 4-MeI appears on the list of known carcinogens that
4 require disclosure at certain levels under Proposition 65. FAC ¶ 1. Proposition 65 calls for
5 disclosure of the presence of 4-MeI at levels above 29 micrograms per day. *Id.* ¶ 15. Testing by
6 Consumer Reports in December of 2013 revealed that Diet Pepsi sold in California contained an
7 average of 30.5 micrograms of 4-MeI per can. *Id.* ¶ 16. Pepsi One sold in California contained an
8 average of 43.5 micrograms of 4-MeI per can. *Id.* ¶ 18. A toxicologist at the Consumer Reports
9 Food Safety & Sustainability Center has opined that there is no “safe level” of 4-MeI, and that the
10 threshold should be “more like 3 micrograms/day.” *Id.* ¶ 15.

11 Mr. Riva contends that he “drank Pepsi One 2 to 3 times each and every week” (*id.* ¶ 3), and
12 Ms. Ardagna alleges that she “consumed 3 to 4 cans of Diet Pepsi per day, or nearly 30 cans of Diet
13 Pepsi per week” (*id.* ¶ 4). The Riva Plaintiffs seek to represent a class of California consumers who
14 purchased Diet Pepsi or Pepsi One during the four-year period from February 13, 2010 to the filing
15 of the original complaint. *Id.* ¶ 32.

16 The Riva Plaintiffs assert three claims: negligence, strict liability based on defective design,
17 and strict liability based on failure to warn. *Id.* ¶¶ 41–59. The Riva Plaintiffs seek medical
18 monitoring as a remedy for all three claims; specifically, they seek an order requiring Pepsi to
19 establish a “fund from which those individual class members can seek monetary recovery for the
20 costs of actual or anticipated medical monitoring expenses incurred by them.” *Id.* at 19.² The Riva
21 Plaintiffs in particular allege that outcomes in bronchioloalveolar cancer show a clinically
22 significant benefit from early evaluation, detection, and diagnosis. *Id.* ¶ 45.

23 The Riva Plaintiffs do not seek to certify a class for the entire action, nor do they seek
24 certification of the damages portion of their case. Instead, the Riva Plaintiffs contemplate a two-step
25 process. First, they seek to certify certain liability issues and issues pertaining to remedies, such as
26 whether medical monitoring is warranted, and what monitoring is “medically and legally justified,”

27 _____
28 ² The Riva Plaintiffs also request that Pepsi pay the cost of providing notice to the class
members and seek an award of costs and fees. *Id.*

1 under Federal Rule of Civil Procedure 23(c)(4). *Id.* ¶ 1. Second, following resolution of those
2 discrete class issues, the Riva Plaintiffs envision that class members would “individually litigate
3 their damages” from the fund created through the class process. *Id.* at ¶ 2. According to the Riva
4 Plaintiffs, litigation of damages at that point would include proof that those individuals ingested
5 Pepsi One or Diet Pepsi “at or above the threshold quantities” that justify medical monitoring. *Id.*

6 Pepsi has moved to dismiss the Riva Plaintiffs’ FAC, arguing that the Riva Plaintiffs lack
7 standing or otherwise have failed to allege actual harm, have failed to allege sufficient factual
8 support for the cancer screenings they seek, and have not adequately pled their class allegations,
9 including ascertainability of the class, commonality and predominance, and superiority of class
10 adjudication. For the reasons discussed herein and on the record at the hearing, the Court **GRANTS**
11 Pepsi’s Motion. Because the currently-pled facts cannot plausibly state a claim and the Riva
12 Plaintiffs have failed to identify any realistic plan to cure the deficiencies in the FAC, the Court
13 grants Pepsi’s Motion with prejudice.

14 **II. DISCUSSION**

15 A. Legal Standard

16 A complaint must contain “a short and plain statement of the claim showing that the pleader
17 is entitled to relief” in order to provide “fair notice of what the claim is and the grounds upon which
18 it rests. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007); Fed. R. Civ. P. 8(a)(2). To survive a
19 motion to dismiss under Rule 12(b)(6), a complaint need not contain “detailed factual allegations,”
20 but it must “contain sufficient factual matter, accepted as true, to ‘state a claim to relief that is
21 plausible on its face.’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at
22 570). In other words, “[t]hreadbare recitals of the elements of a cause of action, supported by mere
23 conclusory statements, do not suffice.” *Id.*

24 For purposes of ruling on a Rule 12(b)(6) motion to dismiss, a court accepts all factual
25 allegations as true and construes the pleadings in the light most favorable to the nonmoving party.
26 *Knievel v. ESPN*, 393 F.3d 1068, 1072 (9th Cir. 2005). While a court assumes the allegations in the
27 complaint are true (even if “doubtful in fact”), the factual allegations must “be enough to raise a
28 right to relief above the speculative level.” *Twombly*, 550 U.S. at 555. “Asking for plausible

1 grounds does not impose a probability requirement at the pleading stage; it simply calls for enough
2 fact to raise a reasonable expectation that discovery will reveal evidence” of wrongdoing. *Id.* at 545.
3 Requiring such factual content to be pled serves the “practical purpose of preventing a plaintiff with
4 a largely groundless claim from taking up the time of a number of other people, with the right to do
5 so representing an *in terrorem* increment of the settlement value.” *Id.* at 546 (quotations omitted).

6 In its motion to dismiss, Pepsi questions not only the factual sufficiency of the FAC, but also
7 whether the Riva Plaintiffs have constitutional standing. “[L]ack of Article III standing requires
8 dismissal for lack of subject matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1).
9 *Maya v. Centex Corp.*, 658 F.3d 1060, 1067 (9th Cir. Cal. 2011). Under Rule 12(b)(1) a court is not
10 as limited as under Rule 12(b)(6) in determining constitutional standing; “it is within the trial court’s
11 power to allow or to require the plaintiff to supply, by amendment to the complaint or by affidavits,
12 further particularized allegations of fact deemed supportive of plaintiff’s standing.” *Maya*, 658 F.3d
13 at 1067.

14 B. Standing

15 The Riva Plaintiffs bear the burden of establishing the core components of constitutional
16 standing. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561 (1992). The “irreducible constitutional
17 minimum of standing” requires establishing three elements. *Id.* at 560-61; *Cent. Delta Water*
18 *Agency v. United States*, 306 F.3d 938, 946-47 (9th Cir. 2002). First, standing requires an “injury in
19 fact,” that is, an invasion of a legally protected interest. *Id.* Such injury must be “concrete and
20 particularized” as well as “actual or imminent,” *i.e.*, “not conjectural or hypothetical.” *Id.* There
21 must be a “credible threat of harm sufficient to constitute actual injury.” *Cent. Delta Water Agency*,
22 306 F.3d at 950. Second, standing requires a “causal connection between the injury and the conduct
23 complained of – the injury has to be fairly traceable to the challenged action of the defendant.” *Id.*
24 Third, it must be “likely as opposed to merely speculative that the injury will be redressed by a
25 favorable decision.” *Id.*

26 The elements of constitutional standing are “an indispensable part of the plaintiff’s case,”
27 and not mere pleading requirements. *Lujan*, 504 U.S. at 561. Thus, each element must be supported
28 in the same way as any other matter on which the plaintiff bears the burden of proof. *Id.* Under

1 Rule 12(b)(1), the plaintiffs must provide factual support to assert an injury-in-fact. *See Maya*, 658
2 F.3d at 1068; *Chapman v. Pier 1 Imps. (U.S.), Inc.*, 631 F.3d 939, 955 n.9 (9th Cir. Cal. 2011) (“To
3 sufficiently allege standing, Chapman must do more than offer “labels and conclusions” that parrot
4 the language of the ADA.”); *Herrington v. Johnson & Johnson Consumer Companies, Inc.*, No. C
5 09-1597 CW, 2010 WL 3448531, at *3 (N.D. Cal. Sept. 1, 2010). Pepsi contends that the Riva
6 Plaintiffs have not demonstrated the injury-in-fact necessary to establish Article III standing.

7 The Court agrees with Pepsi that the Riva Plaintiffs have failed to allege injury-in-fact for
8 constitutional standing. Increased risk of injury can suffice to establish an Article III injury-in-fact
9 where the increased risk of injury is credible and not conjectural. The Ninth Circuit has held that “a
10 credible threat of harm is sufficient to constitute actual injury for standing purposes.” *Cent. Delta*
11 *Water Agency*, 306 F.3d at 950. *Central Delta Water Agency* concerned threatened environmental
12 harm – the plaintiff challenged a plan to release reservoir waters where the plan was projected to
13 violate the state salinity standards for a neighboring river, which would ultimately jeopardize crops.
14 The Ninth Circuit reversed the district court’s grant of summary judgment based on lack of standing,
15 because Plaintiffs had raised a material question of fact with respect to whether they suffered a
16 substantial risk of harm, finding that the “threat of injury resulting from the Bureau’s employing an
17 operational plan that will *likely* lead to violations of the [state salinity] standard is sufficient to
18 confer standing on plaintiffs.” *Id.* at 948 (emphasis added). *Central Delta Water Agency* reasoned
19 that the plaintiffs need not await the anticipated violation or resulting crop damage where the
20 plaintiffs have raised a material dispute of fact as to “whether they suffer a substantial risk of harm.”
21 *Id.*

22 Similarly, in a case involving employee personal information that had been stolen from an
23 employer-owned laptop, but that had not yet been misused, the Ninth Circuit found standing in
24 *Krottner v. Starbucks*, 628 F.3d 1139 (9th Cir. 2010). Citing *Central Delta Water Agency*, the Ninth
25 Circuit held that “[i]f a plaintiff faces a *credible threat of harm*, and that harm is both real and
26 immediate, not conjectural or hypothetical, the plaintiff has met the injury-in-fact requirement for
27 standing under Article III.” *Krottner*, 628 F.3d at 1143 (citations omitted) (emphasis added).
28 *Krottner* concluded that the employees whose data was stolen had sufficiently alleged an increased

1 risk of identity theft that was not conjectural or hypothetical. *Id.*; *cf. Montana Env'tl. Info. Ctr. v.*
 2 *Stone-Manning*, 766 F.3d 1184, 1191 (9th Cir. 2014) (finding failure to adequately allege risk of
 3 harm when there are no allegations about whether the approval of a pending mine application is
 4 imminent or likely).

5 While medical monitoring plaintiffs may have standing to assert claims based on a latent
 6 increased risk of injury where there is a credible risk of harm, *see Cent. Delta Water Agency*, 306
 7 F.3d at 950, the Riva Plaintiffs in this case have failed to establish standing, because they have not
 8 established that the alleged risk of bronchioloalveolar cancer (for which they seek lung scans and
 9 testing) is both credible and substantial, *see id.* 306 F.3d at 948; 950; *Herrington*, 2010 WL
 10 3448531, at *3. As discussed in more detail below, the inferences of increased risk of harm that are
 11 based on the record established by the amended complaint (and studies incorporated therein) are
 12 speculative. In particular, the Riva Plaintiffs have alleged that mice experience increased risk of
 13 harm of a specific form of lung cancer at very high exposures to 4-MeI; but they have not alleged
 14 facts to show that *humans* experience the same increased risk, particularly at the exposures alleged.
 15 *See* FAC ¶¶ 11, 12, 23. The Riva Plaintiffs have effectively invited the Court to engage in an
 16 “ingenious academic exercise in the conceivable to explain how defendants’ actions caused their
 17 injury.” *Maya*, 658 F.3d at 1068 (citation omitted). That is not sufficient to establish Plaintiffs’
 18 standing to bring the instant case seeking medical monitoring for bronchioloalveolar cancer. *See id.*³

19
 20 _____
 21 ³ Defendant contends Plaintiffs also have not adequately alleged traceability, another element
 22 of Article III standing. To survive a motion to dismiss for lack of constitutional standing, plaintiffs
 23 need not “demonstrate that defendants’ actions are the ‘proximate cause’ of plaintiffs’ injuries.”
 24 *Maya*, 658 F.3d at 1070. The critical inquiry is whether the causal chain is plausible. *Id.* In
 25 environmental cases, courts examine the “remoteness of the injury claim.” *Native Vill. of Kivalina*
 26 *v. ExxonMobil Corp.*, 663 F. Supp. 2d 863, 881 (N.D. Cal. 2009) *aff’d*, 696 F.3d 849 (9th Cir. 2012).
 27 Plaintiffs within the “zone of discharge” have satisfied the “fairly traceable” causation requirement,
 28 but others who are far downstream, may not. *Id.* According to Pepsi, the Riva Plaintiffs cannot
 allege direct traceability, because 4-MeI is commonly found in many other everyday food products
 (such as brewed coffee, grilled meats, beer, baked goods, fruit preserves, and sauces). The Riva
 Plaintiffs allege an increased risk of injury due to their consumption of certain Pepsi products that
 contain a toxic compound. Arguably, they allege that they directly consumed the products and thus
 satisfied the Article III traceability requirement. Yet, as discussed herein, there are substantial
 plausibility problems with the Riva Plaintiffs’ allegations of causation on the merits. Although
 Article III standing is broader than causation on the merits, the finding that there is no credible risk
 of injury sufficient to establishing standing to seek medical monitoring obviates the need for the
 Court to resolve this question, except to say it has doubts traceability is met here.

1 C. Medical Monitoring

2 The Riva Plaintiffs have failed to plead entitlement on the merits to medical monitoring, the
3 sole remedy sought herein. FAC ¶¶ 47, 53, 59; *see also Sciortino* ECF, Docket No. 75. “In the
4 context of a toxic exposure action, a claim for medical monitoring seeks to recover the cost of future
5 periodic medical examinations intended to facilitate early detection and treatment of disease caused
6 by a plaintiff’s exposure to toxic substances.” *Potter v. Firestone Tire & Rubber Co.*, 6 Cal. 4th
7 965, 1004-05 (1993). “Medical monitoring claims acknowledge that, in a toxic age, significant
8 harm can be done to an individual by a tortfeasor, notwithstanding latent manifestation of that
9 harm.” *In re Paoli R.R. Yard PCB Litig.*, 916 F.2d 829, 852 (3d Cir. 1990).

10 One of the first cases to deal with the issue of medical monitoring arose from a plane crash
11 during “Operation Babylift,” a rescue mission for Vietnamese orphans in 1975 when the United
12 States withdrew from South Vietnam. One hundred and forty-nine orphans, mostly infants at the
13 time, survived the explosive decompression and impact. *Friends for All Children, Inc. v. Lockheed*
14 *Aircraft Corp.*, 746 F.2d 816, 819 (D.C. Cir. 1984). The guardian ad litem for the surviving children
15 alleged that the accident caused the children to suffer from a neurological development disorder
16 generically classified as Minimal Brain Dysfunction and sought compensation for diagnostic
17 examinations. *Id.* at 819. In *Friends for All Children*, the D.C. Circuit held that District of
18 Columbia tort law encompassed a cause of action for diagnostic examinations even where there was
19 not proof of present injury. *Id.* at 825. The two principal goals of tort law, “the deterrence of
20 misconduct and the provision of just compensation to victims of wrongdoing,” were furthered by
21 allowing a plaintiff to recover for diagnostic examinations. *Id.*

22 On the subject of “injury,” *Friends for All Children* reasoned that “an individual has an
23 interest in avoiding expensive diagnostic examinations just as he or she has an interest in avoiding
24 physical injury.” *Friends for All Children*, 746 F.2d at 826. As a result, even if there is no proof of
25 present physical injury, when “a defendant negligently invades this interest, the injury to which is
26 neither speculative nor resistant to proof, it is elementary that the defendant should make the
27 plaintiff whole by paying for the examinations.” *Id.*

28

1 In the thirty years following *Friends for All Children*, even where there is no evidence of
2 actual physical injury, medical monitoring remedies have increasingly been permitted, particularly
3 in cases involving toxic torts and products liability. *Sutton v. St. Jude Med. S.C., Inc.*, 419 F.3d 568,
4 571 (6th Cir. 2005); *see, e.g., Ayers v. Jackson Twp.*, 106 N.J. 557, 606-07, 525 A.2d 287, 313
5 (1987) (well water contaminated by four known carcinogens due to negligent operation of landfill),
6 *Carey v. Kerr-McGee Chem. Corp.*, 999 F. Supp. 1109, 1119 (N.D. Ill. 1998) (noting in case
7 involving exposure to radioactive thorium “the Illinois Supreme Court would uphold a claim for
8 medical monitoring without requiring plaintiffs to plead and prove either a present physical injury or
9 a reasonable certainty of contracting a disease in the future,” although barring case on statute of
10 limitations grounds); *Day v. NLO*, 851 F. Supp. 869, 881-82 (S.D. Ohio 1994) (allowing remedy of
11 medical monitoring under Ohio law based on excessive radiation exposure); *Burton v. R.J. Reynolds*
12 *Tobacco Co.*, 884 F. Supp. 1515, 1523 (D. Kan. 1995) (acknowledging damages claim for medical
13 surveillance arising from vascular disease caused by cigarettes under Kansas law); *In re Diet Drugs*,
14 582 F.3d 524, 530 (3d Cir. 2009) (mentioning medical monitoring class certifications in “fen-phen”
15 diet drug litigation).

16 In particular, the California Supreme Court, relying on *Friends for All Children* and other
17 cases, held in *Potter* that “the cost of medical monitoring is a compensable item of damages where
18 the proofs demonstrate, through reliable medical expert testimony, that the need for future
19 monitoring is a reasonably certain consequence of a plaintiff’s toxic exposure and that the
20 recommended monitoring is reasonable.” *Potter*, 6 Cal. 4th at 1009. *Potter* agreed with the analysis
21 in *Friends for All Children* that found that medical monitoring may be warranted even in the
22 absence of physical injury. *Id.* at 1007. *Potter* emphasized that “allowing compensation for medical
23 monitoring costs does not require courts to speculate about the probability of future injury[;] [i]t
24 merely requires courts to ascertain the probability that the far less costly remedy of medical
25 supervision is appropriate.” *Id.* at 1007-08 (citation omitted). As guidance, the California Supreme
26 Court identified five factors in determining the reasonableness and necessity of monitoring:

- 27 (1) the significance and extent of the plaintiff’s exposure to
28 chemicals;

- 1 (2) the toxicity of the chemicals;
- 2 (3) the relative increase in the chance of onset of disease in the
3 exposed plaintiff as a result of the exposure, when compared to
4 (a) the plaintiff's chances of developing the disease had he or
5 she not been exposed, and
6 (b) the chances of the members of the public at large of
7 developing the disease;
- 8 (4) the seriousness of the disease for which the plaintiff is at risk;
9 and
- 10 (5) the clinical value of early detection and diagnosis.

11 *Id.* The trier of fact decides, "on the basis of competent medical testimony, whether and to what
12 extent the particular plaintiff's exposure to toxic chemicals in a given situation justifies future
13 periodic medical monitoring." *Id.*

14 Importantly, in *Potter*, the California Supreme Court had addressed the concern regarding a
15 potential flood of meritless litigation. The Court reasoned that the five-factor test that it articulated
16 would prevent claims for medical monitoring damages from being brought based on potentially
17 trivial exposures to toxic chemicals:

18 [t]he five factors provide substantial evidentiary burdens for toxic
19 exposure plaintiffs and do not, as Firestone insists, allow medical
20 monitoring damages to be based "solely upon a showing of an
21 increased but unquantified risk resulting from exposure to toxic
22 chemicals." Moreover, toxic exposure plaintiffs may recover "only if
23 the evidence establishes the necessity, as a direct consequence of the
24 exposure in issue, for specific monitoring beyond that which an
25 individual should pursue as a matter of general good sense and
26 foresight."

27 *Potter*, 6 Cal. 4th at 1009.

28 Subsequently, in a Federal Employers' Liability Act case, the Supreme Court surveyed state
29 decisions that permitted medical monitoring, including *Potter*, and commented that the limits
30 imposed under state law are critical in cases where there are no present physical symptoms;
31 specifically, the Supreme Court expressed doubt that a medical monitoring recovery should
32 encompass a full-blown cause of action for lump-sum damages. *Metro-N. Commuter R. Co. v.*
33 *Buckley*, 521 U.S. 424, 444 (1997) (holding that a separate tort cause of action is not available under

1 FELA to recover lump-sum medical monitoring costs). The Supreme Court commented in dicta as
 2 to some of the drawbacks of allowing unqualified liability for medical monitoring:

3 [T]ens of millions of individuals may have suffered exposure to
 4 substances that might justify some form of substance-exposure-related
 5 medical monitoring. . . . And that fact, along with uncertainty as to the
 6 amount of liability, could threaten both a “flood” of less important
 7 cases (potentially absorbing resources better left available to those
 8 more seriously harmed . . .) and the systemic harms that can
 9 accompany “unlimited and unpredictable liability” (for example, vast
 10 testing liability adversely affecting the allocation of scarce medical
 11 resources).

12 *Metro-North Commuter Railroad*, 521 U.S. at 442.

13 D. Sufficiency of Factual Allegations

14 The parties do not dispute that California law, and hence *Potter*, applies to the case at bar.
 15 Pepsi argues that the claim for medical monitoring lacks sufficient factual support under Rule
 16 12(b)(6), particularly as to the *Potter* factors for whether medical monitoring is reasonable and
 17 necessary.

18 The Riva Plaintiffs respond that the following factual allegations, if proven, would establish
 19 their right to relief.

- 20 • The Riva Plaintiffs regularly ingested either Pepsi One and Diet Pepsi products; these
 21 drinks contain high levels of 4-MeI, which is a carcinogen known to the State of
 22 California to cause cancer;
- 23 • published medical studies show that there is “clear evidence of carcinogenic activity
 24 of 4-methylimidazole [4-MeI] in male and female B6C3F mice based on increased
 25 incidences of alveolar/bronchial neoplasms” (FAC, at ¶ 11);
- 26 • Plaintiffs’ regular ingestion of Diet Pepsi and Pepsi One drinks containing 4-MeI
 27 place them at an increased risk of contracting bronchioloalveolar cancer (Id. at ¶ 46);
- 28 • early detection and screening methods for bronchioloalveolar cancer exist (Id. at ¶¶
 25-26);
- and, that the benefits of such early medical monitoring are significant because
 published peer-reviewed medical studies show a drastic reduction in mortality from
 such cancers if detected early based on early screening.”

Opp. at 10-11; FAC at ¶ 27.

1 The critical dispute is whether the Riva Plaintiffs have sufficiently alleged a causal
2 connection between consuming Pepsi One or Diet Pepsi and an increased risk of developing
3 bronchioloalveolar cancer in humans. This matters not only for pleading entitlement to medical
4 monitoring under the *Potter* factors, but also for determining whether the basic elements of the Riva
5 Plaintiffs’ negligence and strict liability causes of action have been sufficiently pled. As noted
6 above, the analysis also informs the critical standing question – whether there is a credible threat of
7 harm facing the Plaintiffs.

8 The fact and causation of injury are necessary elements of the Riva Plaintiffs’ case. Under
9 California law, whether “under either a negligence or a strict liability theory of products liability, to
10 recover from a manufacturer, a plaintiff must prove that a defect caused injury.” *Merrill v. Navegar,*
11 *Inc.*, 26 Cal. 4th 465, 478-79 (2001). The *Potter* factors specify what is needed in the medical
12 monitoring context to prove a sufficient risk of harm and proximate causation of damage. *Lockheed*
13 *Martin Corp. v. Superior Court*, 29 Cal. 4th 1096, 1105 (2003). Accordingly, the Court examines
14 the critical *Potter* factors.

15 In this case, the parties do not dispute the fourth and fifth *Potter* factors – it appears clear
16 from the FAC that bronchioloalveolar cancer is a serious disease for which there is clinical value of
17 early detection and diagnosis. *See* FAC ¶ 27. Instead, Pepsi challenges the sufficiency of the Riva
18 Plaintiffs’ allegations as to the first, second, and third *Potter* factors: (1) the significance and extent
19 of the plaintiff’s exposure to chemicals; (2) the toxicity of the chemicals; and (3) the relative
20 increase in the chance of onset of disease in the exposed plaintiff as a result of the exposure, when
21 compared to (a) the plaintiff’s chances of developing the disease had he or she not been exposed,
22 and (b) the chances of the members of the public at large of developing the disease.

23 1. Significance and Extent of Exposure

24 To demonstrate proximate causation, among other things, a plaintiff seeking medical
25 monitoring must show the significance of her exposure to the toxic chemical. *Potter*, 6 Cal. 4th at
26 1009; *see also Abuan v. Gen. Elec. Co.*, 3 F.3d 329, 335 (9th Cir. 1993) (applying comparable Guam
27 law on medical monitoring). The California Supreme Court has explained, “[e]vidence of exposure
28 alone cannot support a finding that medical monitoring is . . . necessary.” *Lockheed Martin Corp.*,

1 29 Cal. 4th at 1108-09. A plaintiff must demonstrate sufficient severity of exposure (its significance
2 and extent) and that “the need for future monitoring is a reasonably certain consequence of [the]
3 toxic exposure” *Id.* at 1109 (citation omitted).

4 In this case, Plaintiffs allege that 4-MeI “has been found [by NTP] to cause lung tumors in
5 laboratory animals.” FAC ¶¶ 11–13. As another article cited in the FAC notes, the amounts of 4-
6 MeI provided to the mice in the NTP study were the equivalent to an average daily dose of 4,000,
7 80,000, and 170,000 micrograms per kilogram of body weight. Docket No. 53-4 at 618. In
8 comparison, if a person consumes a bottle of cola, only 3.3 micrograms of 4-MeI per kilogram of
9 body weight (for a person weighing 60 kg) is ingested. *Id.* The study relied on by the Riva
10 Plaintiffs therefore concludes that “the amounts ingested from these beverages may not be
11 significant.” *Id.*

12 The Complaint alleges that Mr. Riva drinks an unspecified amount of Pepsi One 2 to 3 times
13 per week (FAC ¶ 3), and Ms. Ardagna claims that she drank 3 to 4 cans of Diet Pepsi per day, or
14 nearly 30 cans per week (*id.* ¶ 4). Mr. Riva and Ms. Ardagna seek to represent a class of all persons
15 who purchased Diet Pepsi or Pepsi One within a four-year period, regardless of consumption
16 amount. What is missing is any allegation of what the significance of this exposure to 4-MeI is – the
17 Riva Plaintiffs contend that increased risk occurs “at or above threshold levels” of exposure (FAC ¶
18 1), but they do not allege what threshold level of exposure creates the increased risk.⁴

19 The Riva Plaintiffs have provided no context as to the significance and extent of exposure to
20 make the necessary ultimate showing that “the need for future monitoring is a reasonably certain
21 consequence of [the] toxic exposure” *Lockheed Martin Corp.*, 29 Cal. 4th at 1109 (citation omitted).

22
23 ⁴ The FAC alleges that Proposition 65 requires a warning label when 4-MeI is present at
24 levels above 29 micrograms per day. FAC ¶ 15. The “lead agency” charged with implementing
25 Proposition 65, the Office of Environmental Health Hazard Assessment (“OEHHA”), sets a “safe
26 harbor” level of exposure, known as the “no significant risk” level “based on evidence and standards
27 of comparable scientific validity to the evidence and standards which form the scientific basis for the
28 listing of the chemical as known to the state to cause cancer.” Cal. Code Regs. tit. 27, § 25701. “An
exposure level representing ‘no significant risk’ is one which is calculated to result in one excess
case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in
question.” *Baxter Healthcare Corp. v. Denton*, 120 Cal. App. 4th 333, 347 (2004) (citation
omitted); *see also* Cal. Health & Safety Code § 25249.10(c). OEHHA has concluded that there is
“no significant risk” posed by 4-MeI at exposures of 29 micrograms per day. Cal. Code Regs. tit.
27, § 25705(b)(1).

1 They have failed to demonstrate a credible risk of bronchioloalveolar cancer resulting from the
 2 human consumption of cola products at the levels alleged by the named plaintiffs. In fact, if
 3 anything, the specific scientific finding incorporated into the FAC is that the amounts of 4-MeI
 4 ingested in cola products “may not be significant.” Docket No. 53-4 at 618. The cited studies fail to
 5 support any reasonable inference that the Riva Plaintiffs experienced significant exposure of 4-MeI.

6 2. Toxicity of Chemicals

7 The Riva Plaintiffs also have not sufficiently pled their injury or shown the toxicity of 4-
 8 MeI. The FAC alleges, among other things, that 4-MeI is on the Proposition 65 list of known
 9 carcinogens, that a toxicologist has stated that there is “no ‘safe’ level of 4-MeI,” and that advocacy
 10 groups have called for the FDA to ban 4-MeI, because the “imidazole-containing colorings may be
 11 causing hundreds or thousands of cancers.” FAC ¶¶ 1, 15, 22.

12 Pepsi responds that the Federal Food, Drug, and Cosmetic Act (“FDCA”) recognizes that
 13 “caramel coloring” (the manufacturing of which produces 4-MEI as a byproduct) is “generally
 14 recognized as safe” when used in accordance with good manufacturing practice. *See* 21 C.F.R. §
 15 182.1235.⁵ Moreover, the FDA has specifically approved “caramel” for use as a color additive. 21
 16 C.F.R. § 73.85; 21 U.S.C. § 379e.⁶ Under the FDCA, the inclusion of “caramel color” as a “color
 17 additive” means that the FDA has determined that caramel coloring has not been found “to induce

18 ⁵ Similarly, the NTP study notes that the United States Food and Drug Administration lists
 19 caramel color as “generally recognized as safe.” Docket No. 53-2 at 14.

20 ⁶ In support of these points, among others, Pepsi has requested judicial notice of an FDA
 21 publication and an FDA presentation that was accessed from the FDA’s website. These documents
 22 are noticeable as “records and reports” of an administrative body. *Interstate Nat. Gas Co. v. S. California Gas Co.*, 209 F.2d 380, 385 (9th Cir. 1953); *see also Anderson v. Jamba Juice Co.*, 888
 23 F. Supp. 2d 1000, 1003 (N.D. Cal. 2012) (taking judicial notice of FDA guidance document from
 24 FDA website); *Hansen Beverage Co. v. Innovation Ventures, LLC*, No. 08-CV-1166-IEG POR, 2009 WL 6597891, at *2 (S.D. Cal. Dec. 23, 2009); *In re Amgen Inc. Sec. Litig.*, 544 F. Supp. 2d
 25 1009, 1023-24 (C.D. Cal. 2008). Nevertheless, in this case, the documents sought to be noticed
 26 contain disputed facts pertaining to the relative safety of 4-MeI. As a result, the Court **GRANTS in part and DENIES in part** Pepsi’s request for judicial notice. The Court will notice only the
 27 existence of these documents and not the ultimate truth of any disputed facts. *Cf. Lee v. City of Los Angeles*, 250 F.3d 668, 690 (9th Cir. 2001) (“[W]hen a court takes judicial notice of another court’s
 28 opinion, it may do so not for the truth of the facts recited therein, but for the existence of the opinion, which is not subject to reasonable dispute over its authenticity.”); *In re High-Tech Employee Antitrust Litig.*, 856 F. Supp. 2d 1103, 1108 (N.D. Cal. 2012) (“A court may also take judicial notice of the existence of matters of public record, such as a prior order or decision, but not the truth of the facts cited therein.”); *Ritz Camera & Image, LLC v. SanDisk Corp.*, 772 F. Supp. 2d 1100, 1109 (N.D. Cal. 2011) *aff’d*, 700 F.3d 503 (Fed. Cir. 2012); *see also* Fed. R. Evid. 201(b).

1 cancer when ingested by man or animal.” 21 U.S.C. § 379e(b)(5)(B). By law, the FDA must make
2 this determination and cannot include a food additive that poses such a risk. *See Public Citizen v.*
3 *Young*, 831 F.2d 1108, 1112 (D.C. Cir. 1987) (noting that this requirement is rigid and permits no
4 “de minimis” exceptions).⁷ Pepsi also contends that the requirement to issue a Proposition 65
5 warning does not necessarily mean a product is in violation of any product-safety standards or
6 requirements.

7 Viewing the FAC in the light most favorable to the Riva Plaintiffs, the Riva Plaintiffs have
8 adequately pled that 4-MeI is toxic and is, generally speaking, a carcinogen – *i.e.*, that 4-MeI is
9 capable of causing cancer. FAC ¶¶ 1; 15.

10 That said, the Riva Plaintiffs have not adequately pled their specific theory of injury – an
11 increased risk for bronchioloalveolar cancer sufficient to warrant medical monitoring – “above the
12 speculative level.” *Twombly*, 550 U.S. at 555. To support their claim to medical monitoring, the
13 Riva Plaintiffs allege that “the NTP Report found ‘clear evidence of carcinogenic activity of 4-
14 methylimidazole in *male and female B6C3F mice* based on increased incidences of
15 alveolar/bronchial neoplasms.’” FAC ¶ 23 (emphasis added). The Riva Plaintiffs proceed to argue
16 that medical monitoring can be viably administered to screen for this specific form of lung cancer
17 and they tout the benefits of early detection of bronchioloalveolar cancer. FAC ¶¶ 23-27.

18 However, the Riva Plaintiffs are not mice, and there is nothing in the FAC, or the studies
19 incorporated by reference, to suggest that 4-MeI causes this specific form of lung cancer in humans.
20 Critically, the NTP study specifically suggests that the cancer the mice experienced would not result
21 in other species. The NTP study was a two-year study in both rats and mice and found “no evidence
22 of carcinogenic activity of 4-MeI in male rats” and equivocal evidence of carcinogenic activity of 4-
23 MeI in female rats. Docket No. 53-2 at 8. The carcinogenic activity in female rats was mononuclear
24 cell leukemia, not bronchioloalveolar cancer. *Id.* Moreover, the NTP study specifically discusses a
25 “species difference” identified in previous studies in terms of how various species absorb, distribute,
26 metabolize, and excrete 4-MeI. Docket No. 53-2 at 14.

27 ⁷ Pepsi has specifically declined to raise the defense that Court must defer to the FDA’s
28 primary jurisdiction. Motion at 15 n.7. The Court therefore will not consider any preemption
issues.

1 None of the articles relied on by the Riva Plaintiffs links 4-MeI to lung cancer in humans.
2 Indeed, all of the articles acknowledge that the NTP study did not assess any increased risk to
3 humans. Docket Nos. 53-2 at 49; 53-3 at 10; 53-4 at 618. The article the Riva Plaintiffs cite in
4 paragraph nine of their amended complaint, which the Riva Plaintiffs characterized as their “best
5 evidence,” does discuss adverse health outcomes from human exposure to 4-MeI. That article,
6 however, identifies potential neurotoxic effects, and does not suggest 4-MeI causes lung cancer.
7 Docket No. 53-3. That article proceeds to observe that some *in vitro* studies have discussed how 4-
8 MeI might generally act as a carcinogen – they have shown that 4-MeI is capable of inhibiting the
9 breakdown of low-mass carcinogens in the human liver. *Id.* Importantly, however, those studies
10 draw no specific connection to lung cancer. *Id.* The same article expressly notes that the NTP study
11 did not assess the “risk to humans from chemicals found to be carcinogenic in laboratory animals.”
12 *Id.* at 10. Likewise, the other article that was cited in the FAC declined to include any “discussion
13 of possible cancer incidence in humans” within the scope of the study. Docket No. 53-4 at 618.

14 Even assuming that 4-MeI is toxic in humans, the NTP study’s findings in mice do not
15 suggest (1) that the toxicity manifests as cancer in all species (it did not occur in male rats), or that
16 (2) if it did, the type of cancer in humans would be the same as the cancer caused in mice (it was not
17 the same cancer in female rats). In other words, the NTP study does not lead to a plausible inference
18 that the Riva Plaintiffs are at increased risk of the specific lung cancer for which they request
19 screening, *i.e.*, bronchioloalveolar cancer. While the Court does not rule out the possibility that
20 animal studies might ground a claim of increased risk of injury in humans in cases where there is no
21 present injury, in this case, the specific study cited herein does not create a credible inference of
22 harm sufficient to warrant the relief sought herein. *Cf. Daubert v. Merrell Dow Pharm., Inc.*, 509
23 U.S. 579, 583 (2007) (allowing experts to testify that birth defects experienced by plaintiffs were
24 caused by pharmaceutical based on “‘in vitro’ (test tube) and ‘in vivo’ (live) animal studies that
25 found a link between Bendectin and malformations; pharmacological studies of the chemical
26 structure of Bendectin that purported to show similarities between the structure of the drug and that
27 of other substances known to cause birth defects; and the “reanalysis” of previously published
28 epidemiological (human statistical) studies”).

1 Nor have the Plaintiffs demonstrated what level of exposure in humans increases the risk of
2 bronchioloalveolar cancer to above a non-speculative, credible level. As noted above, even
3 considering the rodent studies, the levels allegedly consumed by the named Plaintiffs herein would
4 not appear to come close to the equivalent exposure in those studies.

5 In short, the Riva Plaintiffs have failed to plead factual content to show they have been
6 injured due to a “significant” increase in their risk of lung cancer sufficient to justify medical testing
7 in the absence of any symptoms or present injury. *See Potter*, 6 Cal. 4th at 1008-09. The Riva
8 Plaintiffs have not alleged that they experience any symptoms that would tend to suggest
9 bronchioloalveolar cancer or a risk of that cancer. *Cf. Vavak v. Abbott Labs., Inc.*, No. SACV
10 10-1995 JVS RZX, 2011 WL 10550065, at *1 (C.D. Cal. June 17, 2011) (permitting medical
11 monitoring for long-term gastrointestinal problems where child had suffered from “gastrointestinal
12 discomfort, severe diarrhea, an inability to eat, and an inability to sleep”). The only factual content
13 supporting the allegation of increased risk of lung cancer comes from scientific studies, which, for
14 the reasons discussed above, have no demonstrable bearing on cancer toxicity for humans at the
15 consumption levels alleged in the case at bar. Indeed, there is no allegation that any human
16 diagnosis of bronchioloalveolar cancer has ever been connected to 4-MeI consumption.

17 This case contrasts with other medical monitoring cases involving toxic exposures or
18 defective products which have a demonstrable risk to health. *See Sadler v. PacifiCare of Nev.*, 340
19 P.3d 1264, 1265 (2014) (allowing claim for medical monitoring under Nevada law in case involving
20 heightened risk of blood-borne disease due to unsafe injection practices linked to an existing
21 outbreak of hepatitis C); *Gutierrez v. Cassiar Min. Corp.*, 64 Cal. App. 4th 148, 151 (1998)
22 (involving occupational exposure to asbestos at a cement manufacturing plant); *Lockheed Martin*, 29
23 Cal. 4th at 1111 (declining to certify medical monitoring class in case involving drinking water
24 contaminated by rocket fuel and solvents); *In re Mattel, Inc.*, 588 F. Supp. 2d 1111, 1117 (C.D. Cal.
25 2008) (declining to dismiss medical monitoring claim where children’s toys contained lead paint);
26 *Sutton*, 419 F.3d at 569 (involving device used to attach vein grafts to the heart during cardiac
27 bypass surgery that allegedly led to collapse and scarring of the graft); *In re Diet Drugs*, 1999 WL
28 673066, at *18 (conditionally certifying medical monitoring class in case involving diet drugs,

1 including the combination known as “fen/phen” where echocardiography was recommended for
2 exposed individuals by the Department of Health and Human Services, the American College of
3 Cardiology, and the American Heart Association); *Ayers*, 106 N.J. at 568 (involving well-water
4 contaminated with acetone, benzene, chlorobenzene, chloroform, dichlorofluoromethane,
5 ethylbenzene, methylene chloride, methyl isobutyl ketone, 1,1,2,2-tetrachloroethane,
6 tetrahydrofuran, 1,1,1-trichloroethane, and trichloroethylene from improperly managed landfill).

7 A plaintiff seeking medical monitoring must show a need for “specific monitoring beyond
8 that which an individual should pursue as a matter of general good sense and foresight.” *Potter*, 6
9 Cal. 4th at 1009. In this case, the Riva Plaintiffs seek CT scans of their lungs and molecular
10 screening for lung cancer. FAC ¶ 26. Lung scans are not needed to remedy injury absent a credible
11 showing that 4-MeI causes this lung cancer in humans. Although the Riva Plaintiffs have
12 vigorously argued regarding the general benefits of screening for bronchioloalveolar cancer, FAC ¶¶
13 23-27, they have not sufficiently pled facts establishing that 4-MeI causes heightened risk of
14 bronchioloalveolar cancer in humans or the significance of their exposure sufficient to satisfy *Potter*.

15 The Court acknowledges that 4-MeI is listed as a carcinogen under Proposition 65. The
16 Court’s finding herein that the threat of lung cancer in humans at the levels of consumption alleged
17 is insufficient under *Potter* is not inconsistent with Proposition 65’s listing of 4-MeI as a carcinogen.
18 Proposition 65 is broad; its listing embraces “[s]ubstances listed as human *or animal* carcinogens
19 by the [IARC]’ (Lab. Code, § 6382, subd. (b)(1)) and ‘any substance within the scope of the federal
20 Hazard Communication Standard (29 C.F.R. Sec. 1910.1200)’ (Lab. Code, § 6382, subd. (d)).” *Cal.*
21 *Chamber of Commerce v. Brown*, 196 Cal. App. 4th 233, 240-41 (2011) (emphasis added). In other
22 words, “the Proposition 65 list includes chemicals that are known to cause cancer in animals, even
23 though it has not been definitively established that the chemicals will cause cancer in humans.”
24 *Baxter Healthcare*, 120 Cal. App. 4th at 352. Furthermore, as discussed above, listing under
25 Proposition 65 only requires “one excess case of cancer in an exposed population of 100,000,
26 assuming lifetime exposure at the level in question.” *Id.* at 347 (citation omitted); *see also* Cal.
27 Health & Safety Code § 25249.10(c). Because the burden on a defendant to fund medical screening
28 for thousands, potentially millions, of people is so substantial, the *Potter* factors serve a critical

1 gatekeeping function, regulating a potential flood of costly litigation; *Potter* requires a higher level
 2 of proof of health risk than that required for inclusion of a substance on the Proposition 65 list.

3 3. Relative Increase in Chances of Disease

4 There is a further problem with the Riva Plaintiffs' claim to medical monitoring. Under
 5 California law "in a personal injury action causation must be proven within a reasonable medical
 6 probability based upon competent expert testimony." *Jones v. Ortho Pharm. Corp.*, 163 Cal. App.
 7 3d 396, 402-03 (Ct. App. 1985). *Jones* observed:

8 That there is a distinction between a reasonable medical "probability"
 9 and a medical "possibility" needs little discussion. There can be many
 10 possible "causes," indeed, an infinite number of circumstances which
 11 can produce an injury or disease. A possible cause only becomes
 12 "probable" when, in the absence of other reasonable causal
 13 explanations, it becomes more likely than not that the injury was a
 14 result of its action. This is the outer limit of inference upon which an
 15 issue may be submitted to the jury.

13 *Id.* As a result, under California personal injury law "[m]ere possibility [of causing cancer] alone is
 14 insufficient to establish a prima facie case." *Id.*

15 This concept of causation inheres in the *Potter* test for the reasonableness of medical
 16 monitoring; the trier of fact considers, among other factors, "the relative increase in the chance of
 17 onset of disease in the exposed plaintiff as a result of the exposure, when compared to (a) the
 18 plaintiff's chances of developing the disease had he or she not been exposed, and (b) the chances of
 19 the members of the public at large of developing the disease." *Potter*, 6 Cal. 4th at 1009. Consistent
 20 with this approach, the Ninth Circuit has affirmed a grant of summary judgment where plaintiffs
 21 seeking medical monitoring failed to introduce facts regarding the "quantitative (or even qualitative)
 22 increased risk to individuals." *Abuan*, 3 F.3d at 335 (applying Guam law).

23 In this case, the articles cited by the Riva Plaintiffs in their FAC show that there are many
 24 sources of consumption of 4-MeI, including "baked goods, confectionary, extruded breakfast
 25 cereals, instantaneous soups, and dark beers" as well as "soy sauce and coffee." Docket No. 53-3 at
 26 614; Docket No. 53-4 at 615. The Journal of Agricultural and Food Chemistry reviewed the
 27 scientific literature on 4-MeI concentrations in commercial coffees and beers, and concluded that the
 28 "levels of 4(5)-methylimidazole in commercial cola soft drinks are similar to those in coffees." *Id.*

1 The many alternative sources of 4-MeI is problematic to the establishment of any causation
 2 between the Pepsi products at issue and the Riva Plaintiffs' alleged consumption of 4-MeI "at or
 3 above certain threshold levels" (whatever those threshold levels, if any, may be). The many sources
 4 of 4-MeI prevent the Riva Plaintiffs from satisfying the third *Potter* factor.⁸

5 Where the pleadings reveal so many commonly-consumed foods with similar levels of 4-
 6 MeI, it is implausible to conclude that any alleged increased risk of cancer is "more likely than not"
 7 caused by drinking Pepsi One or Diet Pepsi. *See Jones*, 163 Cal. App. 3d at 403. As a result, the
 8 Riva Plaintiffs' claims must be dismissed. *See Twombly*, 550 U.S. at 557 (discussing how, under
 9 Rule 8 in the securities litigation context, "something beyond the mere possibility of loss causation
 10 must be alleged").

11 E. Class Certification

12 The parties dispute whether Pepsi seeks to dismiss or strike the Riva Plaintiffs' class
 13 certification claims. The dispute regarding how to characterize Pepsi's argument appears moot.
 14 Pepsi has clarified that the question presented is whether the Court should *dismiss* the class
 15 allegations as insufficiently pled under Rule 12(b)(6). Docket No. 55, Reply at 10 n.5. In seeking
 16 dismissal, Pepsi challenges whether, under Rule 23, there is an identifiable and ascertainable class,
 17 whether the Riva Plaintiffs can show commonality and predominance, and whether class resolution
 18 presents a superior method of adjudication.

19 The Court declines to address class certification issues at the pleading stage. The Ninth
 20 Circuit has opined that "compliance with Rule 23 is not to be tested by a motion to dismiss for
 21 failure to state a claim." *Gillibeau v. City of Richmond*, 417 F.2d 426, 432 (9th Cir. 1969); *see also*

22 _____
 23 ⁸ Consider, for example, the small coffee shops and diners that are exempt from Proposition
 24 65's warning label requirements. *See* Cal. Health & Safety Code § 25249.11 (b) (excluding
 25 businesses with fewer than 10 employees). The study incorporated into the FAC finds that coffee
 26 contains 4-MeI at similar if not higher levels than those found in the Pepsi products at issue by the
 27 Consumer Reports testing. Docket No. 53-4 at 615; FAC ¶¶ 18; 20. Under the Riva Plaintiffs'
 28 theory of their case, small cafés could be compelled to create medical monitoring funds to pay for
 CT scans and other lung cancer testing for customers who bought coffee or baked goods, regardless
 of the customers' consumption level. Permitting such medical monitoring claims would open up the
 floodgates of litigation, a result that the *Potter* factors were designed to prevent. *See Metro-North
 Commuter Railroad*, 521 U.S. at 442; *Potter*, 6 Cal. 4th at 1009; *see also Lockheed Martin*, 29 Cal.
 4th at 1108-09 (holding evidence of exposure alone not enough to ground claim for medical
 monitoring).

1 *Parino v. BidRack, Inc.*, 838 F. Supp. 2d 900, 909 (N.D. Cal. 2011) (same); *Swain v. CACH, LLC*,
 2 699 F. Supp. 2d 1117, 1124 (N.D. Cal. 2009) (same); *Astiana v. Ben & Jerry's Homemade, Inc.*, No.
 3 C 10-4387 PJH, 2011 WL 2111796, at *15 (N.D. Cal. May 26, 2011) (“In this court’s view, the
 4 questions whether the class is ascertainable and whether a class action is superior should be resolved
 5 in connection with a class certification motion.”). Moreover, this is not a case where the state law
 6 relied on specifically precludes class treatment.⁹ *Cf. Tasion Commcn’s, Inc. v. Ubiquiti Networks,*
 7 *Inc.*, No. 13-1803-EMC, 2014 WL 1048710, at *3, *10 (N.D. Cal. Mar. 13, 2014) (dismissing class
 8 claims seeking monetary relief where governing state statute did not permit such claims). While the
 9 nature of the claims at issue typically pose class certification challenges, *see, e.g., Amchem*
 10 *Products, Inc. v. Windsor*, 521 U.S. 591, 625 (1997) (discussing Rule 23 Advisory Committee notes
 11 that “mass accident” cases are “ordinarily not appropriate” for class treatment), the Court declines to
 12 reach certification questions in connection with the pending motion to dismiss.

13 F. Leave to Amend

14 In general, a court should “freely give leave [to amend] when justice so requires,” Fed. R.
 15 Civ. P. 15(a)(2). Leave to amend, however, may be denied where there is, “undue delay, bad faith
 16 or dilatory motive on the part of the movant, repeated failure to cure deficiencies by amendments
 17 previously allowed, undue prejudice to the opposing party by virtue of allowance of the amendment,
 18 futility of amendment, etc.” *Foman v. Davis*, 371 U.S. 178, 182 (1962). Of the *Foman* factors,
 19 futility of amendment is of particular relevance to this case.

20 The Court previously expressed concerns about standing issues and the Riva Plaintiffs’
 21 claimed relief of medical monitoring months before the Riva Plaintiffs amended their complaint.
 22 *See* 7/10/14 Hrg. Tr. The FAC, filed after the Court expressed those concerns, still fails to
 23 adequately plead entitlement to medical monitoring. As discussed above, the very scientific studies
 24 that the Riva Plaintiffs rely on to plead necessary elements in their claims fail to support their claims

25 ⁹ In *Lockheed Martin Corp. v. Superior Court*, 29 Cal. 4th 1096 (2003), the California
 26 Supreme Court shed light on the challenges of certifying a medical monitoring class. *Lockheed*
 27 *Martin* involved drinking water contaminated by the manufacture and testing of rocket propellants.
 28 The California Supreme Court held that plaintiffs had not met their burden for class certification
 under California law due to problems showing that common issues predominate as to the *Potter*
 factors. *Id.*, at 1115. *Lockheed Martin* did not, however, categorically rule out the possibility of a
 medical monitoring class action. *Lockheed Martin*, 29 Cal. 4th at 1105-06.

1 that they have experienced significant exposure to a chemical that credibly increases their risk of
2 bronchioloalveolar cancer.

3 At the hearing, the Riva Plaintiffs proposed to cure the defects in their pleading by hiring a
4 toxicologist to offer a “quasi-expert report” regarding extrapolation of the results of lab-animal
5 studies to humans. 1/15/15 Hrg. Tr. at 33. Such a report would not cure the deficiencies in the
6 pleading. The specific problem here is not the general value of animal studies but the lack of any
7 factual content to show that 4-MeI causes bronchioloalveolar cancer in humans and the failure to
8 plead that the levels of consumption alleged herein are sufficient to trigger credible risk of such
9 cancer. At the hearing, Plaintiffs acknowledged they were not aware of any additional scientific
10 studies they could cite to support their claim.

11 For these reasons, the Court finds that “the pleading could not possibly be cured by the
12 allegation of other facts.” *Bly-Magee v. California*, 236 F.3d 1014, 1019 (9th Cir. 2001) (quoting
13 *Lopez v. Smith*, 203 F.3d 1122, 1127 (9th Cir.2000)). Plaintiffs have had ample notice of the issues
14 in contention and have had plenty of opportunity to fashion the strongest complaint possible. They
15 were also given an opportunity at the hearing to articulate how they would cure the alleged
16 deficiencies of their complaint if given the opportunity. The Court finds that any further amendment
17 would be futile.

18 **III. CONCLUSION**

19 The Riva Plaintiffs’ allegations of causation and injury do not have plausible factual support.
20 There is no plausible inference that 4-MeI causes bronchioloalveolar cancer in humans. The
21 threshold levels of exposure that lead to enhanced risk of disease have not been identified. And
22 many other common foods contain similar or higher levels of 4-MeI than the Pepsi products at issue.
23 Thus, the Riva Plaintiffs have not established a plausible claim of entitlement to medical monitoring.
24 Because the Riva Plaintiffs “have not nudged their claims across the line from conceivable to
25 plausible, their complaint must be dismissed.” *Twombly*, 550 U.S. at 547. Plaintiffs have

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1 established neither standing nor their entitlement to relief on the merits under *Potter*. For the
2 reasons stated herein and on the record at the hearing, this dismissal is with prejudice.

3 This order disposes of Docket No. 52. The Clerk is directed to enter judgment and close the
4 file.


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6 IT IS SO ORDERED.

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8 Dated: March 4, 2015

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EDWARD M. CHEN
United States District Judge

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