Case No. 21-15745

IN THE UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS,

Defendant-Intervenor-Appellant,

v.

CALIFORNIA CHAMBER OF COMMERCE, *Plaintiff-Appellee*.

ROB BONTA, in his Official Capacity as Attorney General of the State of California, *Defendant*.

Appeal from a Preliminary Injunction Entered by the United States District Court for the Eastern District of California
District Court Case No. 2:19-cv-02019-KJM-JDP
(Honorable Kimberly J. Mueller, Chief District Judge, Presiding)

AMICUS CURIAE BRIEF OF CONSUMER BRANDS ASSOCIATION, AMERICAN BAKERS ASSOCIATION, AMERICAN BEVERAGE ASSOCIATION, CALIFORNIA GRAIN AND FEED ASSOCIATION, CALIFORNIA LEAGUE OF FOOD PRODUCERS, CALIFORNIA GROCERS ASSOCIATION, CALIFORNIA RETAILERS ASSOCIATION, CALIFORNIA SEED ASSOCIATION, NATIONAL CONFECTIONERS ASSOCIATION, PLANT CALIFORNIA ALLIANCE, AND SNAC INTERNATIONAL IN SUPPORT OF PLAINTIFF-APPELLEE AND AFFIRMANCE

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CORPORATE DISCLOSURE

Pursuant to Rules 26.1 and 29(a)(4)(A) of the Federal Rules of Appellate Procedure, *amici curiae* state that none of them has a parent corporation and no publicly held corporation owns 10% or more stock in any *amici*.

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INTRODUCTION

This case presents important issues about when food and beverage companies can be compelled, consistent with the First Amendment, to provide cancer warnings about their products. Plaintiff-Appellee California Chamber of Commerce ("CalChamber") obtained a preliminary injunction precluding the California attorney general and private attorneys from bringing enforcement actions over exposure to acrylamide in food under the California Safe Drinking Water and Toxic Enforcement Act of 1986, Cal. Health & Safety Code §§ 25249.5 *et seq.*[1] (commonly known as "Proposition 65"). Acrylamide is a chemical that naturally occurs in some foods, and is naturally created when many common foods are heated (whether they are manufactured or cooked at home). The injunction was issued on the basis that a compelled cancer warning for dietary acrylamide is neither factual nor uncontroversial, and thus violates businesses' First Amendment speech rights under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985).

Amici curiae support affirmance of the injunction. We provide

[1] Further non-specific statutory references are to the California Health & Safety Code.

background to the district court's conclusion that businesses are compelled to provide a warning that confuses consumers and leads them to believe that consuming foods that contain acrylamide will increase their risk of cancer. From its shifting of the burden of proof on complex scientific exposure questions to defendants, to its illusory "safe-harbor" approach to warnings and no-significant-risk regulations, Proposition 65 systematically stacks the deck in favor of private parties that claim to enforce the act "in the public interest." It compels businesses faced with enforcement to either provide scientifically baseless, or at best controversial warnings, or otherwise capitulate to the enforcers' demands.

These effects have been magnified in the case of dietary acrylamide, given its natural and unavoidable presence in a variety of foods and beverages. Acrylamide can be naturally present at levels that are asserted to exceed the state's safe-harbor "no-significant-risk level," which was developed from high-dose animal studies. Warning on this basis is inconsistent with substantial epidemiologic evidence regarding human cancer risk from dietary acrylamide.

We also address the impact of arguments that Defendant-

Intervenor-Appellant Council for Education and Research on Toxics ("CERT") makes on appeal. Although it has not served a notice of violation over acrylamide in over five years, and has not identified any anticipated litigation affected by the preliminary injunction, CERT argues that the injunction violates its petitioning rights. It provides no authority for the proposition that it has cognizable petitioning rights, and nothing in the record supports CERT's position that the injunction affects any such rights.

CERT's claim that the district court improperly ignored trial testimony of its experts in a case involving acrylamide in coffee is also irrelevant. This testimony failed to negate substantial evidence that dietary acrylamide's carcinogenicity in humans is *controversial* under *Zauderer*, and that the safe-harbor warning misleads consumers regarding their risk of cancer.

Finally, CERT's proposed remedy—to sever the warning requirement from Proposition 65, but only for nonfactual, controversial warnings—is contrary to the intent of the electorate and would have the unintended effect of prohibiting foods that exceed the no significant risk level, with significant adverse impacts to the consumers that CERT

claims to protect.

For all of these reasons, and the other arguments asserted by CalChamber in its brief, this Court should affirm the district court's order granting the preliminary injunction.

INTEREST OF *AMICI CURIAE*

Amici curiae are California and national associations involved in the manufacture, distribution, and retail sale of food and food products. *Amici* have extensive experience with Proposition 65 and its impacts on food producers, distributors, and retailers. No counsel of any party authored any part of this brief. No party or party's counsel, or person other than *amici*, contributed money that was intended to fund preparing or submitting this brief.

The Consumer Brands Association represents the world's leading consumer-packaged goods companies, as well as local and neighborhood businesses. The consumer-packaged goods industry is the largest U.S. manufacturing employment sector, delivering products vital to the well-being of people's lives every day, and contributes $2 trillion to U.S. gross domestic product and supports more than 20 million American jobs.

The American Bakers Association ("ABA") is the voice of the wholesale baking industry, including more than 1,000 baking facilities and baking company suppliers. The baking industry generates more than $153 billion in economic activity annually, engaging the services of

more than 799,500 highly-skilled individuals in manufacturing and selling its products.

The American Beverage Association represents America's nonalcoholic beverage industry, including manufacturers and bottlers of carbonated and non-carbonated soft drinks, juices and juice drinks, ready to drink coffees and teas, and bottled water. The beverage industry directly employs more than 265,000 people and has a direct economic impact of more than $174 billion.

The California Grain and Feed Association ("CGFA") is a non-profit collaborative organization representing firms that provide feed and nutrients to California's livestock farmers, equestrian industry and companion animals.

The California Grocers Association is a non-profit, statewide trade association representing approximately 500 retail members operating over 6,000 food stores in California and Nevada, and approximately 300 grocery supplier companies. Retail membership includes chain and independent supermarkets, convenience stores, and mass merchandisers.

The California League of Food Producers is a nonprofit, statewide trade association representing the food processing industry since 1905. The League's membership includes most of the processors of fresh agricultural products in California.

The California Retailers Association is a statewide trade association representing all segments of the retail industry including general merchandise, department stores, mass merchandisers, online markets, restaurants, convenience stores, supermarkets and grocery stores, chain drug and specialty retail stores. It represents a quarter of the state's employment and $330 billion worth of gross domestic product.

The California Seed Association is a non-profit trade group representing the members of seed industry including growers, researchers and allied industries. California Seed Association works on behalf of the seed industry to promote the research, development and movement of quality seed to meet the world's demand for food, feed, fiber and fuel.

The National Confectioners Association ("NCA") represents more than 250 companies that manufacture chocolate, confectionery, gum

and mints in the United States and another 250 companies that supply those manufacturers. NCA's members have previously been confronted with a significant number of Proposition 65 private enforcers' claims concerning acrylamide.

The Plant California Alliance is a non-profit trade association serving the nursery industry and entities that bring plants to Californians. The Plant California Alliance works to make sure people understand that plants support the health and well-being of Californians and that plants are essential to the California way of life.

SNAC International is the international trade association of the snack food industry, representing over 400 snack manufacturers, marketers, and suppliers worldwide.

ARGUMENT

I. Proposition 65 compels businesses to provide misleading warnings about dietary acrylamide or capitulate to private enforcers' settlement demands.

A. Proposition 65 private enforcers systematically compel businesses to warn or capitulate to settlement demands, regardless of the merits of a claim.

The pressure that private enforcement of Proposition 65 puts on businesses to provide warnings, even if exposures to listed chemicals do not exceed the warning thresholds, is well-chronicled.[2] The factors that combine to create this intense pressure are manifold.

1. The enforcer's minimal burden.

By design, § 25249.6 puts a minimal burden on a plaintiff to demonstrate a *prima facie* case of liability for failure to warn of exposure. The plaintiff need not prove the amount of the exposure, or that it poses a significant risk of cancer or reproductive toxicity. It must only show that the defendant caused individuals to "come into contact

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[2] *See, e.g.,* Mohan, Geoffrey, *You see the warnings everywhere. But does Prop. 65 really protect you?* LOS ANGELES TIMES, July 23, 2020, https://www.latimes.com/business/story/2020-07-23/prop-65-product-warnings ("Companies in every sector of the consumer economy now routinely attach warnings for any of the more than 900 chemicals and elements covered by Proposition 65, without testing for them or attempting to reformulate products. They fear citizen-enforcer lawsuits more than they fear freaking out customers.").

with a listed chemical." Cal. Code Regs. tit. 22, § 25192(i) (defining "expose").[3] Once the plaintiff establishes a knowing and intentional exposure to any amount of a listed chemical without warning, it has made its prima facie case. The burden then shifts to the defendant to establish that an exposure is exempt from the warning requirement because its amount poses no significant risk of cancer or is 1,000 times below the "no observable effect level" for reproductive toxins. § 25249.10(c); *see Consumer Cause, Inc. v. SmileCare*, 91 Cal. App. 4th 454, 473 (2001). "Needless to say, these provisions make the instigation of Proposition 65 litigation easy–and almost absurdly easy at the pleading stage and pretrial stages." *Consumer Defense Grp. v. Rental Hous. Indus. Members*, 137 Cal. App. 4th 1185, 1215 (2006) (footnote omitted).

2. The illusory safe harbors.

While the California Office of Environmental Health Hazard Assessment ("OEHHA") has promulgated so-called "safe harbors" in its implementing regulations for determining whether an alleged exposure

[3] Further references to the Proposition 65 implementing regulations, found in title 27 of the California Code of Regulations, shall be to "Regulation § [number]."

meets the exposure exemption defense of § 25249.10(c), *e.g.,* Regulation § 25701(a),[4] and for conveying Proposition 65 warnings for consumer products, *see* Regulation § 25600(a),[5] those safe harbors are mandatory in practice. This is because private enforcers assert that the safe harbors are mandatory,[6] and it is expensive and risky for a business to attempt to establish that a non-safe-harbor warning is "clear and reasonable" or to demonstrate no significant risk through a non-safe-harbor exposure exemption defense. CalChamber submitted unrebutted evidence to establish this point on the safe-harbor warning language. 2-ER-149–50, 153–56. The district court found this showing "persuasive," such that "the seas beyond the safe harbor are so perilous that no one risks a voyage." 1-ER-28.

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[4] "Nothing in this article shall be construed to preclude a person from using evidence, standards, risk assessment methodologies, principles, assumptions or levels not described in this article to establish that a level of exposure to a listed chemical poses no significant risk [of cancer]."

[5] "Nothing in this article shall be construed to preclude a person from providing a warning using content or methods other than those specified in this article that nevertheless complies with Section 25249.6 of the Act."

[6] *See* Section I.B below, where we discuss how a California trial court held, at CERT's urging, that the method of determining no significant risk under the "safe-harbor" regulation was mandatory.

3. The significant burden on defendants to prove no significant risk.

Even under the safe-harbor approach, businesses carry a heavy burden to demonstrate that the amount of exposure to a listed chemical is exempt from the warning requirement.

> [T]he burden shifting provisions make it virtually impossible for a private defendant to defend a warning action on the theory that the amount of carcinogenic exposure is so low as to pose "no significant risk" … short of actual trial. There is no way a defendant is going to be able to carry its burden on demurrer based on allegations in the complaint, and a defendant will probably not be able to carry that burden on summary judgment either. [¶] Rather, in a case of a negligible, even microscopic "exposure" …, it may take a full scale scientific study to establish the amount of the carcinogen is so low that there is no need for a warning under Health and Safety Code section 25249.10.

Rental Hous. Indus. Members, 137 Cal. App. at 1214 (citations omitted). Thus, in a case involving dental amalgam fillings containing trace amounts of mercury, where the defendant submitted an expert

declaration that the fillings were approved by the American Dental Association and had been used safely for 150 years without causing adverse physical effects beyond allergic reactions, *and the plaintiff admitted in discovery that it had no evidence that the level of exposure required a warning*, the Court of Appeal reversed summary judgment in favor of the defendant because the expert's declaration did not undertake the "highly technical" analyses of the no observable effect level or the level of exposure to mercury from dental amalgam. *SmileCare*, 91 Cal. App. 4th at 464, 470–74.[7] CERT does not contest the district court's finding that "a successful defense might be impossible to mount, practically speaking." 1-ER-14.

Even where defendants have braved a trial, they have often required a substantial investment of resources from industry members who have banded together. *See, e.g., People ex rel. Lockyer v. Tri-Union Seafoods, LLC*, No. CGC-01-402975, 2006 WL 1544384 (Cal. Super. Ct. May 11, 2006), *aff'd,* 171 Cal. App. 4th 1549 (2009) (five-year litigation

[7] And to our discussion in Section I.A.2 concerning the illusory nature of safe harbors, OEHHA noted in a 2018 rulemaking that the analysis in *SmileCare* is *not* a requirement under § 25249.10(c), but "is only relevant to establishing the *safe-harbor defense*." 3-ER-330 (emphasis added).

over mercury in seafood; defendant's experts included a medical doctor, an FDA/labeling expert, a consumption expert, a toxicologist, and two experts regarding whether the chemical at issue was naturally occurring); *Environmental Law Foundation v. Beech-Nut Nutrition Corp.*, No. RG11597384, 2013 WL 5402373 (Cal. Super. Ct. July 31, 2013), *aff'd,* 235 Cal. App. 4th 307 (2015) (litigation over lead in fruit and fruit juice; defendants used seven experts, including a nutritional biochemist, toxicologists, and a developmental nutritionist); *Council for Education and Research on Toxics v. Starbucks Corp., et al.,* No. BC435759 (Los Angeles Superior Court) (*Starbucks*) (ten-year litigation over acrylamide in coffee; defendants used three experts in the first liability phase and four experts in the second phase, 13-ER-3311–12, 7 ER-1695–97).

4. Private enforcement as a force multiplier effect.

The combination of:

- Potentially crippling penalties of up to $2500 per violation per day;

- The delegation the state's interest in enforcing the warning requirement to private actors who are entitled to a 25 percent "bounty" on such penalties, §25249.7(b); and
- Potential recovery of "private attorney general" fees under Cal. Code Civ. Proc. §1021.5,

puts powerful weapons in the hand of lawyers who are beholden only to their own idiosyncratic goals. While Proposition 65 nominally puts the California attorney general in a position to oversee private enforcement, *see Nat'l Paint & Coatings Assn., Inc. v. State of California*, 58 Cal. App. 4th 753, 763 (1997), the state has no meaningful ability to block private parties from pursuing non-meritorious actions. 2-ER-152–53. Indeed, the attorney general's office has a long-standing policy that it will not pursue enforcement actions where a private enforcer's case is without merit. The only "oversight" it provides of such actions has been to at times send an advisory letter to an enforcer indicating that it considers a notice to be without merit. Such no-merit letters are toothless. 2-ER-152–53.

Private enforcement acts as a "force-multiplier effect" to the burden imposed on businesses by Proposition 65. One California

appellate justice noted that coupling the private enforcement mechanism with the shift of the burden of proof to the defendant "encouraged a form of judicial extortion." *SmileCare*, 91 Cal. App. 4th at 478 (Vogel, J. dissenting). Describing the reality of private enforcement, Justice Vogel stated:

> Here is how it works (it certainly appears to be what was done in this case). Pick a dentist or doctor, any dentist or doctor (but preferably one with a deep pocket). Visit the dentist's or doctor's office. If you don't see Proposition 65 warning signs on the walls or counters, go to the nearest courthouse, file a complaint, allege a failure to warn, and ask for $ 2,500 for each day the dentist or doctor has failed to give the required warnings. Don't be concerned when the dentist or doctor answers and alleges as an affirmative defense that he is exempt from the warning requirements because he uses only trace amounts of the chemical, and certainly not enough so that anyone's exposure to the chemical is 1,000 times the level that will result in an observable effect. Don't worry when the dentist or doctor

> sends you some interrogatories and requests for admissions—go ahead and admit that you have no evidence about the level of the chemical he uses (and thus no reason to believe that he is in violation of the law), and admit that you do not contend that exposure at the level used by the dentist or doctor will result in any observable effect.
>
> The dentist or doctor won't be able to get out of the case by a motion for summary judgment based on your admissions. Instead, he'll have to commission an "assessment" to prove that his level of use is safe, and he will have to pay for the kind of "assessment" done by the State of California when it determines that a chemical should be added to the Proposition 65 list. How many thousands of dollars will that cost? I don't know, but I do know that, whatever the cost, the end product will not guaranty a judgment for the defense. What's a dentist or doctor to do? Settle with the plaintiff, of course. Save the cost of the assessment. Save the legal fees. Get rid of the case.

Id.

Relying on these "trenchant and accurate" "observations about the ease of bringing Proposition 65 litigation," the Court of Appeal later observed "just how simple it is for a hypothetical unemployed lawyer, eager to cash in on Proposition 65, to extract money from businesses using the initiative." *Rental Hous. Indus. Members*, 137 Cal. App. at 1214–17 & n. 23. Reversing approval of a settlement, the court remarked, "this settlement represents the perversity of a shakedown process in which attorney fees are obtained by bargaining away the public's interest in warnings that might actually serve some public purpose." *Id.* at 1219.

In 2013 former Governor Brown announced an ill-fated legislative approach "to revamp Proposition 65 by ending frivolous 'shake-down lawsuits."[8] He acknowledged that Proposition 65 had been "abused by some lawyers, who bring nuisance lawsuits to extract settlements from businesses with little or no benefit to the public or the environment." *Id.* Little came of this effort, which failed to garner enough support to

[8] Office of Governor Edmund G. Brown Jr., "Governor Brown Proposes to Reform Proposition 65" (May 7, 2013), https://www.ca.gov/archive/gov39/2013/05/07/news18026/index.html.

overcome the two-thirds' legislative majority required to amend Proposition 65. Proposition 65, § 7.

Private enforcement has soared since 2013. That year, private enforcers served 1,100 pre-suit notices of violation.[9] By 2020, the number of pre-suit notices had *more than tripled* to 3,551. *Id.* There was a commensurate growth in the number and cost of settlements of these notices. In 2013, the attorney general reported 350 private settlements (court approved and out-of-court combined) with total settlement payments of nearly $17 million (including approximately $12.5 million in attorney's fees).[10] By 2019,[11] there were 899 private settlements costing $30 million, comprising 284 court-approved settlements with payments of $17.5 million ($11.7 million in attorney's fees),[12] and 615 out-of-court settlements with payments of $12.5 million ($11 million in

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[9] "60-Day Notice Search" (last accessed June 22, 2021), https://oag.ca.gov/prop65/60-day-notice-search.

[10] "Proposition 65 Settlement Summary – 2013" (2013), https://oag.ca.gov/sites/all/files/agweb/pdfs/prop65/alpert-rpt2013.pdf.

[11] Litigation and settlements were diminished substantially due to disruption to businesses and courts from the COVID-19 pandemic, making direct comparisons of settlements to notices in 2020 potentially misleading.

[12] Office of the Attorney General, "Judgments by Plaintiff Report" (last accessed June 22, 2021), https://oag.ca.gov/prop65/report/judgments-by-plaintiffs?year%5Bvalue%5D%5Byear%5D=2019.

attorney's fees).[13] What was once a cottage industry has become big business for private enforcers and their counsel.

B. The pressures on businesses to provide a confusing and misleading warning about the risk of cancer from their food products.

Soon after the discovery of acrylamide in food in April 2002, CERT commenced Proposition 65 enforcement over French fries and potato chips. Since 2002, over 350 companies had received pre-suit notices of alleged violation over acrylamide in a variety of foods through the date CalChamber filed its motion. 2-ER-147. Even with the pandemic at its height, 465 of the 3,551 pre-suit notices served in 2020 (13 percent) alleged exposure to acrylamide in a food product.[14] Through June 22, 2021, another 129 such notices were served this year, including 31 notices that have been served since the district court issued its injunction on March 30.[15] Many of these notices were served on small and mid-sized food companies who may not have the resources to

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[13] "Out-of-Court Settlements Report" (last accessed June 22, 2021), https://oag.ca.gov/prop65/report/out-of-court-settlements?year%5Bvalue%5D%5Byear%5D=2019.
[14] "60-Day Notice Search" (last accessed June 22, 2021), https://oag.ca.gov/prop65/60-day-notice-search.
[15] *Id.*

litigate with private enforcers. And a number of factors make it difficult for even the bravest of companies to attempt to defend against acrylamide claims on the merits.

First, the "absurdly easy" description of a plaintiff's burden is exemplified in claims involving acrylamide in food. Acrylamide "has likely always been a part of many foods," because it occurs naturally or as a result of a reaction between sugars and the amino acid asparagine (a building block of proteins). 1-ER-5. It is found in a variety of foods, including almonds, bread, cereal, cookies, coffee, crackers, French fries, olives, pancakes, peanuts, pizza, and prune juice. 8-ER-1819.

Second, the defense burden to prove no significant risk can be substantial in cases involving dietary acrylamide. The safe-harbor no-significant-risk level ("NSRL") is 0.2 micrograms[16] per day. Regulation § 25705(b). During a later-withdrawn 2005 rulemaking over dietary acrylamide, OEHHA calculated the average daily exposure to acrylamide from a variety of foods and found that, depending on frequency of consumption, many exceeded the safe-harbor NSRL, and a

[16] A microgram is 1/1,000,000th of a gram. Accordingly, daily exposure to 0.0000002 grams of acrylamide (equivalent to 0.00511 grams over a 70-year lifetime) exceeds the safe-harbor NSRL.

number also exceeded an alternative significant risk level the agency was considering. 8-ER-1822-29.

Thus, with bulls-eyes painted squarely on their backs, businesses that want to avoid a confusing and misleading warning for acrylamide that naturally occurs in food would need to do the following, through expert testimony that will be contested:

- Establish a higher NSRL than the 0.2 micrograms per day safe harbor;
- Provide test data that is materially lower than the U.S. Food & Drug Administration published data on acrylamide in foods;
- Establish a lower frequency of intake of the food at issue;
- Demonstrate no significant risk by a method other than the safe harbor; and/or
- Establish an "alternative significant risk level" under Regulation § 25703(b)(1) (allowing an alternative level of "no significant risk … where sound considerations of public health support an alternative level, as, for example: (1) where chemicals in food are produced by cooking necessary

> to render the food palatable or to avoid microbiological contamination.").

The litigation brought by CERT over exposure to acrylamide in coffee demonstrates the heavy burden borne by companies, large and small, in defending such cases. CERT sued dozens of manufacturers and retailers of coffee, claiming that they violated Proposition 65 by exposing individuals to acrylamide. 1-ER-146. The companies tried all of the above approaches, without success.

The first phase of trial included the no-significant-risk and First Amendment defenses. 7-ER-1680. At trial, the defendants offered epidemiology studies showing that there was no significant risk of cancer from ingesting coffee. Even though the implementing regulation specifically states that the safe-harbor approach is *not* mandatory,[17] the trial court stated that the defendants were *required* to use the safe-harbor calculation in Regulation § 25721(c) to prove no significant risk, including a quantitative risk assessment. 7-ER-1664–65. The court further criticized the defendants' use of epidemiologic studies of cancer in coffee drinkers, because "coffee was not a 'substance[s] known to the

[17] *Infra*, note 4.

state to cause cancer.'" *Id.* These assertions had been advanced by CERT, whose proposed statement of decision quoted liberally from the safe-harbor no-significant-risk regulations as if they were mandatory and binding on defendants. *See* 13-ER-3357–69.

The superior court also gave short shrift to the first-amendment defense, improperly putting the burden on the defendants *and* making the defense "dependent on the success of their 'no-significant-risk-level defense.'" 7-ER-1667.

In the second phase, the defendants put forth the "alternative-significant-risk-level" defense under Regulation § 25703(b)(1), because acrylamide is "produced by cooking necessary to render the food palatable or to avoid microbiological contamination." 7-ER-1691. Again, at CERT's urging, the court ignored the language of Regulation § 25721(a) and determined that the safe-harbor approach was binding, stating, "it is necessary to perform a quantitative assessment of the risk of developing cancer from acrylamide in coffee." 7-ER-1693. The court rejected all of defendants' evidence, including testimony from former FDA Commissioner David Kessler regarding the sound considerations of public health used by FDA to determine an alternative-risk level for

chemicals in foods. 7-ER-1695–97. *Despite* finding that "roasting coffee beans is necessary to make coffee palatable and … reduces microbiological contamination," as required by the regulation, the court concluded that the defendants failed to support their conclusion that sound considerations of public health justified an alternative-risk level. 7-ER-1698–99.

OEHHA's rationale for adopting Regulation § 25704, which exempted acrylamide and other heat-formed chemicals in coffee, took the exact approach rejected by the superior court in first phase, relying on an extensive set of epidemiological and other data on cancer in coffee drinkers to determine that these chemicals posed no significant risk of cancer. Contrary to CERT's claim, 13-ER-3310–11, and the superior court's finding, 7-ER-1666, OEHHA found no impediment to analyzing cancer risk from exposure to coffee as a mixture of chemicals, as opposed to the individual chemicals in the mixture. 3-ER-375–376.

Regulation 25704 mooted further discussion or appeal of the superior court's findings on the no-significant-risk and alternative-significant-risk defenses raised for acrylamide in coffee. 2-ER-149. But assuming all's well that ends well for the coffee companies, it took 10

years of litigation, and millions of dollars of defense fees to prevail in the face of CERT's request for over a billion dollars in civil penalties.

Many enforcers do not take CERT's approach to litigation, however. Instead, they prey on the uncertainty of Proposition 65 litigation, and absence of understandable compliance standards in the statute or implementing regulations, by offering to settle with a "reformulation" limit that will be deemed to comply with Proposition 65, in exchange for a bounty that typically consists of a large proportion of attorney's fees. They are not persuaded by scientific assessments that demonstrate no warning is required, even when these assessments scrupulously comply with the parameters set out in OEHHA's regulations. Rather, they price their settlement demands below the significant cost of defending the threatened enforcement action, making it economically difficult for most companies to do anything other than take the settlement terms offered. *Amici*'s counsel and much of the Proposition 65 defense bar regularly advise clients to resolve cases on such terms, even when they are defensible, rather than spending far more on defense lawyers and experts, with no certainty of prevailing.

As if to prove that the private enforcers are firmly in the driver's seat, OEHHA issued a notice of proposed rulemaking in August 2020 that would establish safe-harbor levels for acrylamide in a variety of foods.[18] The Agency's Initial Statement of Reasons[19] stated that *the proposed levels were based exclusively on settlements reached by private enforcers*, *id.* at 15-30, rather than any independent data or analysis by OEHHA, because

> where a food industry defendant has agreed to a given concentration level in a court-approved settlement, OEHHA is presuming that the level is currently feasible. This may not always be the case, but absent evidence demonstrating otherwise, OEHHA is treating the levels established in the selected court-approved settlements as identifying the lowest levels currently feasible.

Id. at 12. Based on our experience, the levels in these settlements are likely well *below* the "level of exposure" to acrylamide that could be

[18] OEHHA, "Notice of Proposed Rulemaking" (Aug. 7, 2020), https://oehha.ca.gov/media/downloads/crnr/nprmcookingheat080720.pdf.
[19] OEHHA, "Initial Statement of Reasons" (Aug. 7, 2020), https://oehha.ca.gov/media/downloads/crnr/isor080720.pdf.

established as posing no significant risk. While these levels may indeed be feasible, given how private enforcers and courts have treated other safe-harbor provisions in the implementing regulations, they are likely to become "ceilings" that businesses will be wary of exceeding.

Simply put, few food companies served with pre-suit notices of exposure to acrylamide in food, let alone summonses and complaints, will have the resources and risk tolerance to fight them on the merits.

II. CERT's right to bring lawsuits under Proposition 65 "in the public interest" does not justify burdening businesses' First Amendment rights by compelling misleading warnings.

CERT's primary argument on appeal is that a preliminary injunction is an improper prior restraint on its First Amendment petitioning right. CERT's brief fails to cite any authority for the proposition that a private party's right to enforce a statute "in the public interest" against third parties, subject to a right-of-first-refusal held by public prosecutors, is a cognizable First Amendment "petitioning right." Nor does it cite any authority that extends the doctrine prohibiting prior restraint on speech to an injunction precluding private enforcers from filing lawsuits. And by painting itself as the victim, CERT fails to acknowledge the undisputed First

Amendment rights of *amici's* members to be free from being compelled to provide a confusing and misleading warning that is not purely factual and non-controversial.

Nor, even if a private-enforcer lawsuit is somehow protected petitioning, does CERT offer any analysis of how a court is to weigh competing First Amendment rights in a case such as this. But the answer to that question is not difficult to discern, and it involves the tools every court of equity uses in assessing injunctive relief: consideration of the likelihood of success, irreparable harm, balancing the equities, and the public interest. *CTIA - The Wireless Ass'n v. City of Berkeley, California*, 928 F.3d 832, 841 (9th Cir. 2019) (citing *Winter v. Nat'l Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)), *cert. denied*, 140 S. Ct. 658 (2019).

The harm to food businesses from providing a compelled cancer warning that is not factual and uncontroversial and thus violates their First Amendment rights is readily apparent. "Irreparable harm is relatively easy to establish in a First Amendment case. '[A] party seeking preliminary injunctive relief in a First Amendment context can establish irreparable injury … by demonstrating the existence of a

colorable First Amendment claim.'" *CTIA*, 928 F.3d at 851 (quoting *Sammartano v. First Judicial District Court*, 303 F.3d 959, 973 (9th Cir. 2002)).

Several factors lead quickly to the conclusion that the impingement on CERT's claimed right to petition by filing actions against food companies is not substantial and far from irreparable. *First*, it is a non-constitutional right that derives solely from the State's interest in requiring warnings; absent the statutory grant of the right to bring actions "in the public interest," CERT would have no right to bring such actions. It has not been injured by any alleged violations of Proposition 65 relating to acrylamide in food,[20] and the act specifically precludes the use of § 25249.6's warning requirement as a basis for imposing any other liability. *See* § 25249.13. CERT's alleged petitioning right is derivative of, secondary to, and dependent on, the state's right to enforce Proposition 65.

[20] Indeed, CERT's counsel served coffee at depositions and meetings relating to the *Starbucks* litigation that were held at his office without providing visible Proposition 65 warnings to employees or visitors, while presumably asserting in the litigation that the company supplying him with the coffee was liable for failing to do so.

Second, CERT's right to file enforcement actions is always subject to the right-of-first-refusal held by public prosecutors. CERT and other private enforcers are required to provide a pre-suit notice of violation to the alleged violators and dozens of public prosecutors, and may only file an enforcement action if 60 days have passed and none of those prosecutors "has commenced and is diligently prosecuting an action against the violation." § 25249.7(d)(2). The purpose of the notice requirement is *not* to give a private party the right to sue in the public interest; it is "to facilitate and encourage the alleged polluter to comply with the law, and to encourage the public attorney charged with enforcement to undertake its duty." *Yeroushalmi v. Miramar Sheraton*, 88 Cal. App. 4th 738, 750 (2001). CERT's assertion that the prior restraint doctrine precludes a court from enjoining it from filing Proposition 65 lawsuits leads to the absurd result that the attorney general is prohibited from "undertak[ing] its duty" by filing enforcement actions, while CERT is able to do so. In fact, it renders the attorney general's oversight a complete nullity, since there is nothing he can do to stop CERT or other enforcers from pursuing actions, whether meritorious or not.

Third, the district court acknowledged that the preliminary injunction did not fully prohibit CERT's alleged petitioning activities, as it allowed CERT to continue to issue demand letters and notices of violation and to engage in settlement negotiations. 1-ER-21. CERT continues to have petitioning rights regarding acrylamide in food. If CERT believes that the public should be warned about exposure to dietary acrylamide, it can petition the state or FDA to issue that warning. And it certainly retains its right to publicly speak on the topic. The injunction simply prevents CERT from using its alleged petitioning rights to file lawsuits that trample the First Amendment rights of *amici's* members not to be compelled to give a warning that misleads consumers to believe that their foods increase the risk of cancer.

Moreover, CERT made no showing that the proposed injunction would actually harm any petitioning rights. In its opposition to the motion for preliminary injunction, CERT mentioned the *Starbucks* litigation and other cases it had previously filed, but did not identify *any* enforcement actions that would be foreclosed by an injunction against new filings. 2-ER-99–100. According to a June 22, 2021, search

of the attorney general's database of pre-suit notices,[21] the most recent notice in which CERT alleged exposure to acrylamide in food was served *over five years ago* on May 24, 2016. Any enforcement action based on that notice was long ago barred by the one-year statute of limitation for civil penalties under Proposition 65. *Shamsian v. Atlantic Richfield Co.*, 107 Cal. App. 4th 967, 976-78 (2009). A court may consider the lack of an evidentiary showing in determining whether irreparable harm to First Amendment rights has been established. *See, e.g., CTIA*, 928 F.3d at 851 ("there is nothing in the record showing harm to CTIA or its members through actual or threatened reduction in sales of cell phones caused by the disclosure compelled by the ordinance."). CERT's attempt to manufacture a prior restraint on its claimed petitioning activities from the injunction is simply not supported by a factual showing in the district court and should be disregarded on appeal.

Fourth, as the district court correctly acknowledged, CERT's position that a preliminary injunction violates the prior restraint doctrine, regardless of the likelihood of success on the merits, had the

[21] "60-Day Notice Search" (last accessed June 22, 2021), https://oag.ca.gov/prop65/60-day-notice-search.

effect of elevating its alleged petitioning right *above amici's* members' actual First Amendment right to be free from compelled misleading speech about their products, and led to the "absurd conclusion" that CERT had a "right to pursue Proposition 65 litigation in state court regardless of any constitutional implications of that litigation." 1-ER-23.

III. CERT has failed to show the District Court abused its discretion in finding that CalChamber was likely to prevail on the merits or that the public interest justified the injunction.

CERT acknowledges that this Court reviews a district court's determination of the moving party's likelihood of success for abuse of discretion. Appellant's Opening Brief ("AOB") at 15-16; *see also Gregorio T. v. Wilson*, 59 F.3d 1002, 1004 (9th Cir. 1995) ("As long as the district court got the law right, 'it will not be reversed simply because the appellate court would have arrived at a different result if it had applied the law to the facts of the case. Rather, the appellate court will reverse only if the district court abused its discretion.'") (citation omitted).

CERT's argument in this regard is that the court's reliance on *Nat'l Assoc. of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (E.D. Cal. 2020), was improper, and that the court ignored testimony of its experts from the *Starbucks* litigation. Neither contention has merit.

CERT's primary objection to the court's reliance on the *Wheat Growers* decision was that the facts regarding government agencies' conclusions on carcinogenicity about glyphosate in *Wheat Growers* differed from agency conclusions about acrylamide. AOB at 38. But this is not responsive to CalChamber's argument, or the district court's conclusion, that a warning implying that *dietary acrylamide* increases the risk of cancer is not "purely factual and uncontroversial." *See* Appellee's Ans. Br. at 52-54.

CERT's argument that the district court abused its discretion by ignoring the *Starbucks* trial testimony of its experts fares no better. That testimony was duplicative of the testimony submitted by the attorney general. And CERT's argument misses the point: the testimony did not negate the evidence CalChamber submitted or establish that a compelled warning was purely factual and uncontroversial. At best, it reinforced that the issue was controversial.

CERT makes no mention of the public interest. The evidence in the record supports the district court's conclusion that the public interest is served by the injunction, well beyond "'the significant public interest in upholding First Amendment principles'" identified by the

district court. 1-ER-32. FDA has stated its concerns that "premature labeling of many foods with warnings about dangerous levels of acrylamide would confuse and could potentially mislead consumers," and by avoiding foods with warning labels on them consumers would "encounter greater risks because they would have less fiber and other beneficial nutrients in their diets." 2-ER-190. According to FDA, "[l]abeling 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." 2-ER-194.

As discussed in Section I, Proposition 65 systematically compels companies that manufacture, distribute, and sell food products to either provide non-factual, controversial warnings or capitulate to settlement demands, despite any scientific agreement that their products cause cancer in humans. For that reason, and because the state has alternate means to convey its concerns about the potential carcinogenicity of dietary acrylamide in humans, the district court rightly concluded that CalChamber was likely to prevail on its challenge and the public interest justified the injunction.

IV. CERT's suggestion that constitutional issues can be avoided by striking the warning requirement from a "right-to-know" law makes no sense.

CERT contends that if a Proposition 65 warning for acrylamide in food violates the First Amendment rights of businesses, the remedy is to strike the warning requirement from the act. AOB at 46–48. The only authority CERT offers for this is the savings clause of Proposition 65, which allows for severance of "any provision of this initiative or the application thereof." Proposition 65, § 6. This remedy, violates California law because it is contrary to the intent of the voters in adopting Proposition 65. It would also make any foods that cannot meet the no significant risk level illegal to sell in California.

Proposition 65 enacted two substantive prohibitions: (i) discharging listed chemicals into water, § 25249.5, and (ii) exposing individuals to listed chemicals without providing clear and reasonable warning. § 25249.6. The ballot argument in favor of Proposition 65 makes clear its intent[22]:

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[22] California courts routinely refer to ballot arguments to interpret initiatives. *See, e.g., People ex rel. Lungren v American Standard, Inc.*, 14 Cal. 4th 294, 306-308 (1996) (construing "source of drinking water" under Proposition 65).

> There are certain chemicals that are scientifically known, not merely suspected, but known to cause cancer and birth defects. Proposition 65 would:
>
> - Keep these chemicals out of our drinking water.
> - *Warn us before we're exposed to any of these dangerous chemicals.*
> - Give private citizens the right to enforce these laws in court.
> - Make government officials tell the public when an illegal discharge of hazardous waste could cause serious harm.

Ballot Argument in Favor of Proposition 65, General Election, November 1986.[23] Thus, the electorate did *not* intend to prohibit exposures to listed chemicals, so long as warnings were provided.

CERT's suggestion that the language requiring a warning in § 25249.6 should be "severed" from the remaining language of that section if its application results in a First Amendment violation would improperly transform a law specifically designed to require warnings into one that *bans products when a warning is controversial*. This is

[23] https://oehha.ca.gov/media/downloads/proposition-65/general-info/prop65ballot1986.pdf.

inconsistent with the electorate's intent to *require* warnings for exposures to "known" carcinogens, and thus does not comport with California law on severability. *See Santa Barbara Sch. Dist. v. Superior Court,* 13 Cal. 3d 315, 331 (1975); *Gerken v. Fair Political Practices Com.*, 6 Cal. 4th 707, 714–715 (1993). And CERT cites no authority to support the implicit premise in its argument that a court may selectively sever language in a statute for some applications, but not others.

Moreover, such a result could have an unintended impact on the availability of foods, and in so doing would have unpredictable and negative consequences on public health. As discussed *infra*, section I.B, acrylamide is found in a number of foods at levels that OEHHA has suggested result in daily exposure above its safe-harbor NSRL of 0.2 micrograms per day, including foods that FDA considers nutritious and may reduce cancer risks. 2-ER-190, 194.

Faced with the prospect of having to defend the exposure under the no-significant-risk regulations without being able to provide a warning, companies may choose to stop selling foods containing

acrylamide, rather than risk huge penalties and attorney's fees if they are unable to sustain their burden of proof in litigation.

V. Conclusion.

The district court appropriately considered all of the factors it was required to consider, and neither got the law wrong nor abused its discretion. *Amici* therefore urge this Court to reject CERT's attempt to continue to expose their members to unwarranted and unconstitutional enforcement of Proposition 65 over dietary acrylamide.

Dated: June 23, 2021

Respectfully submitted,

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Attorneys for Amici Curiae Consumer Brands Association, American Bakers Association, American Beverage Association, California Grain and Feed Association, California League of Food Producers, California Grocers Association, California Retailers Association, California Seed Association, National Confectioners Association, Plant California Alliance, and SNAC International

FORM 8. CERTIFICATE OF COMPLIANCE FOR BRIEFS

Pursuant to Federal Rule of Appellate Procedure 32(a)(7)(C) and Ninth Circuit Rule 32-1, I certify that the attached Brief of *Amicus Curiae* Consumer Brands in Support of Plaintiff-Appellee and Affirmance is proportionally spaced, in a typeface of 14 points or more and contains 6,999 words, exclusive of those materials not required to be counted under Rule 32(a)(7)(B)(iii), according to the word count function of the Microsoft Word software program.

Dated: June 23, 2021

s/ Jeffrey Margulies
Jeffrey Margulies

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Ninth Circuit by using the appellate CM/ECF system. I certify that participants in the case who are registered CM/ECF users will be served by that system.

Dated: June 23, 2021

s/ Jeffrey B. Margulies
Jeffrey B. Margulies