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CALIFORNIA CHAMBER OF COMMERCE

8  
9 **UNITED STATES DISTRICT COURT**  
10 **EASTERN DISTRICT OF CALIFORNIA**

11  
12 CALIFORNIA CHAMBER OF  
COMMERCE,

13  
14 Plaintiff,

15 v.

16 XAVIER BECERRA, IN HIS OFFICIAL  
CAPACITY AS ATTORNEY GENERAL  
17 OF THE STATE OF CALIFORNIA,

18 Defendant.

Case No. 2:19-cv-02019-KJM-EFB

**FIRST AMENDED COMPLAINT FOR  
DECLARATORY AND INJUNCTIVE  
RELIEF**

1 Plaintiff California Chamber of Commerce (“Plaintiff” or “CalChamber”) seeks prospective  
2 declaratory and injunctive relief against Defendant Xavier Becerra, in his official capacity as  
3 Attorney General of the State of California, and alleges as follows:

4 **PRELIMINARY STATEMENT**

5 1. Plaintiff CalChamber brings this suit to enjoin Defendant and those in privity with and  
6 acting in concert with Defendant from enforcing in the future a requirement to provide a false,  
7 misleading, and highly controversial cancer warning for food and beverage products (collectively  
8 referred to herein as “food products”) that contain the chemical acrylamide.

9 2. Acrylamide is not intentionally added to food products. Rather, acrylamide is formed  
10 naturally in many types of foods when cooked at high temperatures or otherwise processed with heat.  
11 It is formed in cooking at home, in restaurants, and in food processing and manufacturing facilities,  
12 and it has been present in these foods for as long as they have been cooked. Common sources of  
13 acrylamide in the human diet include, among others, breakfast cereals, crackers, bread crusts, coffee,  
14 grilled or roasted asparagus, French fries, potato chips and other fried and baked snack foods, canned  
15 sweet potatoes, canned black olives, prune juice, roasted nuts, and toast. Acrylamide is found in  
16 dozens of other types of foods and in thousands of food products sold and served at grocery stores  
17 and restaurants. Acrylamide is also widely used during the manufacturing of paper, dye, and other  
18 industrial products.

19 3. Acrylamide has been identified by certain governmental and scientific entities as a  
20 carcinogen based on studies in laboratory animals. Scientific studies in humans, however, have  
21 found no reliable evidence that exposure to acrylamide in food products is associated with an  
22 increased risk of developing any type of cancer. In fact, the epidemiologic evidence suggests that  
23 dietary acrylamide—i.e., acrylamide that forms naturally in normal cooking of many food products—  
24 does *not* cause cancer in humans or pose an increased risk of cancer in humans. Indeed, some food  
25 products that contain acrylamide (e.g., whole grains and coffee) have been shown to reduce the risk  
26 of certain diseases, including cancer.

27 4. Under California’s Safe Drinking Water and Toxic Enforcement Act of 1986  
28 (“Proposition 65”), businesses are required to warn consumers about an exposure to any chemical

1 that has been identified by the California Office of Environmental Health Hazard Assessment  
2 (“OEHHA”) as “known to the State to cause cancer,” unless a defense to the warning requirement  
3 applies. OEHHA has listed acrylamide as a carcinogen.

4 5. As a result of the acrylamide listing, and despite the scientific studies showing that  
5 exposure to acrylamide in food products does not increase the risk of cancer in humans, businesses  
6 that produce, distribute, or sell food products that contain acrylamide are presumptively required to  
7 provide a Proposition 65 cancer warning for their food products. This is so even though neither  
8 OEHHA nor any other governmental entity has determined that acrylamide is a known human  
9 carcinogen, and in fact OEHHA has acknowledged that the agency does not *know* that acrylamide  
10 increases the risk of cancer in humans.

11 6. A Proposition 65 cancer warning for acrylamide in food products that are intended for  
12 human consumption conveys to consumers the false and misleading message that consuming the  
13 products will increase consumers’ risk of cancer, even though there is no reliable evidence that  
14 exposure to dietary acrylamide increases the risk of cancer in humans.

15 7. California’s presumptive requirement that businesses provide a Proposition 65 cancer  
16 warning for food products that contain acrylamide therefore violates the First Amendment of the  
17 United States Constitution by compelling Plaintiff’s members and other entities that produce,  
18 distribute, or sell acrylamide-containing food products to make false, misleading, and highly  
19 controversial statements about their products.

20 8. In addition to being illegal, California’s treatment under Proposition 65 of acrylamide  
21 that forms naturally in normal cooking of many food products harms both businesses and the public.  
22 Businesses, including many of CalChamber’s members, must either take action to provide false,  
23 misleading, and highly controversial warnings to California consumers about the safety of their food  
24 products, or face potential costly enforcement actions initiated by Defendant or private enforcers for  
25 failing to do so.

26 9. Members of the public, meanwhile, will be misled about the risks posed by food  
27 products containing acrylamide, potentially frightening them away from a variety of foods—  
28 including whole grains, peanuts, almonds, nut butters, olives, and coffee—that are part of a well-

1 balanced diet and may actually *reduce* the risk of cancer. Cancer warnings for acrylamide in food  
2 products also can mislead consumers into believing that acrylamide is present only in store-bought  
3 food products, when in fact consumer exposure to acrylamide in food products may be greatest  
4 through home cooking (for which no Proposition 65 warnings are required).

5 10. Given the lack of reliable scientific evidence suggesting a causal relationship between  
6 acrylamide in food products and cancer risk, requiring cancer warnings for dietary acrylamide also  
7 will result in over-warning, diluting the effectiveness of Proposition 65 warnings on other products  
8 that actually do pose a risk of harm to consumers and diminishing consumers' confidence in public  
9 health messages and the authorities who promulgate them.

10 11. For these reasons, with respect to Proposition 65 claims that are not currently pending  
11 in state court and that concern acrylamide in food products, the Court should declare that mandating  
12 Proposition 65 cancer warnings for acrylamide in food products is unconstitutional under the First  
13 Amendment and enjoin Defendant and those in privity with and/or acting in concert with Defendant  
14 (including Proposition 65 private enforcers) from enforcing the Proposition 65 warning requirement  
15 as applied to acrylamide in food products.

16 **PARTIES**

17 12. Plaintiff CalChamber is a nonprofit business association with over 13,000 members,  
18 both individual and corporate, representing virtually every economic interest in the State of  
19 California, including among others food producers, suppliers, and retailers. CalChamber's members  
20 include several of the largest businesses in California, but seventy-five percent of its members are  
21 small businesses with 100 or fewer employees. CalChamber acts on behalf of the business  
22 community to improve the state's economic and employment climate by representing business on a  
23 broad range of legislative, regulatory, and legal issues. CalChamber's members employ millions of  
24 Californians. Because so many of its members are directly impacted by Proposition 65, CalChamber  
25 has historically been and continues to be deeply involved in a variety of Proposition 65-related  
26 regulatory and litigation matters. Specifically, CalChamber has coordinated and spearheaded policy  
27 discussions on Proposition 65 issues involving business leaders, policy makers, scientists, and  
28 advocacy groups in both the regulatory and legislative forums. CalChamber has also closely

1 monitored proposed listings of chemicals and other regulatory activities under Proposition 65, has  
2 advised its members on these issues, and has represented its members in policy discussions and  
3 litigation, including litigation challenging Proposition 65 provisions and regulations promulgated  
4 under Proposition 65. CalChamber has been intimately involved in Proposition 65 reform initiatives  
5 and related regulatory efforts, coordinating and participating in numerous policy discussions,  
6 providing extensive comments on behalf of its members, presenting detailed proposals, monitoring  
7 developments, advising members on developments, and initiating legislative proposals.

8 13. Defendant Xavier Becerra is the Attorney General of the State of California and the  
9 highest-ranking officer in the California Department of Justice. Attorney General Becerra is sued in  
10 his official capacity. He performs his official duties in Sacramento and throughout the State of  
11 California. As Attorney General, he is specifically empowered to enforce the provisions of  
12 Proposition 65, and indeed the California Attorney General has done so in the past with respect to  
13 dietary acrylamide in a variety of lawsuits against manufacturers of food products, all of which have  
14 been resolved through settlement as of the date of this Amended Complaint.

#### 15 **JURISDICTION AND VENUE**

16 14. This Court has jurisdiction over this action under 28 U.S.C. § 1331, which confers  
17 original jurisdiction on federal district courts over actions arising under the Constitution or laws of  
18 the United States.

19 15. Venue is proper under 28 U.S.C. § 1391(b)(1) and (b)(2), because the Attorney  
20 General is located within this district and a substantial part of the events giving rise to Plaintiff's  
21 claims occurred in this district.

#### 22 **FACTUAL BACKGROUND**

##### 23 **A. Overview of Acrylamide in Food Products**

24 16. Acrylamide forms naturally from chemical reactions in certain types of starchy foods  
25 when cooked at high temperatures or otherwise processed using heat. Acrylamide is found mainly in  
26 food made from plants, such as potato products (e.g., French fries, potato chips), grain products (e.g.,  
27 breakfast cereals, cookies, and toast), and coffee. Although acrylamide was not detected in foods  
28 until 2002, “[a]crylamide has probably always been present in cooked foods.” *See* Food and Drug

1 Administration, *Acrylamide Questions and Answers* (Updated Sept. 25, 2019) (“FDA Q&A”),  
2 <https://www.fda.gov/food/chemicals/acrylamide-questions-and-answers>.

3 17. Dietary acrylamide forms as part of a chemical reaction, known as the Maillard  
4 reaction, that takes place during high temperature cooking processes, including frying, roasting,  
5 grilling, and baking. During this reaction, sugars such as glucose and fructose react with a naturally-  
6 occurring free amino acid, asparagine, to form acrylamide. The Maillard reaction contributes to the  
7 aroma, taste, and color of certain foods. *See* National Institute of Environmental Health Sciences,  
8 *Acrylamide* (May 14, 2019), <https://www.niehs.nih.gov/health/topics/agents/acrylamide/index.cfm>.

9 18. Common sources of acrylamide in the diet include, among others, breakfast cereals,  
10 crackers, bread crusts, roasted asparagus, French fries, potato chips and other fried and baked snack  
11 foods, canned sweet potatoes and pumpkin, canned black olives, roasted nuts, prune juice, cookies,  
12 and toast. *See* OEHHA, *Acrylamide Fact Sheet* (Feb. 2019),  
13 [https://www.p65warnings.ca.gov/sites/default/files/downloads/factsheets/acrylamide\\_fact\\_sheet.pdf](https://www.p65warnings.ca.gov/sites/default/files/downloads/factsheets/acrylamide_fact_sheet.pdf).

14 19. According to the United States Food and Drug Administration (“FDA”), the presence  
15 of acrylamide in foods is so widespread that “it isn’t feasible to completely eliminate acrylamide  
16 exposure.” Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA’s Support for  
17 Exempting Coffee from California’s Cancer Warning Law (Aug. 29, 2018).

18 20. Because acrylamide in food products is formed through cooking, FDA states that  
19 acrylamide levels in cooked organic foods should be similar to levels in cooked non-organic foods.  
20 *See* FDA Q&A, ¶ 16, *supra*. FDA also has explained that consumer exposure to dietary acrylamide  
21 “may be greatest through home cooking,” as acrylamide forms naturally during the cooking process  
22 and is not present only in store-bought foods. *See* Letter from Lester M. Crawford, DVM, Ph.D.,  
23 Deputy Commissioner, FDA, to Joan E. Denton, M.S., Ph.D., Director, California Office of  
24 Environmental Health Hazard Assessment (July 13, 2003).

25 21. Although acrylamide can form in many foods that are fried, roasted, or baked, FDA  
26 does not recommend that consumers avoid eating these foods. Instead, FDA recommends that  
27 consumers adopt a healthy eating plan consistent with the Office of Disease Prevention and Health  
28 Promotion’s Dietary Guidelines for Americans (2015-2020) (“Dietary Guidelines”). *See* FDA Q&A,

¶ 16, *supra*. The Dietary Guidelines, in turn, advise that a healthy diet should consist of a variety of food products, including vegetables, whole grains, and nuts. *Id.* These food products often contain acrylamide and have been the subject of Proposition 65 enforcement actions, as described below.

**B. Epidemiologic Studies Demonstrate That Acrylamide From Food Products Does Not Increase the Risk of Cancer in Humans**

22. Current scientific evidence does not support a finding that exposure to acrylamide from food products increases the risk of cancer in humans.

23. As the National Cancer Institute (“NCI”) explains, “a large number of epidemiologic studies (both case-control and cohort studies) in humans have found no consistent evidence that dietary acrylamide exposure is associated with the risk of any type of cancer.” NCI, *Acrylamide and Cancer Risk* (Dec. 5, 2017), <https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/acrylamide-fact-sheet>. The NCI is the federal government’s principal agency for cancer research and training and is part of the National Institutes of Health, one of 11 agencies that make up the U.S. Department of Health and Human Services.

24. Likewise, the American Cancer Society explains on its website that, “[s]o far, reviews of studies done in groups of people (epidemiologic studies) suggest that dietary acrylamide isn’t likely to be related to risk for most common types of cancer.” *See* American Cancer Society, *Acrylamide and Cancer Risk* (Feb. 11, 2019), <https://www.cancer.org/cancer/cancer-causes/acrylamide.html>. The American Cancer Society further states that “[i]t’s not yet clear if the levels of acrylamide in foods raise cancer risk. . . .” *Id.*

25. Numerous scientific studies support the conclusion that exposure to acrylamide from food products does not increase cancer risk in humans. In a 2012 systematic review published in the *European Journal of Cancer Prevention*, for example, researchers evaluated the association between dietary acrylamide and cancer. *See* L. Lipworth, et al., Review of Epidemiologic Studies of Dietary Acrylamide Intake and the Risk of Cancer, *European Journal of Cancer Prevention*, Vol. 21(4):375-386 (2012). The researchers explained that “[c]onjectured associations between dietary acrylamide intake and cancer have been evaluated in more than 15 epidemiologic studies examining almost every major cancer site.” *Id.* After critically reviewing the available studies, the researchers concluded:

1 After an extensive examination of the published literature, we found no  
2 consistent or credible evidence that dietary acrylamide increases the  
3 risk of any type of cancer in humans, either overall or among  
4 nonsmokers. In particular, the collective evidence suggests that a high  
level of dietary acrylamide intake is not a risk factor for breast,  
endometrial, or ovarian cancers. . . .

5 In conclusion, epidemiologic studies of dietary acrylamide intake have  
6 failed to demonstrate an increased risk of cancer. In fact, the  
7 sporadically and slightly increased and decreased risk ratios reported in  
8 more than two dozen papers examined in this review strongly suggest  
the pattern one would expect to find for a true null association over the  
course of a series of trials.

9 *Id.*

10 26. Since 2012, there have been several additional studies, across multiple different  
11 populations, evaluating whether there is an association between dietary acrylamide and cancer, and  
12 those studies have consistently found that exposure to acrylamide in food products does not increase  
13 human cancer risk. *See, e.g.,* C. Pelucchi, *et al.*, Dietary Acrylamide and Cancer Risk: An Updated  
14 Meta-Analysis, *Int'l Journal of Cancer*, Vol. 136(12):2912–22 (2015) (“This systematic review and  
15 meta-analysis of epidemiological studies indicates that dietary acrylamide is not related to the risk of  
16 most common cancers.”); A. Kotemori, *et al.*, Dietary Acrylamide Intake and Risk of Breast Cancer:  
17 the Japan Public Health Center-Based Prospective Study, *Cancer Science*, Vol. 109(3):843-53 (2018)  
18 (“In conclusion, dietary acrylamide intake was not associated with the risk of breast cancer in this  
19 population-based prospective cohort study of Japanese women.”); M. McCullough, *et al.*, Dietary  
20 Acrylamide Is Not Associated with Renal Cell Cancer Risk in the CPS-II Nutrition Cohort, *Cancer*  
21 *Epidemiology, Biomarkers & Prevention*, Vol. 28(3):616-619 (2019) (“In conclusion, we found no  
22 evidence that greater dietary acrylamide intake was associated with risk of RCC [renal cell  
23 carcinoma.]”); J. Hogervorst, *et al.*, Interaction Between Dietary Acrylamide Intake and Genetic  
24 Variants for Estrogen Receptor-Positive Breast Cancer Risk, *European Journal of Nutrition*, Vol.  
25 58:1033-1045 (2019) (“This study did not provide evidence for a positive association between  
26 acrylamide intake and ER+ [estrogen receptor-positive] breast cancer risk. If anything, acrylamide  
27 was associated with a decreased ER+ breast cancer risk.”).

28 27. In fact, studies have shown that certain foods that contain acrylamide may actually



1 *reduce* the risk of cancer in humans. For example, in June 2018, the International Agency for  
2 Research on Cancer (“IARC”) concluded that there is an “inverse association” between drinking  
3 coffee (which contains acrylamide) and certain types of cancer. *See* IARC Monographs on the  
4 Evaluation of Carcinogenic Risks to Humans, *Drinking Coffee, Mate, and Very Hot Beverages*, Vol.  
5 116 at 434 (2018). Likewise, a recent study showed that whole-grain foods may reduce the risk of  
6 liver cancer. *See* American Cancer Society, *Study Ties Whole Grains to Lower Risk of Liver Cancer*  
7 (Feb. 27, 2019), [https://www.cancer.org/latest-news/study-ties-whole-grains-to-lower-risk-of-liver-](https://www.cancer.org/latest-news/study-ties-whole-grains-to-lower-risk-of-liver-cancer.html)  
8 [cancer.html](https://www.cancer.org/latest-news/study-ties-whole-grains-to-lower-risk-of-liver-cancer.html).

9         28. Some regulatory and scientific entities have identified acrylamide as a possible or  
10 probable carcinogen based on studies in laboratory animals in which virtually pure acrylamide was  
11 administered orally or via injection to rats and mice. As NCI has explained, however, “toxicology  
12 studies have shown that humans and rodents not only absorb acrylamide at different rates, they  
13 metabolize it differently as well.” NCI, *Acrylamide and Cancer Risk* (Updated Dec. 5, 2017),  
14 <https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/acrylamide-fact-sheet>. The  
15 evidence that acrylamide causes cancer in animals is insufficient to conclude that acrylamide that  
16 forms naturally in certain food products increases cancer risk in humans, particularly in light of the  
17 epidemiologic data that strongly suggest that dietary acrylamide does *not* increase human cancer risk.

18         29. There are other examples of chemicals that have been shown to cause cancer in  
19 animals but not in humans. For example, studies in laboratory rats during the early 1970s linked the  
20 artificial sweetener saccharin to development of bladder cancer. Subsequent studies showed,  
21 however, that those results applied only to rats and not to humans, and human epidemiology studies  
22 have found no consistent evidence that saccharin is associated with bladder cancer in humans. *See*  
23 NCI, *Artificial Sweeteners and Cancer* (Aug. 10, 2016), [https://www.cancer.gov/about-](https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/artificial-sweeteners-fact-sheet)  
24 [cancer/causes-prevention/risk/diet/artificial-sweeteners-fact-sheet](https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/artificial-sweeteners-fact-sheet). As NCI explained: “Because the  
25 bladder tumors seen in rats are due to a mechanism not relevant to humans and because there is no  
26 clear evidence that saccharin causes cancer in humans, saccharin was delisted in 2000 from the U.S.  
27 National Toxicology Program’s *Report on Carcinogens*, where it had been listed since 1981 as a  
28 substance reasonably anticipated to be a human carcinogen (a substance known to cause cancer).” *Id.*

1           **C.     Proposition 65 Regulatory Framework**

2           30.     In 1986, California voters, by initiative, enacted the Safe Drinking Water and Toxic  
3 Enforcement Act of 1986—commonly known as Proposition 65. In relevant part, Proposition 65  
4 prohibits businesses with ten or more employees from knowingly and intentionally exposing  
5 California residents to a chemical known to the State to cause cancer without providing required  
6 warnings, unless an exemption or affirmative defense applies. Cal. Health & Safety Code  
7 §§ 25249.6, 25249.10.

8           31.     Proposition 65 requires OEHHA to maintain “a list of those chemicals known to the  
9 state to cause cancer or reproductive toxicity” and provides mechanisms by which OEHHA may (or  
10 must) place a chemical on the list. *Id.* §§ 25249.8(a)-(b).

11           32.     As relevant here, the statute provides that a chemical is “known to the state to cause  
12 cancer” if “a body considered to be authoritative by [the state’s qualified] experts has formally  
13 identified it as causing cancer” (the “Authoritative Bodies” listing mechanism). *Id.* § 25249.8(b); *see*  
14 *also* 27 Cal. Code Regs. § 25306(a). IARC and the U.S. Environmental Protection Agency (“EPA”)  
15 have been identified as “authoritative bodies” for the identification of chemicals as causing cancer.  
16 *Id.* § 25306(m).

17           33.     After a chemical is added to the Proposition 65 list, and following a 12-month grace  
18 period, Proposition 65 requires that any “person in the course of doing business” provide a “clear and  
19 reasonable warning” before “expos[ing] any individual to” the listed chemical, unless an exemption  
20 or affirmative defense applies. Cal. Health & Safety Code § 25249.6.

21           34.     Although Proposition 65 does not define what content suffices to convey a “clear and  
22 reasonable warning,” OEHHA’s regulations had for more than 30 years provided that the warning  
23 “must clearly communicate that the chemical in question is known to the state to cause cancer. . . .”  
24 27 Cal. Code Regs. § 25601 (effective until Aug. 30, 2018). OEHHA also provided a “safe harbor”  
25 for warnings that used the following language: “**WARNING:** This product contains a chemical  
26 known to the State of California to cause cancer.” *Id.* § 25603.2 (effective until Aug. 30, 2018).

27           35.     In August 2016, OEHHA adopted new regulations providing that safe harbor  
28 Proposition 65 warnings must provide consumers with additional information.

1           36. Under the new warning regulations, cancer warnings for food products are deemed to  
2 be “clear and reasonable” if they state: “**WARNING:** Consuming this product can expose you to  
3 [name of chemical], which is known to the State of California to cause cancer. For more information,  
4 go to [www.P65Warnings.ca.gov/food](http://www.P65Warnings.ca.gov/food).” 27 Cal. Code Regs § 25607.2(a)(2).<sup>1</sup> In addition, where the  
5 warning is provided on the food product label, it “must be set off from other surrounding  
6 information” and “enclosed in a box.” *Id.* § 25607.1(b).

7           37. Proposition 65 provides a statutory exemption to the warning requirement, which can  
8 be asserted as an affirmative defense in a Proposition 65 enforcement action, if “the person  
9 responsible can show that the exposure poses no significant risk assuming lifetime exposure at the  
10 level in question for substances known to the state to cause cancer.” Cal Health & Safety Code  
11 § 25249.10(c). This threshold is commonly referred to as the “No Significant Risk Level” (“NSRL”).  
12 The NSRL is not a concentration limit, but rather an exposure-based limit based on the highest level  
13 of exposure causing no more than a 1 in 100,000 risk of cancer over a lifetime of exposure to that  
14 level. Cal Health & Safety Code § 25249.10(c); 27 Cal. Code Regs. § 25703(b).

15           38. For some listed substances, OEHHA has published a quantitative NSRL, often  
16 referred to as a “safe harbor” NSRL because it is a presumptive NSRL such that a private enforcer  
17 cannot argue for a more stringent NSRL in litigation. 27 Cal. Code Regs. § 25705. A safe harbor  
18 NSRL is also an exposure-based limit. All safe harbor NSRLs for listed chemicals are described in  
19 micrograms of exposure per day. *Id.*

20           39. Under Proposition 65, to determine whether an exposure from a consumer product  
21 exceeds the NSRL, the regulations require that exposures be calculated based on the “average rate of  
22 intake or exposure for average users of the consumer product.” 27 Cal. Code Regs. § 25721(d)(4).  
23 Thus, unlike other laws and regulations affecting businesses that set concentration-based thresholds,  
24 it is not facially apparent from the NSRL described in the statute or from a safe harbor NSRL adopted  
25 by OEHHA and listed in the regulations whether there is a duty to warn under Proposition 65.

26 \_\_\_\_\_  
27 <sup>1</sup> Where a warning is being provided for an exposure to more than one listed carcinogen, the warning  
28 must state: “**WARNING:** Consuming this product can expose you to chemicals including [name of  
one or more chemicals], which is [are] known to the State of California to cause cancer.” 27 Cal.  
Code Regs §§ 25607.2(a)(2), (6).

1           40. Under the statute, it is the burden of a business to demonstrate that the exposure at  
2 issue does not exceed the NSRL. In addition, the NSRL provides only an “affirmative defense” to  
3 liability under Proposition 65 and does not immunize industry from enforcement actions in the first  
4 instance. *See DiPirro v. Bondo Corp.*, 153 Cal. App. 4th 150, 185 (2007).

5           41. Courts have found that no warning is required where a business can demonstrate that  
6 exposures to the chemical do not pose a significant risk of cancer at *any* level. In *Baxter Healthcare*  
7 *Corporation v. Denton*, 120 Cal. App. 4th 333 (2004), the California Court of Appeal held that “a  
8 warning is not required if . . . the exposure poses no significant risk of causing cancer in humans.”  
9 *Id.* at 343-44. The court determined that the chemical at issue in that case (DEHP) does not cause  
10 cancer in humans and therefore no warning was required, even though the court found that the  
11 chemical was properly listed and DEHP remains on the list today. Importantly, however, the court  
12 explained that the business (Baxter Healthcare Corporation) bore the burden of proof to establish that  
13 exposure to DEHP presented no significant risk of cancer in humans. *Id.* at 364-369.

14           **D. Enforcement of Proposition 65**

15           42. Proposition 65 employs an unusual enforcement scheme. First, the Attorney General,  
16 a district attorney, or a variety of local government officials may bring an enforcement action under  
17 Cal. Health & Safety Code § 25249.7(c). The statute imposes penalties up to \$2,500 per day for each  
18 violation. *Id.* § 25249.7(b). In addition to these penalties, the statute also provides that any person  
19 who “threatens to violate” the warning requirement may be “enjoined in a court of competent  
20 jurisdiction.” *Id.* § 25249.7(a).

21           43. Second, any *person* (even one who has suffered no injury in fact) may bring a private  
22 enforcement action for an alleged failure to provide an adequate warning and without having to plead  
23 or prove injury or harm. *Id.* § 25249.7(d). These private enforcers are eligible to recover 25 percent  
24 of the penalty (with the remaining 75 percent going to the State of California’s Safe Drinking Water  
25 and Toxic Enforcement Fund in the State Treasury), *id.* § 25249.12, as well as their reasonable  
26 attorneys’ fees and costs, Cal. Code Civ. Proc. § 1021.5, creating very strong incentives for private  
27 enforcement. Defendants usually cannot remove these enforcement actions to federal court because  
28 the plaintiff has no Article III standing.

1           44. Private parties are required to provide 60-days' notice—to the California Attorney  
2 General, the district attorney, city attorney, or prosecutor in whose jurisdiction the violation is alleged  
3 to have occurred, and to the alleged violator—before initiating an enforcement action. *See* Cal.  
4 Health & Safety Code § 25249.7(d)(1). If, after 60 days, “[n]either the Attorney General, a district  
5 attorney, a city attorney, nor a prosecutor has commenced and is diligently prosecuting an action  
6 against the violation,” the private enforcer may bring an action in state court. *Id.* § 25249.7(d)(2).  
7 The Attorney General also is authorized to review proposed settlements in enforcement actions  
8 initiated by private enforcers and to challenge a proposed settlement that is not in the public interest.  
9 *Id.* § 25249.7(f); Cal. Code Regs. tit. 11, § 3003(a).

10           45. The private enforcement mechanism of Proposition 65 is unique and allows any  
11 person or law firm to act as a private enforcer to prosecute alleged violations of the Act. Courts and  
12 commentators have recognized the widescale abuse of Proposition 65 through private enforcement  
13 actions. *See, e.g.,* Anthony T. Caso, *Bounty Hunters and the Public Interest—A Study of California*  
14 *Proposition 65*, 13 Engage 30, 31 (Mar. 2012) (describing case in which “law firm created an  
15 ‘astroturf’ environmental group to be a plaintiff in Proposition 65 litigation,” which group “consisted  
16 of partners from the law firm” and which “sent out hundreds of demand letters charging businesses  
17 with failure to provide warnings” and “extort[ing] payments of attorney fees or contributions to the  
18 front group”).

19           46. Significantly, private enforcement actions are pervasive even for chemicals, like  
20 acrylamide, for which OEHHA has adopted a “safe harbor” NSRL. Even where OEHHA has  
21 adopted a safe harbor NSRL, the defendant still bears the burden under the statute of establishing as  
22 an affirmative defense that any exposures fall within the safe harbor. Cal. Health & Safety Code  
23 § 25249.10(c). In alleging an exposure to a listed chemical, a private enforcer is not required to  
24 prove that an exposure exceeds the NSRL. *Consumer Cause, Inc. v. SmileCare*, 91 Cal. App. 4th  
25 454, 474 (2001). Instead, under the statute, the burden to prove that the exposure *does not* exceed the  
26 NSRL rests with the defendant business. And proving this negative in court is a costly and time-  
27 consuming endeavor, typically requiring expert testimony and evidence. *See, e.g., Env'tl. Law Found.*  
28 *v. Beech-Nut Nutrition Corp.*, 235 Cal. App. 4th 307, 314 (2015) (safe harbor defense litigated at

1 trial); *Council for Educ. & Research on Toxics v. Starbucks Corp.*, No. BC435759 (Cal. Super. Ct.,  
 2 June 2, 2017) (rejecting Starbucks’s “no significant risk level” defense at summary judgment). In  
 3 other words, a safe harbor NSRL does not effectively deter a private enforcer with significant  
 4 financial incentives from initiating suit in the hopes of collecting a settlement.

5 47. California jurists have recognized how onerous private enforcement suits can be for  
 6 industry. “[L]awsuits under Proposition 65 can be filed and prosecuted by any person against any  
 7 business based on bare *allegations* of a violation unsupported by any evidence of an actual  
 8 violation—or even a good faith belief that a defendant is using an unsafe amount of a chemical  
 9 known by the state to cause cancer.” *SmileCare*, 91 Cal. App. 4th at 477 (Vogel, J., dissenting)  
 10 (emphasis in original). This burden-shifting regime results in “judicial extortion” where many  
 11 private parties bring Proposition 65 claims (without an appropriate assessment that an exposure  
 12 exceeds the NSRL) and force the defendant to settle to avoid legal fees and the costs of performing  
 13 an expensive expert scientific assessment. *Id.* at 477-79.

14 48. Thus, in practice, businesses faced with the threat of costly litigation to prove a  
 15 defense to the warning requirement often are forced to acquiesce and provide a warning, regardless of  
 16 whether the businesses know the warning is affirmatively false or misleading. *See* All. for Nat.  
 17 Health, *PROPOSITION 65: Evaluating Effectiveness and a Call for Reform*, at 7, [https://www.anh-](https://www.anh-usa.org/wp-content/uploads/2015/09/Prop-65.pdf)  
 18 [usa.org/wp-content/uploads/2015/09/Prop-65.pdf](https://www.anh-usa.org/wp-content/uploads/2015/09/Prop-65.pdf) (last accessed October 7, 2019); *see also* LATIMES,  
 19 *Warning: Too Many Warnings Signs are Bad for Your Health* (Sept. 30, 2017) (noting “Starbucks,  
 20 Whole Foods and about 80 other places in California that sell coffee” are exposed under  
 21 Proposition 65 even though “research increasingly” indicates coffee does *not* cause cancer),  
 22 [http://beta.latimes.com/opinion/editorials/](http://beta.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-20170930-story.html)  
 23 [la-ed-proposition-65-warning-coffee-20170930-story.html](http://beta.latimes.com/opinion/editorials/la-ed-proposition-65-warning-coffee-20170930-story.html);  
 24 Richard Berman, *Thanks to a Poorly-Designed Law, California Classifies Soft Drinks as a Cancer*  
 25 *Risk*, *Forbes* (Feb. 20, 2014) (compelling warnings for soda drinks on the basis that if consumers  
 26 drink “over 1,000 sodas a day” they would have increased cancer risk); Greg Ryan, *Rice Sellers*  
 27 *Threatened with Prop 65 Suits over Lead, Arsenic*, *Law360* (Feb. 20, 2014).

27 **E. Proposition 65 Listing of Acrylamide and Subsequent Enforcement Actions**

28 49. OEHHHA added acrylamide to the Proposition 65 list of carcinogens in 1990 pursuant

1 to the Authoritative Bodies listing mechanism, based on EPA’s determination that acrylamide was a  
2 “probable” human carcinogen and IARC’s classification of acrylamide as Group 2B (“possibly  
3 carcinogenic to humans”). IARC has since re-classified acrylamide as Group 2A (“probably  
4 carcinogenic to humans”).

5 50. The initial Proposition 65 listing of acrylamide was premised on potential exposures to  
6 acrylamide in industrial settings. At that time, it was not known that acrylamide was present in  
7 cooked foods. Acrylamide was not detected in foods until 2002.

8 51. Both the EPA and IARC classifications of acrylamide as a “probable” human  
9 carcinogen are based on studies in laboratory animals in which virtually pure acrylamide was  
10 administered orally or via injection to rats and mice. EPA and IARC *did not* classify acrylamide as a  
11 probable carcinogen based on studies in *humans*. In its most recent assessment of acrylamide, for  
12 example, IARC concluded in 1994 that there was “*inadequate evidence* in humans for the  
13 carcinogenicity of acrylamide.” *See* IARC Monographs on the Identification of Carcinogenic Risks  
14 to Humans, *Some Industrial Chemicals*, Vol. 60 at 425 (Feb. 1994), [https://monographs.iarc.fr/wp-](https://monographs.iarc.fr/wp-content/uploads/2018/06/mono60.pdf)  
15 [content/uploads/2018/06/mono60.pdf](https://monographs.iarc.fr/wp-content/uploads/2018/06/mono60.pdf). Similarly, in its most recent toxicological review of  
16 acrylamide in 2010, EPA explained that human studies assessing the carcinogenicity of acrylamide  
17 (including studies of both dietary and industrial exposures) “are judged as providing limited or no  
18 evidence of carcinogenicity in humans.” U.S. EPA, *Toxicological Review of Acrylamide* at 167  
19 (March 2010), [https://cfpub.epa.gov/ncea/iris/iris\\_documents/documents/toxreviews/0286tr.pdf](https://cfpub.epa.gov/ncea/iris/iris_documents/documents/toxreviews/0286tr.pdf).

20 52. OEHHA itself conceded in 2007 that acrylamide is not actually known to cause cancer  
21 in humans. Specifically, Martha Sandy—now the Branch Chief of OEHHA’s Reproductive and  
22 Cancer Hazard Assessment Branch—was designated as OEHHA’s “Person Most Knowledgeable” in  
23 an action involving acrylamide. *See* Cal. Code Civ. P. § 2025.230. Ms. Sandy testified that (a) she  
24 was not aware of any governmental health organization listing acrylamide as a known human  
25 carcinogen, (b) she was not aware of any pharmacodynamic data regarding rats and humans and  
26 acrylamide, and (c) OEHHA did not actually “know” that acrylamide was a human carcinogen.

27 53. OEHHA also has recognized that acrylamide in certain food products—namely,  
28 coffee—does not increase human cancer risk. In particular, in June 2019, OEHHA adopted a new

1 regulation that states: “Exposures to chemicals in coffee, listed on or before March 15, 2019 as  
2 known to the state to cause cancer, that are created by and inherent in the processes of roasting coffee  
3 beans or brewing coffee do not pose a significant risk of cancer.” 27 Cal. Code Regs. § 25704  
4 (effective Oct. 1, 2019). In adopting this regulation, OEHHA explained that “[t]he weight of the  
5 evidence from the very large number of studies in the scientific literature does not support an  
6 association between the complex mixture of chemicals that is coffee [including acrylamide] and a  
7 significant risk of cancer.” OEHHA, Final Statement of Reasons, Adoption of New Section 25704  
8 Exposures to Listed Chemicals in Coffee Posing No Significant Risk (June 7, 2019),  
9 <https://oehha.ca.gov/media/downloads/crn/fsorcoffee060719.pdf>. This regulation became effective  
10 on October 1, 2019.

11 54. Since its listing in 1990, acrylamide has been the target of significant Proposition 65  
12 enforcement activity, particularly with respect to food products. In the first such litigation, several  
13 private enforcers were joined by the California Attorney General in pursuing claims that several  
14 major restaurants and food manufacturers failed to provide Proposition 65 warnings for acrylamide in  
15 French fries, potato chips, and other potato products. The California Attorney General eventually  
16 settled these claims with each of the defendants. Under the terms of the settlements, the restaurant  
17 defendants, which include McDonald’s, Wendy’s, Burger King, and KFC, must provide warnings for  
18 acrylamide in French fries and similar products. The manufacturer defendants, which include the  
19 makers of Pringles, Lay’s, Baked Lay’s, Kettle, and other potato chip products, must either reduce  
20 the levels of acrylamide in their products or provide warnings to consumers. Likewise, the makers of  
21 Ore-Ida frozen potato products must change their cooking instructions in order to encourage  
22 consumers to reduce the levels of acrylamide in the finished products they cook at home. The  
23 Attorney General has also entered into settlements with makers of other snack food products on  
24 similar terms that require warnings if acrylamide concentrations exceed specified levels.

25 55. As described above, under Proposition 65, private parties are required to provide 60-  
26 days’ notice—to the California Attorney General, the district attorney, city attorney, or prosecutor in  
27 whose jurisdiction the violation is alleged to have occurred, and to the alleged violator—before  
28 initiating an enforcement action. *See* Cal. Health & Safety Code § 25249.7(d)(1). The California



1 Attorney General maintains a database of these 60-day notices (the “AG Database”), available at  
2 <https://oag.ca.gov/prop65/60-day-notice-search>.

3 56. To date, there have been more than *six hundred sixty* 60-day notices for alleged  
4 violations of the Proposition 65 warning requirement with respect to alleged exposures to acrylamide  
5 in food products.

6 57. These 60-day notices include alleged violations related to, among others: potato and  
7 potato-based products (more than 90 notices); nut butters, including peanut and almond butter (more  
8 than 40 notices); almonds (more than 40 notices); cereals (more than 20 notices); and olives (more  
9 than 10 notices).

10 58. Notably, although acrylamide has been on the Proposition 65 list for many years, the  
11 number of 60-day notices has increased exponentially in recent years, going from only three notices  
12 in 2015 to: 32 notices in 2016; 144 notices in 2017; 147 notices in 2018; and 205 notices in 2019. In  
13 fact, since Plaintiff filed its initial Complaint on October 7, 2019, private enforcers have served **86**  
14 new (and 21 renewed or amended) notices of violation concerning alleged exposures to acrylamide in  
15 food products such as roasted almonds, vanilla wafers, baked beans, macadamia nuts and ice cream  
16 cones.

17 59. Many of these 60-day notices have resulted in lawsuits or settlements, and there is a  
18 real and credible threat that other companies are likely to be future targets of Proposition 65 litigation  
19 related to alleged exposures to acrylamide in food products. Indeed, in February 2020 alone, private  
20 enforcers filed *forty-five* 60-day notices for alleged exposures to acrylamide in food products.

21 *Thirty-three* of these notices were filed in the two-week span between February 14, 2020 and  
22 February 28, 2020 by a private enforcer who had not previously served a 60-day notice of violation  
23 for acrylamide in food products. This new private enforcer has also served ten notices of violation so  
24 far in March 2020. This new private enforcer has served notices of violation for alleged exposures to  
25 acrylamide in, among other products, pistachios, macadamia nuts, sunflower seeds, baked beans, and  
26 organic canned tomatoes—none of which had previously been the target of a Proposition 65  
27 enforcement action.

28 60. Although there have been numerous Proposition 65 lawsuits in state court concerning

1 acrylamide in food—and although many of the defendant businesses in those cases have asserted the  
2 First Amendment as an affirmative defense in their responsive pleadings—the First Amendment issue  
3 has largely evaded review in state courts. This is driven by Proposition 65’s enforcement structure: a  
4 business faced with the threat of costly litigation and civil penalties has overwhelming economic  
5 incentives to acquiesce and settle, regardless of whether the business believes the warning is false or  
6 misleading. Few companies are able to accept the risk of litigating a Proposition 65 enforcement  
7 action through trial while incurring significant legal fees to do so.

8         61. In fact, the First Amendment issue has been litigated only twice in state court  
9 enforcement actions, and only once on the merits:

10             a. In the first case in 2008—*People v. Frito-Lay, Inc., et al.* (Los Angeles County  
11 Sup. Ct., No. BC 338956)—the California Superior Court denied the defendant businesses’ motion  
12 for summary judgment and the Attorney General’s cross-motion for summary adjudication on First  
13 Amendment grounds, finding that there was a triable issue of material fact. Facing the risk and  
14 expense of trial, the defendants in that lawsuit subsequently settled, and therefore the Superior Court  
15 never issued a ruling on the merits of the businesses’ First Amendment defense.

16             b. In the second case—*Council for Education & Research on Toxics v. Starbucks,*  
17 *et al.* (Los Angeles County Sup. Ct., No. BC 435759)—the California Superior Court ruled after the  
18 first phase of trial that certain of the defendants failed to meet their burden to show that compelling a  
19 cancer warning on coffee products violated their First Amendment rights. But the California Court of  
20 Appeal has not yet considered the merits of the First Amendment issue in the *Starbucks* case. Indeed,  
21 the California Court of Appeal likely will never address the First Amendment issue in the *Starbucks*  
22 case. The Superior Court is currently considering CERT’s challenges to the validity of OEHHA’s  
23 special coffee regulation (27 Cal. Code Regs. § 25704), which became effective on October 1, 2019,  
24 only a few days before Plaintiff CalChamber initiated this action. If upheld by the Court of Appeal,  
25 that regulation will resolve the *Starbucks* case on non-constitutional grounds without any need for  
26 consideration of the First Amendment issue.

27             **ADVERSE IMPACTS TO PLAINTIFF, ITS MEMBERS, AND THE PUBLIC**

28         62. If not prospectively enjoined, the Proposition 65 warning requirement for chemicals

1 listed as “known to the State of California to cause cancer,” as applied to acrylamide in food  
2 products, will have an immediate and irreversible impact on Plaintiff, its members, and the public.

3 63. More than 250 companies, including many of Plaintiff’s members that sell food  
4 products containing acrylamide, have been targeted with 60-day pre-litigation notices in connection  
5 with alleged exposures to acrylamide in their food products. Several of Plaintiff’s members also have  
6 been sued in connection with these 60-day notices. Indeed, several of the companies represented on  
7 Plaintiff’s Board of Directors have received 60-day notices on acrylamide in food products and been  
8 sued in connection with such notices.

9 64. At the same time, due to the widespread presence of acrylamide in thousands of food  
10 products, many of Plaintiff’s members that sell or produce acrylamide-containing food products have  
11 not yet been sued under Proposition 65 in connection with some, or all, of their acrylamide-  
12 containing food products. Because of California’s listing of acrylamide and the attendant  
13 Proposition 65 warning requirement, these members must either take action, in conjunction with their  
14 distributors and customers, to provide false, misleading, and factually controversial warnings to  
15 California consumers about acrylamide in their food products—conveying the unsubstantiated  
16 message that acrylamide in food products increases cancer risk in humans—or face a significant and  
17 imminent risk of an enforcement action seeking substantial civil penalties and attorneys’ fees for  
18 failing to do so.

19 65. Alternatively, Plaintiff’s many members that have not yet been sued may be forced to  
20 undertake costly exposure assessments for their acrylamide-containing products to demonstrate that  
21 any exposures to acrylamide from their products do not exceed the NSRL and do not require  
22 warnings. And even if Plaintiff’s members’ assessments indicate that exposures to acrylamide from  
23 their products do not exceed the NSRL, they still would need to prepare to defend against likely  
24 enforcement actions by private enforcers. Private enforcers are not required to defer to a company’s  
25 exposure assessment and may dispute the exposure assessment. Thus, a company that wishes to  
26 defend its exposure assessment and to prove that an exposure does not exceed the NSRL faces the  
27 prospect of costly and risky litigation on a technical and expert-heavy defense.

28 66. The requirement to place a false, misleading, and highly controversial Proposition 65

1 cancer warning for acrylamide on food products has had, and will continue to have, a substantial  
2 adverse impact on Plaintiff's members. Such a warning disparages Plaintiff's members and their  
3 food products by creating the false impression among consumers that those products are unsafe and  
4 increase human cancer risk, despite scientific evidence suggesting that acrylamide that forms  
5 naturally in food does not increase (and may even *reduce*) the risk of cancer in humans.

6 67. Applying a false, misleading, and highly controversial Proposition 65 cancer warning  
7 on food products also would have a substantial adverse impact on the public.

8 68. First, a Proposition 65 cancer warning for acrylamide in food products would mislead  
9 consumers about the human health risks posed by foods containing acrylamide and frighten  
10 consumers away from those foods that are part of a well-balanced diet.

11 69. FDA has explained, for example, that "requiring a cancer warning on coffee, based on  
12 the presence of acrylamide, would be more likely to mislead consumers than to inform them." FDA,  
13 *Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's Support for Exempting Coffee*  
14 *from California's Cancer Warning Law* (August 29, 2018) ("*FDA Statement on Coffee*"); *see also*  
15 *Letter from Lester M. Crawford, DVM, Ph.D, Deputy Commissioner, FDA, to Joan E. Denton, M.S.,*  
16 *Ph.D., Director, California Office of Environmental Health Hazard Assessment* (July 13, 2003)  
17 ("*2003 FDA Letter*") ("[W]arning labels based on the presence of acrylamide in food might be  
18 misleading.").

19 70. Foods that contain acrylamide are part of a well-balanced diet. These include whole  
20 grains, almonds, and nut butters as examples. With respect to whole grains, for example, FDA  
21 Commissioner Dr. Scott Gottlieb explained in August 2018: "We recognize that some [whole grain  
22 food] products may contain acrylamide. But we also know that consumption of whole grains is  
23 beneficial for health and nutrition. Labeling whole grain foods with a cancer warning may cause  
24 American consumers to avoid foods that would have a benefit to their health, including avoiding  
25 foods that may reduce cancer risks." *See* FDA Statement on Coffee; *see also* 2003 FDA Letter ("[A]  
26 requirement for warning labels on food might deter consumers from eating foods with such labels.  
27 Consumers who avoid eating some of these foods, such as breads and cereals, may encounter greater  
28 risks because they would have less fiber and other beneficial nutrients in their diets.").

1           71.     Similarly, the Dietary Guidelines (*see* ¶ 21, *supra*) emphasize that vegetables and nuts  
2 are part of a healthy diet. Because of California’s listing of acrylamide and the attendant warning  
3 requirement, numerous food products that the Dietary Guidelines recommend as part of a healthy  
4 diet—including olives, peanuts, almonds, and nut butters—already have been the target of 60-day  
5 notice letters and enforcement litigation under Proposition 65, and there are many other such products  
6 that are likely to be the target of such enforcement in the future. If Plaintiff’s members are forced to  
7 provide warnings for these products, consumers will be misled to avoid them.

8           72.     In addition, requiring businesses to apply a Proposition 65 cancer warning for  
9 acrylamide in food products will mislead consumers into thinking that acrylamide is only present in  
10 store-bought food. Raw foods ordinarily do not contain acrylamide. Because acrylamide forms  
11 naturally during the cooking process, however, acrylamide can form in those foods when cooked at  
12 consumers’ homes. Indeed, FDA has observed that consumer exposure to acrylamide “may be  
13 greatest through home cooking.” *See* Letter from Lester M. Crawford, DVM, Ph.D, Deputy  
14 Commissioner, FDA, to Joan E. Denton, M.S., Ph.D., Director, California Office of Environmental  
15 Health Hazard Assessment (July 13, 2003).

16           73.     Finally, requiring businesses to apply a Proposition 65 cancer warning for acrylamide  
17 in food products, despite the lack of reliable scientific evidence supporting a finding that acrylamide  
18 from food products increases human cancer risk, dilutes the effectiveness of legitimate Proposition 65  
19 warnings. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2 cmt. j (1998) (noting  
20 that excessive, multitudinous warnings “may be ignored by users and consumers and may diminish  
21 the significance of warnings about [other] risks” and “could reduce the efficacy of warnings  
22 generally.”); *Nicolle-Wagner v. Deukmejian*, 230 Cal. App. 3d 652, 661 (1991) (“[U]nnecessary  
23 warnings . . . could distract the public from other important warnings on consumer products.’ Since  
24 one of the principal purposes of [Proposition 65] is to provide ‘clear and reasonable warning’ of  
25 exposure to carcinogens and reproductive toxins, such warnings would be diluted to the point of  
26 meaninglessness if they were to be found on most or all food products.”) (quoting the Final Statement  
27 of Reasons for the “naturally occurring” regulation now found at CAL. CODE REGS. tit. 27, §25501));  
28 *accord Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 70 (2008) (quoting *Finn v. G.D. Searle & Co.*,

1 35 Cal. 3d 691, 701 (1984)).

2 74. Indeed, the California Supreme Court in another context has recognized that excessive  
3 warnings “produce a cacophony . . . that by reason of their sheer volume would add little to the  
4 effective protection of the public.” *Thompson v. Cty. of Alameda*, 27 Cal. 3d 741, 754–55 (1980); *see*  
5 *also Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal. 4th 910, 932 (2004) (“The  
6 problems of overwarning are exacerbated if warnings must be given even as to very remote risks . . . .  
7 Against the benefits that may be gained by a warning must be balanced the dangers of overwarning  
8 and of less meaningful warnings crowding out necessary warnings, the problem of remote risks, and  
9 the seriousness of the possible harm to the consumer.”) (internal citation omitted).

10 75. An order enjoining future enforcement of the Proposition 65 warning requirement for  
11 cancer as applied to acrylamide in food products would redress the harms described above.

12 **CLAIMS FOR RELIEF**

13 **COUNT I**

14 **(Violation of the First Amendment to the U.S. Constitution — 22 U.S.C. § 2201)**

15 76. The foregoing Paragraphs are incorporated by reference as if set forth in full herein.

16 77. The Free Speech Clause of the First Amendment of the United States Constitution  
17 provides that “Congress shall make no law . . . abridging the freedom of speech.” U.S. Const. amend.  
18 I. The Fourteenth Amendment of the United States Constitution made this proscription applicable to  
19 the States and their political subdivisions. *See id.* amend. XIV § 1.

20 78. In addition to providing protections against restrictions on speech, the First  
21 Amendment provides protection against the government *compelling* individuals or entities to engage  
22 in speech.

23 79. Under the First Amendment, laws compelling speech ordinarily receive strict scrutiny.  
24 *See Wooley v. Maynard*, 430 U.S. 705, 715-16 (1977). Laws regulating commercial speech generally  
25 receive at least intermediate scrutiny, *i.e.*, they are prohibited if they do not directly and materially  
26 advance the government’s interest, or are more extensive than necessary. *Cent. Hudson Gas & Elec.*  
27 *Corp. v. Pub. Serv. Comm’n*, 447 U.S. 557, 566 (1980). And even laws that require businesses to  
28 provide information in connection with commercial transactions are permissible only if the

1 compelled disclosure is of information that is purely factual and uncontroversial, reasonably related  
2 to a substantial government purpose, and not unjustified or unduly burdensome. *See Nat'l Inst. of*  
3 *Family & Life Advocates v. Becerra*, 138 S. Ct. 2361, 2372, 2377 (2018) (“NIFLA”); *Zauderer v.*  
4 *Office of Disciplinary Counsel*, 471 U.S. 626, 651 (1985). The Government bears the burden to show  
5 that a compelled disclosure is permissible under the First Amendment.

6 80. A Proposition 65-compliant cancer warning—irrespective of the specific language  
7 used—conveys to the average consumer of products intended for human consumption that the  
8 chemical at issue (here, acrylamide) causes cancer in humans.

9 81. Contrary to the warning mandated by Proposition 65, there is no reliable scientific  
10 evidence that dietary acrylamide increases the risk of cancer in humans. To the contrary, a large  
11 number of epidemiological studies suggest that there is no association between exposure to  
12 acrylamide from food products and cancer in humans.

13 82. Nor does California “know” that dietary acrylamide causes cancer. In fact, the  
14 California agency responsible for implementing Proposition 65—OEHHA—has admitted that  
15 OEHHA does *not* know that acrylamide is a *human* carcinogen. *See* ¶ 52, *supra*.

16 83. Moreover, even the agencies on which OEHHA relied to add acrylamide to the  
17 Proposition 65 list—EPA and IARC—have not said that they “know” that exposure to acrylamide  
18 causes cancer in humans. Rather, they have only identified acrylamide as a “probable” human  
19 carcinogen based on studies in laboratory animals in which virtually pure acrylamide was  
20 administered orally or via injection to rats and mice. EPA and IARC have concluded, respectively,  
21 that studies of acrylamide in humans (of which there are many) provide “inadequate” and “limited or  
22 no” evidence of carcinogenicity in humans. *See* ¶ 51, *supra*.

23 84. The Proposition 65 cancer warning requirement as applied to acrylamide in food  
24 products thus compels speech that is false, misleading, and factually controversial. *See* ¶¶ 22-29, 51-  
25 52, 64, *supra*.

26 85. Because Proposition 65’s cancer warning requirement as applied to acrylamide in food  
27 products is false, misleading, and factually controversial, it cannot survive any level of constitutional  
28 scrutiny. *See Video Software Dealers Ass’n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009)

1 (“[T]he State has no legitimate reason to force retailers to affix false information on their products.”).  
2 Proposition 65’s cancer warning requirement as applied to acrylamide in food products therefore  
3 constitutes impermissible compelled speech under the First Amendment.

4 86. In the alternative, the Proposition 65 warning requirement also is unconstitutional on  
5 its face. In *NIFLA*, the U.S. Supreme Court made clear that the State has the burden to show that a  
6 warning is “justified” before it may compel a business to provide one consistent with the First  
7 Amendment. *See* 138 S. Ct. at 2377. A Proposition 65 warning requirement is “justified” only for an  
8 exposure to a listed chemical at a level that exceeds the NSRL. Proposition 65, however, reverses  
9 this burden, stating that “the burden of showing that an exposure [poses no significant risk] shall be  
10 on the defendant.” Cal. Health & Safety Code § 25249.10(c). The Proposition 65 warning  
11 requirement is thus unconstitutional on its face because it places the burden on the *business* to  
12 disprove that a warning is justified, when *NIFLA* and other U.S. Supreme Court precedent hold that it  
13 is the *government’s* burden to prove that a warning is justified.

14 87. Plaintiff’s members include entities that have already been harmed by California’s  
15 requirement to provide a false, misleading, and/or highly controversial cancer warning for acrylamide  
16 in food products, and will be injured further if forced to either comply with Proposition 65’s  
17 compelled false warning requirement, or incur costly other burdens and face the threat of private  
18 enforcement suits or other enforcement actions.

19 **COUNT II**  
20 **(Violation of the First Amendment to the U.S. Constitution — 42 U.S.C. § 1983)**

21 88. The foregoing Paragraphs are incorporated by reference as if set forth in full herein.

22 89. 42 U.S.C. § 1983 provides in relevant part that “[e]very person who, under color of  
23 any statute, ordinance, regulation, custom, or usage, of any State or Territory or the District of  
24 Columbia, subjects, or causes to be subjected, any citizen of the United States or other person within  
25 the jurisdiction thereof to the deprivation of any rights, privileges, or immunities secured by the  
26 Constitution and laws, shall be liable to the party injured in an action at law, suit in equity, or other  
27 proper proceed for redress . . . .”

28 90. The Proposition 65 cancer warning requirement as applied to acrylamide in food



1 products compels speech that is false, misleading, and factually controversial. *See* ¶¶ 22-29, 51-52,  
2 64, *supra*.

3 91. Because Proposition 65’s cancer warning requirement as applied to acrylamide in food  
4 products compels speech that is false, misleading, and factually controversial, it cannot survive any  
5 level of constitutional scrutiny. Proposition 65’s cancer warning requirement as applied to  
6 acrylamide in food products therefore constitutes impermissible compelled speech under the First  
7 Amendment.

8 92. In the alternative, the Proposition 65 warning requirement also is unconstitutional on  
9 its face under the First Amendment. *See* ¶ 86, *supra*.

10 93. Plaintiff and its members are persons within the meaning of 42 U.S.C. § 1983 and  
11 have a right to free speech (which includes the right not to speak) under the First Amendment to the  
12 United States Constitution, as applicable to the States and their political subdivisions through the  
13 Fourteenth Amendment to the United States Constitution.

14 94. Plaintiff’s members include entities that have already been harmed by California’s  
15 requirement to provide a false, misleading, and/or highly controversial cancer warning for acrylamide  
16 in food products, and will be injured further if forced to either comply with Proposition 65’s compelled  
17 false warning requirement, or incur costly other burdens and face the threat of private enforcement  
18 suits or other enforcement actions. Plaintiff’s members also include entities that have yet not been  
19 targeted in private enforcement actions for exposures to acrylamide in food products but—because of  
20 the widespread presence of acrylamide in thousands of food products sold and served at grocery stores  
21 and restaurants—face a real and credible threat of being targeted in future enforcement actions.

22 95. Defendant is responsible for enforcing Proposition 65 and does so under color of state  
23 law. In addition, private enforcers under Cal. Health & Safety Code § 25249.7(d) also act under  
24 color of state law because, *inter alia*:

25 a. Private enforcement actions are authorized by state statute to be brought only  
26 “in the public interest.” *Id.* § 25249.7(d);

27 b. Private enforcers must provide notice to the Attorney General and other public  
28 prosecutors before initiating an enforcement action. *Id.* § 25249.7(d)(1);

1 c. The Attorney General screens and evaluates private enforcers' notices of  
2 prospective enforcement actions and is obligated to object to any enforcement action he believes  
3 lacks merit. *Id.* § 25249.7(e)(1)(A);

4 d. Private enforcers may initiate an enforcement action only if the Attorney  
5 General and all district attorneys and city attorneys of certain large cities have not begun prosecuting  
6 the alleged violation themselves, *id.* § 25249.7(d)(2);

7 e. The State, through the Attorney General, is authorized to review and challenge  
8 proposed settlements in private enforcement actions, *id.* § 25249.7(f); and

9 f. Seventy-five percent of any penalties assessed in private enforcement actions  
10 go to the State treasury, *id.* § 25249.12.

11 96. In other words, private enforcers of Proposition 65 stand in the shoes of the State when  
12 enforcing the Proposition 65 statute. The activities of "persons in the public interest" are both directly  
13 and indirectly regulated, monitored, controlled, and guided by the California Attorney General's  
14 Office.

15 **PRAYER FOR RELIEF**

16 WHEREFORE, excluding Proposition 65 acrylamide claims that are currently pending in  
17 state court, Plaintiff demands judgment against Defendant as follows:

18 1. A declaration, pursuant to 28 U.S.C. § 2201 and/or 42 U.S.C. § 1983, that the  
19 Proposition 65 warning requirement for cancer, Cal. Health & Safety Code § 25249.6, as applied to  
20 acrylamide in food products, violates the First Amendment of the United States Constitution.

21 2. In the alternative, a declaration, pursuant to 28 U.S.C. § 2201 and/or 42 U.S.C.  
22 § 1983, that the Proposition 65 warning requirement, Cal. Health & Safety Code § 25249.6, on its  
23 face violates the First Amendment of the United States Constitution.

24 3. Prospective preliminary and permanent injunctions, pursuant to 42 U.S.C. § 1983 and  
25 other applicable law, prohibiting Defendant or any of its officers, employees, or agents, and all those  
26 in privity with and/or acting in concert with those entities or individuals (including private enforcers  
27 of Proposition 65 under Cal. Health & Safety Code § 25249.7(d)), from enforcing or threatening to  
28 enforce in the future the Proposition 65 warning requirement for cancer with respect to acrylamide in

1 food products intended for human consumption.

2 4. All costs, attorneys' fees, and expenses that Plaintiff reasonably incurs, *see* 42 U.S.C.  
3 § 1988; and

4 5. Such other and further relief as this Court deems just and proper.

5  
6 Dated: March 16, 2020

Respectfully submitted,

7 By: /s/ Trenton H. Norris  
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