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-MeI"), 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

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

According to a study cited in the First Amended Complaint ("FAC"), 4-MeI is "used in the manufacture of pharmaceuticals, photographic chemicals, dyes and pigments, cleaning and agricultural chemicals, and rubber." Docket No. 53-2 at 7.[1] Four-MeI has "been identified as a by-product of fermentation in foods and has been detected in mainstream and sidestream tobacco smoke." *Id.* The 4-MeI compound is generated during the caramelization process of caramel colors, a color additive used in a wide range of foods and beverages, including beer and some soft drinks, because of its color, flavor, and other properties. Docket No. 53-3*; see also* FAC ¶ 9.

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

[1] The Court **GRANTS** for purposes of the motion to dismiss Pepsi's request for judicial notice over three scientific articles that the Riva Plaintiffs specifically relied on in the FAC to provide factual support for the Riva Plaintiffs' claims. Docket No. 53-2, Pandya Decl. Ex. A, ("NTP Study"); Docket No. 53-2, Pandya Decl., Ex. B; Docket No. 53-2, Pandya Decl., Ex. C. The Riva Plaintiffs do not oppose the request for judicial notice or question the authenticity of the articles. The documents are publicly-available for download or purchase from the websites of government entities and organizations that host scientific academic journal articles. Pandya Decl. ¶¶ 2-4. The Court deems these three articles to be incorporated by reference into the FAC. The incorporation by reference doctrine allows a court ruling on a Rule 12(b)(6) motion to look beyond the pleadings to "documents whose contents are alleged in a complaint and whose authenticity no party questions, but which are not physically attached to the plaintiff's pleading." *Davis v. HSBC Bank Nevada, N.A.*, 691 F.3d 1152, 1160 (9th Cir. 2012) (citations omitted). Such documents may be considered 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.

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

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

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

The Riva Plaintiffs assert three claims: negligence, strict liability based on defective design, and strict liability based on failure to warn. *Id*. ¶¶ 41–59. The Riva Plaintiffs seek medical monitoring as a remedy for all three claims; specifically, they seek an order requiring Pepsi to establish a "fund from which those individual class members can seek monetary recovery for the costs of actual or anticipated medical monitoring expenses incurred by them." *Id*. at 19.[2] The Riva Plaintiffs in particular allege that outcomes in bronchioloalveolar cancer show a clinically significant benefit from early evaluation, detection, and diagnosis. *Id.* ¶ 45.

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

[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.*

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

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

II. DISCUSSION

A. Legal Standard

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

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

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

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

B. Standing

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

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

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

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

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

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

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

[3] Defendant contends Plaintiffs also have not adequately alleged traceability, another element of Article III standing. To survive a motion to dismiss for lack of constitutional standing, plaintiffs need not "demonstrate that defendants' actions are the 'proximate cause' of plaintiffs' injuries." *Maya*, 658 F.3d at 1070. The critical inquiry is whether the causal chain is plausible. *Id.* In environmental cases, courts examine the "remoteness of the injury claim." *Native Vill. of Kivalina v. ExxonMobil Corp.*, 663 F. Supp. 2d 863, 881 (N.D. Cal. 2009) *aff'd*, 696 F.3d 849 (9th Cir. 2012). Plaintiffs within the "zone of discharge" have satisfied the "fairly traceable" causation requirement, 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.

C. Medical Monitoring

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

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

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

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

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

> (1) the significance and extent of the plaintiff's exposure to chemicals;

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

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

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

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

Potter, 6 Cal. 4th at 1009.

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

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

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

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

D. Sufficiency of Factual Allegations

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

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

- The Riva Plaintiffs regularly ingested either Pepsi One and Diet Pepsi products; these drinks contain high levels of 4-MeI, which is a carcinogen known to the State of California to cause cancer;
- published medical studies show that there is "clear evidence of carcinogenic activity of 4-methylimidazole [4-MeI] in male and female B6C3F mice based on increased incidences of alveolar/bronchial neoplasms" (FAC, at ¶ 11);
- Plaintiffs' regular ingestion of Diet Pepsi and Pepsi One drinks containing 4-MeI place them at an increased risk of contracting bronchioloalveolar cancer (Id. at ¶ 46);
- 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.

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

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

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

1. Significance and Extent of Exposure

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

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

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

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

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

[4] The FAC alleges that Proposition 65 requires a warning label when 4-MeI is present at levels above 29 micrograms per day. FAC ¶ 15. The "lead agency" charged with implementing Proposition 65, the Office of Environmental Health Hazard Assessment ("OEHHA"), sets a "safe harbor" level of exposure, known as the "no significant risk" level "based on evidence and standards of comparable scientific validity to the evidence and standards which form the scientific basis for the 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).

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

2. Toxicity of Chemicals

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

Pepsi responds that the Federal Food, Drug, and Cosmetic Act ("FDCA") recognizes that "caramel coloring" (the manufacturing of which produces 4-MEI as a byproduct) is "generally recognized as safe" when used in accordance with good manufacturing practice. *See* 21 C.F.R. § 182.1235.[5] Moreover, the FDA has specifically approved "caramel" for use as a color additive. 21 C.F.R. § 73.85; 21 U.S.C. § 379e.[6] Under the FDCA, the inclusion of "caramel color" as a "color additive" means that the FDA has determined that caramel coloring has not been found "to induce

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

[6] In support of these points, among others, Pepsi has requested judicial notice of an FDA publication and an FDA presentation that was accessed from the FDA's website. These documents 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 F. Supp. 2d 1000, 1003 (N.D. Cal. 2012) (taking judicial notice of FDA guidance document from 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 1009, 1023-24 (C.D. Cal. 2008). Nevertheless, in this case, the documents sought to be noticed 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 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 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).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

3. Relative Increase in Chances of Disease

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

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

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

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

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

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

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

E. Class Certification

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

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

[8] Consider, for example, the small coffee shops and diners that are exempt from Proposition 65's warning label requirements. *See* Cal. Health & Safety Code § 25249.11 (b) (excluding businesses with fewer than 10 employees). The study incorporated into the FAC finds that coffee contains 4-MeI at similar if not higher levels than those found in the Pepsi products at issue by the Consumer Reports testing. Docket No. 53-4 at 615; FAC ¶¶ 18; 20. Under the Riva Plaintiffs' 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).

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

F. Leave to Amend

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

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

[9] In *Lockheed Martin Corp. v. Superior Court*, 29 Cal. 4th 1096 (2003), the California Supreme Court shed light on the challenges of certifying a medical monitoring class. *Lockheed Martin* involved drinking water contaminated by the manufacture and testing of rocket propellants. 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.

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

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

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

III. CONCLUSION

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

///

///

///

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

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

IT IS SO ORDERED.

Dated: March 4, 2015

EDWARD M. CHEN
United States District Judge