[]	Case 2:19-cv-02019-KJM-EFB Docum	ment 1 Filed 10/07/19 Page 1 of 23		
1 2 3 4 5 6	Trenton H. Norris (CA Bar No. 164781) Sarah Esmaili (CA Bar No. 206053) S. Zachary Fayne (CA Bar No. 307288) David M. Barnes (CA Bar No. 318547) ARNOLD & PORTER KAYE SCHOLER LLI Three Embarcadero Center, 10th Floor San Francisco, CA 94111-4024 Telephone: 415.471.3100 Facsimile: 415.471.3400 trent.norris@arnoldporter.com	P		
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8	UNITED STATES DISTRICT COURT			
9	EASTERN DISTRICT OF CALIFORNIA			
10	CALIFORNIA CHAMBER OF			
11	COMMERCE, Plaintiff,			
12		Civil Action No.		
13	v. XAVIER BECERRA, IN HIS OFFICIAL	COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF		
14	CAPACITY AS ATTORNEY GENERAL OF THE STATE OF CALIFORNIA,			
15	Defendant.			
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	COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF			

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

# PRELIMINARY STATEMENT

1. Plaintiff CalChamber brings this suit to enjoin Defendant and those in privity with and acting in concert with Defendant from enforcing a requirement to provide a false, misleading, and highly controversial cancer warning for food and beverage (collectively 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
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,
and it has been present in these foods for as long as they have been cooked. Common sources of
acrylamide in the human diet include, among others, breakfast cereals, crackers, bread crusts, coffee,
grilled or roasted asparagus, French fries, potato chips and other fried and baked snack foods, canned
sweet potatoes, canned black olives, prune juice, roasted nuts, and toast. Acrylamide is also widely
used during the manufacturing of paper, dye, and other industrial products.

17 3. Acrylamide has been identified by certain governmental and scientific entities as a 18 carcinogen based on studies in laboratory animals. Scientific studies in humans, however, have 19 found no reliable evidence that exposure to acrylamide in food products is associated with an 20 increased risk of developing any type of cancer. In fact, the epidemiologic evidence suggests that 21 dietary acrylamide—i.e., acrylamide that forms naturally in normal cooking of many food products— 22 does not cause cancer in humans or pose an increased risk of cancer in humans. Indeed, some food 23 products that contain acrylamide (e.g., whole grains and coffee) have been shown to reduce the risk 24 of certain diseases, including cancer.

4. Under California's Safe Drinking Water and Toxic Enforcement Act of 1986
 ("Proposition 65"), businesses are required to warn consumers about an exposure to any chemical
 that has been identified by the California Office of Environmental Health Hazard Assessment
 ("OEHHA") as "known to the State to cause cancer," unless a defense to the warning requirement

applies. OEHHA has listed acrylamide as a carcinogen.

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

9 6. A Proposition 65 cancer warning for acrylamide in food products that are intended for human consumption conveys to consumers the false and misleading message that consuming the 10 11 products will increase consumers' risk of cancer, even though there is no reliable evidence that 12 exposure to dietary acrylamide increases the risk of cancer in humans.

California's presumptive requirement that businesses provide a Proposition 65 cancer 13 7. 14 warning for food products that contain acrylamide therefore violates the First Amendment of the 15 United States Constitution by compelling Plaintiff's members and other entities that produce, distribute, or sell acrylamide-containing food products to make false, misleading, and highly 16 17 controversial statements about their products.

8. 18 In addition to being illegal, California's treatment under Proposition 65 of acrylamide 19 that forms naturally in normal cooking of many food products harms both businesses and the public. 20 Businesses, including many of CalChamber's members, must either take action to provide false, 21 misleading, and highly controversial warnings to California consumers about the safety of their food 22 products, or face potential costly enforcement actions initiated by Defendant or private enforcers for 23 failing to do so.

9. 24 Members of the public, meanwhile, will be misled about the risks posed by food 25 products containing acrylamide, potentially frightening them away from a variety of foods-26 including whole grains, peanuts, almonds, nut butters, olives, and coffee-that are part of a well-27 balanced diet and may actually reduce the risk of cancer. Cancer warnings for acrylamide in food 28 products also can mislead consumers into believing that acrylamide is present only in store-bought foods, when in fact consumer exposure to acrylamide in foods may be greatest through home cooking (for which no Proposition 65 warnings are required).

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

8 11. For these reasons, the Court should declare that mandating Proposition 65 cancer
9 warnings for acrylamide in food products is unconstitutional under the First Amendment and enjoin
0 Defendant and those in privity with and/or acting in concert with Defendant (including
1 Proposition 65 private enforcers) from enforcing the Proposition 65 warning requirement as applied
2 to acrylamide in food products.

#### PARTIES

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

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under Proposition 65. CalChamber has been intimately involved in Proposition 65 reform initiatives and related regulatory efforts, coordinating and participating in numerous policy discussions, providing extensive comments on behalf of its members, presenting detailed proposals, monitoring developments, advising members on developments, and initiating legislative proposals.

5 13. Defendant Xavier Becerra is the Attorney General of the State of California and the 6 highest-ranking officer in the California Department of Justice. Attorney General Becerra is sued in his official capacity. He performs his official duties in Sacramento and throughout the State of 8 California. As Attorney General, he is specifically empowered to enforce the provisions of Proposition 65, and indeed the California Attorney General has done so in the past with respect to dietary acrylamide in a variety of lawsuits against manufacturers of food products, all of which have been resolved through settlement as of the date of this Complaint.

## JURISDICTION AND VENUE

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

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

FACTUAL BACKGROUND

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#### **Overview of Acrylamide in Food Products**

16. Acrylamide forms naturally from chemical reactions in certain types of starchy foods when cooked at high temperatures or otherwise processed using heat. Acrylamide is found mainly in food made from plants, such as potato products (e.g., French fries, potato chips), grain products (e.g., breakfast cereals, cookies, and toast), and coffee. Although acrylamide was not detected in foods until 2002, "[a]crylamide has probably always been present in cooked foods." See Food and Drug Administration, Acrylamide Questions and Answers (Updated Sept. 25, 2019) ("FDA Q&A"), https://www.fda.gov/food/chemicals/acrylamide-questions-and-answers.

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17. Dietary acrylamide forms as part of a chemical reaction, known as the Maillard

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

18. Common sources of acrylamide in the diet include, among others, breakfast cereals, crackers, bread crusts, roasted asparagus, French fries, potato chips and other fried and baked snack foods, canned sweet potatoes, canned black olives, roasted nuts, and toast. *See* OEHHA, *Acrylamide Fact Sheet* (Feb. 2019), https://www.p65warnings.ca.gov/sites/default/files

/downloads/factsheets/acrylamide\_fact\_sheet.pdf.

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

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

21. Although acrylamide can form in many foods that are fried, roasted, or baked, FDA
does not recommend that consumers avoid eating these foods. Instead, FDA recommends that
consumers adopt a healthy eating plan consistent with the Office of Disease Prevention and Health
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.

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#### 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-

9 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 10 make up the U.S. Department of Health and Human Services.

Likewise, the American Cancer Society explains on its website that, "[s]o far, reviews 12 24. of studies done in groups of people (epidemiologic studies) suggest that dietary acrylamide isn't 13 likely to be related to risk for most common types of cancer." See American Cancer Society, 14 Acrylamide and Cancer Risk (Feb. 11, 2019), https://www.cancer.org/cancer/cancer-15 causes/acrylamide.html. The American Cancer Society further states that "[i]t's not yet clear if the 16 17 levels of acrylamide in foods raise cancer risk. ...." Id.

25. 18 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 19 20 European Journal of Cancer Prevention, for example, researchers evaluated the association between 21 dietary acrylamide and cancer. See L. Lipworth, et al., Review of Epidemiologic Studies of Dietary 22 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 23 intake and cancer have been evaluated in more than 15 epidemiologic studies examining almost every 24 major cancer site." Id. After critically reviewing the available studies, the researchers concluded: 25

> After an extensive examination of the published literature, we found no consistent or credible evidence that dietary acrylamide increases the risk of any type of cancer in humans, either overall or among nonsmokers. In particular, the collective evidence suggests that a high

Case 2:19-cv-02019-KJM-EFB Document 1 Filed 10/07/19 Page 8 of 23 1 level of dietary acrylamide intake is not a risk factor for breast, endometrial, or ovarian cancers. . . . 2 In conclusion, epidemiologic studies of dietary acrylamide intake have 3 failed to demonstrate an increased risk of cancer. In fact, the sporadically and slightly increased and decreased risk ratios reported in more than two dozen papers examined in this review strongly suggest 5 the pattern one would expect to find for a true null association over the course of a series of trials. 6 7 Id. 8 26. Since 2012, there have been several additional studies, across multiple different 9 populations, evaluating whether there is an association between dietary acrylamide and cancer, and 10 those studies have consistently found that exposure to acrylamide in food products does not increase human cancer risk. See, e.g., C. Pelucchi, et al., Dietary Acrylamide and Cancer Risk: An Updated 11 12 Meta-Analysis, Int'l Journal of Cancer, Vol. 136(12):2912–22 (2015) ("This systematic review and 13 meta-analysis of epidemiological studies indicates that dietary acrylamide is not related to the risk of 14 most common cancers."); A. Kotemori, et al., Dietary Acrylamide Intake and Risk of Breast Cancer: 15 the Japan Public Health Center-Based Prospective Study, Cancer Science, Vol. 109(3):843-53 (2018) ("In conclusion, dietary acrylamide intake was not associated with the risk of breast cancer in this 16 17 population-based prospective cohort study of Japanese women."); M. McCullough, et al., Dietary 18 Acrylamide Is Not Associated with Renal Cell Cancer Risk in the CPS-II Nutrition Cohort, Cancer Epidemiology, Biomarkers & Prevention, Vol. 28(3):616-619 (2019) ("In conclusion, we found no 19 20 evidence that greater dietary acrylamide intake was associated with risk of RCC [renal cell 21 carcinoma]."); J. Hogervorst, et al., Interaction Between Dietary Acrylamide Intake and Genetic 22 Variants for Estrogen Receptor-Positive Breast Cancer Risk, European Journal of Nutrition, Vol. 23 58:1033-1045 (2019) ("This study did not provide evidence for a positive association between 24 acrylamide intake and ER+ [estrogen receptor-positive] breast cancer risk. If anything, acrylamide 25 was associated with a decreased ER+ breast cancer risk.").

26 27. In fact, studies have shown that certain foods that contain acrylamide may actually
27 *reduce* the risk of cancer in humans. For example, in June 2018, the International Agency for
28 Research on Cancer ("IARC") concluded that there is an "inverse association" between drinking

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coffee (which contains acrylamide) and certain types of cancer. *See* IARC Monographs on the Evaluation of Carcinogenic Risks to Humans, *Drinking Coffee, Mate, and Very Hot Beverages*, Vol. 116 at 434 (2018). Likewise, a recent study showed that whole-grain foods may reduce the risk of liver cancer. *See* American Cancer Society, *Study Ties Whole Grains to Lower Risk of Liver Cancer* (Feb. 27, 2019), https://www.cancer.org/latest-news/study-ties-whole-grains-to-lower-risk-of-liver-cancer.html.

7 28. Some regulatory and scientific entities have identified acrylamide as a possible or 8 probable carcinogen based on studies in laboratory animals in which virtually pure acrylamide was 9 administered orally or via injection to rats and mice. As NCI has explained, however, "toxicology 10 studies have shown that humans and rodents not only absorb acrylamide at different rates, they 11 metabolize it differently as well." NCI, Acrylamide and Cancer Risk (Updated Dec. 5, 2017), 12 https://www.cancer.gov/about-cancer/causes-prevention/risk/diet/acrylamide-fact-sheet. The 13 evidence that acrylamide causes cancer in animals is insufficient to conclude that acrylamide that 14 forms naturally in certain food products increases cancer risk in humans, particularly in light of the 15 epidemiologic data that strongly suggest that dietary acrylamide does *not* increase human cancer risk.

29. 16 There are other examples of chemicals that have been shown to cause cancer in 17 animals but not in humans. For example, studies in laboratory rats during the early 1970s linked the 18 artificial sweetener saccharin to development of bladder cancer. Subsequent studies showed, 19 however, that those results applied only to rats and not to humans, and human epidemiology studies 20 have found no consistent evidence that saccharin is associated with bladder cancer in humans. See 21 NCI, Artificial Sweeteners and Cancer (Aug. 10, 2016), https://www.cancer.gov/about-22 cancer/causes-prevention/risk/diet/artificial-sweeteners-fact-sheet. As NCI explained: "Because the 23 bladder tumors seen in rats are due to a mechanism not relevant to humans and because there is no 24 clear evidence that saccharin causes cancer in humans, saccharin was delisted in 2000 from the U.S. 25 National Toxicology Program's Report on Carcinogens, where it had been listed since 1981 as a 26 substance reasonably anticipated to be a human carcinogen (a substance known to cause cancer)." Id.

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**Proposition 65 Regulatory Framework** 

In 1986, California voters, by initiative, enacted the Safe Drinking Water and Toxic

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

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

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

15 33. After a chemical is added to the Proposition 65 list, and following a 12-month grace period, Proposition 65 requires that any "person in the course of doing business" provide a "clear and 16 reasonable warning" before "expos[ing] any individual to" the listed chemical, unless an exemption 18 or affirmative defense applies. Cal. Health & Safety Code § 25249.6.

19 34. Although Proposition 65 does not define what content suffices to convey a "clear and 20 reasonable warning," OEHHA's regulations had for more than 30 years provided that the warning 21 "must clearly communicate that the chemical in question is known to the state to cause cancer...." 22 27 Cal. Code Regs. § 25601 (effective until Aug. 30, 2018). OEHHA also provided a "safe harbor" 23 for warnings that used the following language: "WARNING: This product contains a chemical 24 known to the State of California to cause cancer." Id. § 25603.2 (effective until Aug. 30, 2018).

25 35. In August 2016, OEHHA adopted new regulations providing that safe harbor 26 Proposition 65 warnings must provide consumers with additional information.

27 36. Under the new warning regulations, cancer warnings for food products are deemed to 28 be "clear and reasonable" if they state: "WARNING: Consuming this product can expose you to

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[name of chemical], which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov/food." 27 Cal. Code Regs § 25607.2(a)(2).<sup>1</sup> In addition, where the warning is provided on the food product label, it "must be set off from other surrounding information" and "enclosed in a box." Id. § 25607.1(b).

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

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

18 39. Under Proposition 65, to determine whether an exposure from a consumer product 19 exceeds the NSRL, the regulations require that exposures be calculated based on the "average rate of 20 intake or exposure for average users of the consumer product." 27 Cal. Code Regs. § 25721(d)(4). Thus, unlike other laws and regulations affecting businesses that set concentration-based thresholds, 22 it is not facially apparent from the NSRL described in the statute or from a safe harbor NSRL adopted 23 by OEHHA and listed in the regulations whether there is a duty to warn under Proposition 65.

40. Under the statute, it is the burden of a business to demonstrate that the exposure at issue does not exceed the NSRL. In addition, the NSRL provides only an "affirmative defense" to

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<sup>27</sup> <sup>1</sup> Where a warning is being provided for an exposure to more than one listed carcinogen, the warning must state: "WARNING: Consuming this product can expose you to chemicals including [name of 28 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).

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liability under Proposition 65 and does not immunize industry from enforcement actions in the first instance. See DiPirro v. Bondo Corp., 153 Cal. App. 4th 150, 185 (2007).

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

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#### **Enforcement of Proposition 65**

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

19 43. Second, any *person* (even one who has suffered no injury in fact) may bring a private 20 enforcement action for an alleged failure to provide an adequate warning and without having to plead or prove injury or harm. Id. § 25249.7(d). These private enforcers are eligible to recover 25 percent 22 of the penalty, *id.* § 25249.12(d), as well as their reasonable attorneys' fees and costs, Cal. Code Civ. 23 Proc. § 1021.5, creating very strong incentives for private enforcement. Defendants usually cannot 24 remove these enforcement actions to federal court because the plaintiff has no Article III standing.

25 44. The private enforcement mechanism of Proposition 65 is unique and allows any 26 person or law firm to act as a private enforcer to prosecute alleged violations of the Act. Courts and 27 commentators have recognized the widescale abuse of Proposition 65 through private enforcement 28 actions. See, e.g., Anthony T. Caso, Bounty Hunters and the Public Interest-A Study of California

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Proposition 65, 13 Engage 30, 31 (Mar. 2012) (describing case in which "law firm created an 'astroturf' environmental group to be a plaintiff in Proposition 65 litigation," which group "consisted of partners from the law firm" and which "sent out hundreds of demand letters charging businesses with failure to provide warnings" and "extort[ing] payments of attorney fees or contributions to the front group").

45. Significantly, private enforcement actions are pervasive even for chemicals, like 6 acrylamide, for which OEHHA has adopted a "safe harbor" NSRL. Even where OEHHA has 8 adopted a safe harbor NSRL, the defendant still bears the burden under the statute of establishing as an affirmative defense that any exposures fall within the safe harbor. Cal. Health & Safety Code § 25249.10(c). In alleging an exposure to a listed chemical, a private enforcer is not required to prove that an exposure exceeds the NSRL. Consumer Cause, Inc. v. SmileCare, 91 Cal. App. 4th 454, 474 (2001). Instead, under the statute, the burden to prove that the exposure *does not* exceed the NSRL rests with the defendant business. And proving this negative in court is a costly and timeconsuming endeavor, typically requiring expert testimony and evidence. See, e.g., Envtl. Law Found. v. Beech-Nut Nutrition Corp., 235 Cal. App. 4th 307, 314 (2015) (safe harbor defense litigated at trial); Council for Educ. & Research on Toxics v. Starbucks Corp., No. BC435759 (Cal. Super. Ct., June 2, 2017) (rejecting Starbucks's "no significant risk level" defense at summary judgment). In other words, a safe harbor NSRL does not effectively deter a private enforcer with significant financial incentives from initiating suit in the hopes of collecting a settlement.

20 46. California jurists have recognized how onerous private enforcement suits can be for 21 industry. "[L]awsuits under Proposition 65 can be filed and prosecuted by any person against any 22 business based on bare *allegations* of a violation unsupported by any evidence of an actual 23 violation—or even a good faith belief that a defendant is using an unsafe amount of a chemical 24 known by the state to cause cancer." SmileCare, 91 Cal. App. 4th at 477 (Vogel, J., dissenting) 25 (emphasis in original). This burden-shifting regime results in "judicial extortion" where many 26 private parties bring Proposition 65 claims (without an appropriate assessment that an exposure 27 exceeds the NSRL) and force the defendant to settle to avoid legal fees and the costs of performing 28 an expensive expert scientific assessment. Id. at 477-79.

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47. 1 Thus, in practice, businesses faced with the threat of costly litigation to prove a 2 defense to the warning requirement often are forced to acquiesce and provide a warning, regardless of 3 whether the businesses know the warning is affirmatively false or misleading. See All. for Nat. 4 Health, PROPOSITION 65: Evaluating Effectiveness and a Call for Reform, at 7, https://www.anh-5 usa.org/wp-content/uploads/2015/09/Prop-65.pdf (last accessed October 7, 2019); see also LATIMES, 6 Warning: Too Many Warnings Signs are Bad for Your Health (Sept. 30, 2017) (noting "Starbucks, 7 Whole Foods and about 80 other places in California that sell coffee" are exposed under 8 Proposition 65 even though "research increasingly" indicates coffee does *not* cause cancer), 9 http://beta.latimes.com/opinion/editorials/ la-ed-proposition-65-warning-coffee-20170930-story.html; 10 Richard Berman, Thanks to a Poorly-Designed Law, California Classifies Soft Drinks as a Cancer Risk, Forbes (Feb. 20, 2014) (compelling warnings for soda drinks on the basis that if consumers 12 drink "over 1,000 sodas a day" they would have increased cancer risk); Greg Ryan, *Rice Sellers* 13 Threatened with Prop 65 Suits over Lead, Arsenic, Law360 (Feb. 20, 2014).

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**Proposition 65 Listing of Acrylamide and Subsequent Enforcement Actions** 

48. OEHHA added acrylamide to the Proposition 65 list of carcinogens in 1990 pursuant to the Authoritative Bodies listing mechanism, based on EPA's determination that acrylamide was a "probable" human carcinogen and IARC's classification of acrylamide as Group 2B ("possibly carcinogenic to humans"). IARC has since re-classified acrylamide as Group 2A ("probably carcinogenic to humans").

20 49. The initial Proposition 65 listing of acrylamide was premised on potential exposures to 21 acrylamide in industrial settings. At that time, it was not known that acrylamide was present in 22 cooked foods. Acrylamide was not detected in foods until 2002.

23 50. Both the EPA and IARC classifications of acrylamide as a "probable" human 24 carcinogen are based on studies in laboratory animals in which virtually pure acrylamide was 25 administered orally or via injection to rats and mice. EPA and IARC did not classify acrylamide as a 26 probable carcinogen based on studies in *humans*. In its most recent assessment of acrylamide, for 27 example, IARC concluded in 1994 that there was "inadequate evidence in humans for the carcinogenicity of acrylamide." See IARC Monographs on the Identification of Carcinogenic Risks 28

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to Humans, *Some Industrial Chemicals*, Vol. 60 at 425 (Feb. 1994), https://monographs.iarc.fr/wpcontent/uploads/2018/06/mono60.pdf. Similarly, in its most recent toxicological review of acrylamide in 2010, EPA explained that human studies assessing the carcinogenicity of acrylamide (including studies of both dietary and industrial exposures) "are judged as providing limited or no evidence of carcinogenicity in humans." U.S. EPA, *Toxicological Review of Acrylamide* at 167 (March 2010), https://cfpub.epa.gov/ncea/iris/iris\_documents/documents/toxreviews/0286tr.pdf.

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

14 52. OEHHA also has recognized that acrylamide in certain food products-namely, 15 coffee—does not increase human cancer risk. In particular, in June 2019, OEHHA adopted a new regulation that states: "Exposures to chemicals in coffee, listed on or before March 15, 2019 as 16 17 known to the state to cause cancer, that are created by and inherent in the processes of roasting coffee beans or brewing coffee do not pose a significant risk of cancer." 27 Cal. Code Regs. § 25704 18 19 (effective Oct. 1, 2019). In adopting this regulation, OEHHA explained that "[t]he weight of the 20 evidence from the very large number of studies in the scientific literature does not support an 21 association between the complex mixture of chemicals that is coffee [including acrylamide] and a 22 significant risk of cancer." OEHHA, Final Statement of Reasons, Adoption of New Section 25704 23 Exposures to Listed Chemicals in Coffee Posing No Significant Risk (June 7, 2019), 24 https://oehha.ca.gov/media/downloads/crnr/fsorcoffee060719.pdf.

53. Since its listing in 1990, acrylamide has been the target of significant Proposition 65
enforcement activity, particularly with respect to food products. In the first such litigation, several
private enforcers were joined by the California Attorney General in pursuing claims that several
major restaurants and food manufacturers failed to provide Proposition 65 warnings for acrylamide in

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French fries, potato chips, and other potato products. The California Attorney General eventually settled these claims with each of the defendants. Under the terms of the settlements, the restaurant 3 defendants, which include McDonald's, Wendy's, Burger King, and KFC, must provide warnings for acrylamide in French fries and similar products. The manufacturer defendants, which include the makers of Pringles, Lay's, Baked Lay's, Kettle, and other potato chip products, must either reduce the levels of acrylamide in their products or provide warnings to consumers. Likewise, the makers of 6 Ore-Ida frozen potato products must change their cooking instructions in order to encourage 8 consumers to reduce the levels of acrylamide in the finished products they cook at home. The Attorney General has also entered into settlements with makers of other snack food products on similar terms that require warnings if acrylamide concentrations exceed specified levels.

54. Under Proposition 65, private parties are required to provide 60-days' notice-to the California Attorney General, the district attorney, city attorney, or prosecutor in whose jurisdiction the violation is alleged to have occurred, and to the alleged violator—before initiating an enforcement action. See Cal. Health & Safety Code § 25249.7(d)(1). The California Attorney General maintains a database of these 60-day notices (the "AG Database"), available at https://oag.ca.gov/prop65/60day-notice-search.

55. To date, there have been more than *five hundred sixty* 60-day notices for alleged violations of the Proposition 65 warning requirement with respect to alleged exposures to acrylamide. More than *five hundred* of these 60-day notices relate to acrylamide in food products.

20 56. These 60-day notices include alleged violations related to, among others: potato and 21 potato-based products (more than 90 notices); nut butters, including peanut and almond butter (more 22 than 40 notices); almonds (more than 30 notices); cereals (more than 20 notices); and olives (more than 10 notices). 23

24 57. Notably, although acrylamide has been on the Proposition 65 list for many years, the 25 number of 60-day notices has increased exponentially in recent years, going from only three notices 26 in 2015 to 32 notices in 2016 to 144 and 147 notices in 2017 and 2018, respectively. The number of 27 notices filed for 2019, moreover, has already exceeded 2018's amount, as 170 notices were filed by 28 October 4, 2019.

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58. Many of these 60-day notices have resulted in litigation or settlements, and there is a real and credible threat that other companies are likely to be future targets of Proposition 65 litigation related to alleged exposures to acrylamide in food products. Indeed, in July 2019 alone, just three private enforcers filed *forty-four* 60-day notices for the alleged presence of acrylamide in food products.

## ADVERSE IMPACTS TO PLAINTIFF, ITS MEMBERS, AND THE PUBLIC

59. If not enjoined, the Proposition 65 warning requirement for chemicals listed as "known to the State of California to cause cancer," as applied to acrylamide in food products, will have an immediate and irreversible impact on Plaintiff, its members, and the public.

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

61. Because of California's listing of acrylamide and the attendant Proposition 65 warning
requirement, Plaintiff's members must either take action, in conjunction with their distributors and
customers, to provide false, misleading, and factually controversial warnings to California consumers
about acrylamide in their food products—conveying the unsubstantiated message that acrylamide in
food products increases cancer risk in humans—or face enforcement actions seeking substantial civil
penalties and attorneys' fees for failing to do so.

62. Alternatively, Plaintiff's members may be forced to undertake costly exposure
assessments for their acrylamide-containing products to demonstrate that any exposures to
acrylamide from their products do not exceed the NSRL and do not require warnings. And even if
Plaintiff's members' assessments indicate that exposures to acrylamide from their products do not
exceed the NSRL, they still would need to prepare to defend against likely enforcement actions by
private enforcers. Private enforcers are not required to defer to a company's exposure assessment
and may dispute the exposure assessment. Thus, a company that wishes to defend its exposure

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assessment and to prove that an exposure does not exceed the NSRL faces the prospect of costly and risky litigation on a technical and expert-heavy defense.

63. The requirement to place a false, misleading, and highly controversial Proposition 65 cancer warning for acrylamide on food products has had, and will continue to have, a substantial adverse impact on Plaintiff's members. Such a warning disparages Plaintiff's members and their food products by creating the false impression among consumers that those products are unsafe and increase human cancer risk, despite scientific evidence suggesting that acrylamide that forms naturally in food does not increase (and may even *reduce*) the risk of cancer in humans.

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

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

14 66. FDA has explained, for example, that "requiring a cancer warning on coffee, based on 15 the presence of acrylamide, would be more likely to mislead consumers than to inform them." FDA, Statement from FDA Commissioner Scott Gottlieb, M.D., on FDA's Support for Exempting Coffee 16 17 from California's Cancer Warning Law (August 29, 2018) ("FDA Statement on Coffee"); see also 18 Letter from Lester M. Crawford, DVM, Ph.D, Deputy Commissioner, FDA, to Joan E. Denton, M.S., 19 Ph.D., Director, California Office of Environmental Health Hazard Assessment (July 13, 2003) 20 ("2003 FDA Letter") ("[W]arning labels based on the presence of acrylamide in food might be 21 misleading.").

67. Foods that contain acrylamide are part of a well-balanced diet. These include whole
grains, almonds, and nut butters as examples. With respect to whole grains, for example, FDA
Commissioner Dr. Scott Gottlieb explained in August 2018: "We recognize that some [whole grain
food] products may contain acrylamide. But we also know that consumption of whole grains is
beneficial for health and nutrition. Labeling whole grain foods with a cancer warning may cause
American consumers to avoid foods that would have a benefit to their health, including avoiding
foods that may reduce cancer risks." *See* FDA Statement on Coffee; *see also* 2003 FDA Letter ("[A]

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requirement for warning labels on food might deter consumers from eating foods with such labels. Consumers who avoid eating some of these foods, such as breads and cereals, may encounter greater risks because they would have less fiber and other beneficial nutrients in their diets.").

68. Similarly, the Dietary Guidelines (see  $\P 21$ , supra) emphasize that vegetables and nuts are part of a healthy diet. Because of California's listing of acrylamide and the attendant warning requirement, numerous food products that the Dietary Guidelines recommend as part of a healthy diet—including olives, peanuts, almonds, and nut butters—have been the target of 60-day notice letters and enforcement litigation under Proposition 65. If Plaintiff's members are forced to provide warnings for these products, consumers will be misled to avoid them.

10 69. In addition, requiring businesses to apply a Proposition 65 cancer warning for acrylamide in food products will mislead consumers into thinking that acrylamide is only present in 12 store-bought food. Raw foods ordinarily do not contain acrylamide. Because acrylamide forms 13 naturally during the cooking process, however, acrylamide can form in those foods when cooked at 14 consumers' homes. Indeed, FDA has observed that consumer exposure to acrylamide "may be 15 greatest through home cooking." See Letter from Lester M. Crawford, DVM, Ph.D, Deputy Commissioner, FDA, to Joan E. Denton, M.S., Ph.D., Director, California Office of Environmental 16 Health Hazard Assessment (July 13, 2003).

18 70. Finally, requiring businesses to apply a Proposition 65 cancer warning for acrylamide 19 in food products, despite the lack of reliable scientific evidence supporting a finding that acrylamide 20 from food products increases human cancer risk, dilutes the effectiveness of legitimate Proposition 65 21 warnings. See, e.g., RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY §2 cmt. j (1998) (noting 22 that excessive, multitudinous warnings "may be ignored by users and consumers and may diminish 23 the significance of warnings about [other] risks" and "could reduce the efficacy of warnings 24 generally."); Nicolle-Wagner v. Deukmejian, 230 Cal. App. 3d 652, 661 (1991) ("'[U]nnecessary 25 warnings . . . could distract the public from other important warnings on consumer products.' Since 26 one of the principal purposes of [Proposition 65] is to provide 'clear and reasonable warning' of 27 exposure to carcinogens and reproductive toxins, such warnings would be diluted to the point of 28 meaninglessness if they were to be found on most or all food products.") (quoting the Final Statement

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of Reasons for the "naturally occurring" regulation now found at CAL. CODE REGS. tit. 27, §25501)); *accord Johnson v. Am. Standard, Inc.*, 43 Cal. 4th 56, 70 (2008) (quoting *Finn v. G.D. Searle & Co.*, 35 Cal. 3d 691, 701 (1984)).

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

72. An order enjoining the Proposition 65 warning requirement for cancer as applied to acrylamide in food products would redress the harms described above.

## **CLAIM FOR RELIEF**

#### (Violation of the First Amendment to the U.S. Constitution)

73. The foregoing Paragraphs are incorporated by reference as if set forth in full herein.
74. The Free Speech Clause of the First Amendment of the United States Constitution
provides that "Congress shall make no law . . . abridging the freedom of speech." U.S. Const. amend.
I. The Fourteenth Amendment of the United States Constitution made this proscription applicable to
the States and their political subdivisions. *See id.* amend. XIV § 1.

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

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

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provide information in connection with commercial transactions are permissible only if the compelled disclosure is of information that is purely factual and uncontroversial, reasonably related to a substantial government purpose, and not unjustified or unduly burdensome. See Nat'l Inst. of Family & Life Advocates v. Becerra, 138 S. Ct. 2361, 2372, 2377 (2018) ("NIFLA"); Zauderer v. Office of Disciplinary Counsel, 471 U.S. 626, 651 (1985). The Government bears the burden to show that a compelled disclosure is permissible under the First Amendment.

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

78. 10 Contrary to the warning mandated by Proposition 65, there is no reliable scientific evidence that dietary acrylamide increases the risk of cancer in humans. To the contrary, a large 12 number of epidemiological studies suggest that there is no association between exposure to 13 acrylamide from food products and cancer in humans.

14 79. Nor does California "know" that dietary acrylamide causes cancer. In fact, the 15 California agency responsible for implementing Proposition 65—OEHHA—has admitted that OEHHA does not know that acrylamide is a human carcinogen. See ¶ 51, supra. 16

80. Moreover, even the agencies on which OEHHA relied to add acrylamide to the 18 Proposition 65 list—EPA and IARC—have not said that they "know" that exposure to acrylamide 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 administered orally or via injection to rats and mice. EPA and IARC have concluded, respectively, that studies of acrylamide in humans (of which there are many) provide "inadequate" and "limited or no" evidence of carcinogenicity in humans. See ¶ 50, supra.

81. The Proposition 65 cancer warning requirement as applied to acrylamide in food products thus compels speech that is false, misleading, and factually controversial.

82. 26 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 scrutiny. See Video Software Dealers Ass'n v. Schwarzenegger, 556 F.3d 950, 967 (9th Cir. 2009) 28

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

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

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant as follows:

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

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

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1	individuals (including private enforcers of Proposition 65 under Cal. Health & Safety Code				
2	§ 25249.7(d)), from enforcing or threatening to enforce the Proposition 65 warning requirement for				
3	cancer with respect to acrylamide in food products intended for human consumption.				
4	4. All costs, attorneys' fees, and expenses that Plaintiff reasonably incurs, <i>see</i> 42	All costs, attorneys' fees, and expenses that Plaintiff reasonably incurs, see 42 U.S.C.			
5	5 § 1988; and				
6	5. Such other and further relief as this Court deems just and proper.	Such other and further relief as this Court deems just and proper.			
7	7				
8	8 Dated: October 7, 2019 Respectfully submitted,				
9	9				
10	Trenton H. Norris (CA Bar No. 164781)				
11	Sarah Esmaili (CA Bar No. 206053) S. Zachary Fayne (CA Bar No. 307288)				
12	ARNOLD & PORTER KAYE SCHOLER LLP				
13	San Francisco, CA 94111-4024				
14 15	trent norris@arnoldporter.com				
15	Attorneys for Plaintiff California Chamber of C	ommerce			
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1	COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF				