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Attorneys for Plaintiff THE PERSONAL CARE PRODUCTS COUNCIL

UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF CALIFORNIA

THE PERSONAL CARE PRODUCTS COUNCIL,

Plaintiff,

v.

ROB BONTA, IN HIS OFFICIAL CAPACITY AS ATTORNEY GENERAL OF THE STATE OF CALIFORNIA,

Defendant.

CASE NO. 2:26-cv-00682-DJC-CKD

PLAINTIFF THE PERSONAL CARE PRODUCTS COUNCIL'S NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT

Date: August 27, 2026
Time: 1:30 p.m.
Courtroom: 7

Judge Daniel J. Calabretta

Complaint Filed: March 2, 2026
Trial Date: None Set

NOTICE OF MOTION

TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE that on August 27, 2026, at 1:30 p.m., or as soon thereafter as this matter may be heard before the Honorable Daniel Calabretta, United States District Judge for the Eastern District of California, in Courtroom 7, Robert T. Matsui United States Courthouse, 501 "I" Street, Sacramento, California 95814, Plaintiff The Personal Care Products Council ("PCPC"), will and hereby does move the Court pursuant to Rule 56 of the Federal Rules of Civil Procedure ("FRCP") for summary judgment against Defendant Rob Bonta, in his official capacity as Attorney General of the State of California, and for the relief set forth in the Memorandum of Points and Authorities.

This Motion is based upon this Notice of Motion and Motion, the accompanying Memorandum of Points and Authorities in Support of the Motion, the Declarations of Willis Wagner, Emily Manoso, and Dr. James Bus, the Statement of Undisputed Material Facts, the Request for Judicial Notice, the records in this case and all matters of which this Court can take judicial notice, and such further evidence, authorities, and argument as may be presented in advance of, or during, the hearing on this Motion.

CERTIFICATION

Pursuant to the Court's Standing Order in Civil Cases, counsel for Plaintiff hereby certifies that, on Monday, April 20, 2026, at 2:30 PM, counsel for Plaintiff and counsel for Defendant met and conferred to discuss the issues raised in the Motion. On Friday, March 6, 2026, counsel for Plaintiff first informed counsel for Defendant that Plaintiff planned to file a motion for summary judgment.

In the meet and confer, Plaintiff explained its position with respect to the constitutional requirements for government-compelled commercial speech under *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), and the application thereof to the science and message underlying California's Proposition 65 cancer warning requirement for diethanolamine ("DEA"). Plaintiff and Defendant fundamentally disagreed about these issues but came to agreement in concept on a schedule for briefing the motion, including depositions of experts, which was later incorporated into a stipulation containing precise dates for the Court's review.

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Respectfully submitted,

DATED: April 27, 2026

HOGAN LOVELLS US LLP

By: */s/ Trenton H. Norris*
Trenton H. Norris

Attorneys for Plaintiff
THE PERSONAL CARE PRODUCTS COUNCIL

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MEMORANDUM OF POINTS AND AUTHORITIES

I. INTRODUCTION

Under Proposition 65, California compels businesses to warn consumers that they are exposed to a chemical, diethanolamine ("DEA"), that is "known to cause cancer" even though the State has never determined that DEA is carcinogenic to humans. In fact, the available evidence affirmatively demonstrates that DEA does not cause cancer in humans, and no regulatory body anywhere in the world has determined that DEA is a human carcinogen.

Plaintiff Personal Care Products Council ("PCPC") filed this suit because California compels its members to provide a Proposition 65 warning solely on the basis of a classification by the International Agency for Research on Cancer ("IARC") that DEA is "possibly carcinogenic." Even the State must concede that this also means DEA is possibly not carcinogenic. In short, California compels a warning for DEA that is undisputedly controversial and, ultimately, false. As the Eastern District has ruled three times in recent years in factually and legally similar Proposition 65 cases, PCPC respectfully requests that this Court declare the State's compulsion of Proposition 65 warnings for DEA unconstitutional under the First Amendment to the United States Constitution. *See Nat'l Ass'n of Wheat Growers v. Becerra*, 468 F. Supp. 3d 1247 (2020) ("*Wheat Growers II*") (Shubb, J.), *affirmed sub nom. Nat'l Ass'n of Wheat Growers v. Bonta*, 85 F.4th 1263 (2023) ("*NAWG*") (glyphosate); *Cal. Chamber of Com. v. Bonta*, 781 F. Supp. 3d 1071 (2025) ("*CalChamber*") (Calabretta, J.) (acrylamide); *Pers. Care Prod. Coun. v. Bonta*, 799 F. Supp. 3d 1075 (2025) ("*PCPC*") (Nunley, C.J.) (titanium dioxide). *See also Cal. Chamber of Com.. v. Council for Educ. & Rsch. on Toxics*, 29 F.4th 468 (9th Cir. 2022) ("*CERT*"), *aff'g Cal. Chamber of Com. v. Becerra*, 529 F. Supp. 3d 1099 (2021) (granting preliminary injunction) (Mueller, C.J.) (acrylamide).

The material facts are undisputed. No governmental body in this country or any other has concluded that DEA causes cancer in humans. Even IARC's 2011 "Group 2B" classification of DEA, its weakest classification of cancer potential, is challenged by numerous governments and agencies and reputable scientists worldwide. IARC relied exclusively upon a single mouse study for its determination. That study's results could not be replicated in other animal studies; it employed a controversial strain of mice known to be overly susceptible to the observed tumors; tumors appeared

only after chronic exposure at extreme doses; and the mice liver tumors developed through a biological mechanism that does not exist in humans. Tellingly, a different panel of IARC scientists had previously found that same unreliable mouse study, cumulated with all other evidence, was insufficient for even the low 2B classification. Indeed, the State agency charged with listing chemicals under Proposition 65 likewise came to the same conclusion when it explained, in 2003, that it was removing DEA from its list of chemicals under consideration for listing under Proposition 65.

The record against the carcinogenicity of DEA is stronger yet: no epidemiological evidence shows an increased cancer risk to humans from DEA exposures. In fact, the U.S. Food & Drug Administration ("FDA") has long allowed DEA to be used in cosmetics and foods and has even approved a drug as safe and effective that uses DEA as an active ingredient at 21 percent of the formula.

Despite this scientific evidence, Proposition 65 compels a warning that cosmetics and personal care products containing DEA expose consumers to a chemical "known to the State of California to cause cancer." Either a business inscribes this unsupported and highly misleading warning on product labels, or it must incur the significant expense of litigation to prove scientifically that it is not required. Such a defense is costly and would have to establish that the level of exposure to DEA to average consumers from use of their product poses "no significant risk" based on expert evaluations and unestablished and debatable standards that start by assuming, contrary to the evidence, that DEA causes cancer in humans. Private enforcers, by contrast, risk almost nothing and incur comparatively little cost to file an enforcement action under which they can obtain 25% of the civil penalties as well as their attorney fees. Indeed, dozens of companies, including PCPC members, are currently subject to active litigation in state court where they must either prove the costly "no significant risk" defense or be compelled to deliver misleading DEA cancer warnings on their personal care products.

Given these lopsided burdens for businesses and the clear availability of less restrictive measures to achieve the State's objectives—whatever they might be in disseminating counter-factual information—the State cannot meet its burden to justify compelling these warnings under the First Amendment. This Court should follow the clear weight of the scientific evidence and First Amendment

precedent as applied to Proposition 65 and hold that the compelled DEA cancer warnings are unconstitutional.

II. BACKGROUND

A. DEA, Its Classification by IARC, and the Proposition 65 Listing.

DEA is present in some cosmetic and personal care products, including shampoos, conditioners, hair gels, hair dyes, shaving gels, makeup, body lotions, sunscreens, and skin care products. Statement of Material Facts ("SUMF") No. 1. DEA is often present in trace amounts because of the manufacturing process for disclosed ingredients, such as triethanolamine. SUMF No. 2.

In 2011, IARC classified DEA as "possibly carcinogenic to humans (Group 2B)" based on "sufficient evidence" of carcinogenicity in experimental animals. SUMF No. 11. IARC is not a regulator; its sole directive is to assess hazards. SUMF No. 12. From these assessments, IARC "identifie[s] cancer hazards but does not evaluate the risks associated with specific levels or circumstances of exposure."[1] SUMF No. 12. IARC classifies an agent into one of four groups[2] based on the strength of evidence. SUMF No. 17. IARC based its Group 2B cancer classification for DEA on a slender reed—a single 1999 National Toxicology Program ("NTP") mouse bioassay showing evidence of liver cancer in the B6C3F1 mouse strain—even though other studies found no link between DEA and cancer in mice. SUMF Nos. 23-26, 29. IARC also could not identify *any* valid study that established a link between DEA and cancer in humans. SUMF No. 26. Indeed, IARC concluded: "There is inadequate evidence in humans for the carcinogenicity of [DEA]." SUMF No. 23.

More than a decade earlier, in 2000, IARC had reviewed the evidence of DEA carcinogenicity, including the NTP study, and classified DEA as Group 3, meaning "not classifiable as to its carcinogenicity to humans." SUMF Nos. 33-35. Without any new data, and without justifying its change of position, a different IARC panel decided in 2011 to classify DEA as a Group 2B substance, based solely on the theoretical possibility that the choline-deficiency mode of action (discussed

[1] A substance is considered a cancer *hazard* if it is capable of causing cancer at some theoretical level, whereas a *risk* measures the probability that cancer will occur considering the level of exposure. IARC identifies cancer hazards even when risks are very low with known patterns of exposure. SUMF Nos. 14-16. *NAWG*, 85 F.4th at 1269.

[2] Group 1 ("carcinogenic to humans") applies when there is "sufficient evidence" in humans. Group 2A ("probably carcinogenic") chemicals have "limited evidence" in humans or "sufficient evidence of carcinogenicity" in animals. Group 2B ("possibly carcinogenic") chemicals can have "limited evidence" in humans or "inadequate evidence" in humans but "sufficient evidence" in animals. Group 3 applies when the chemical is "not classifiable as to its carcinogenicity to humans." SUMF Nos. 17-21.

below) observed in B6C3F1 mice might apply to humans, even though IARC acknowledged that "the relationship between exposure to diethanolamine, a reduction in liver choline levels and the development of liver cancer in humans is not known." SUMF Nos. 37-38. Reinforcing that IARC was relying on speculation, it failed to identify a single example of this mode of action ever causing cancer in humans or susceptible subpopulations. SUMF No. 39.

In 2012, based solely on IARC's 2011 reclassification and no independent review, California's Office of Environmental Health Hazard Assessment ("OEHHA") listed DEA as a chemical "known to the State to cause cancer." SUMF No. 8. OEHHA made no determination that DEA causes cancer in humans, and it has not done so since. SUMF No. 9-10. Rather, OEHHA listed DEA pursuant to Health and Safety Code Section 25249.8(a), which incorporates California Labor Code Section 6382(d) and requires that substances identified as potential carcinogens by IARC be listed as "known to cause cancer." *Monsanto v. Off. of Env't Health Hazard Assessment*, 22 Cal. App. 5th 534, 544 (2018).[3]

Like IARC, OEHHA also had previously reached a different conclusion on DEA. In 1999, OEHHA identified DEA as a chemical under consideration for possible listing under Proposition 65 and undertook an independent evaluation of the available science, including the very B6C3F1 mouse study on which IARC based its 2011 classification. SUMF No. 36. After that review, OEHHA determined in 2003 not to proceed with listing DEA under Proposition 65 "[b]ecause it is not clear that the scientific criteria for listing under the authoritative bodies mechanism has been met." *Id*. OEHHA was right not to list DEA then, and the science has not evolved to compel a different conclusion today.

B. There Is No Scientific Evidence That DEA Is Carcinogenic to Humans.

Epidemiological studies are critical for determining whether a substance poses a cancer risk in human populations. SUMF Nos. 27-28. Epidemiology is "the study of the distribution of disease in human populations and the factors that may influence that distribution." Bus Decl. ¶ 17. Yet no epidemiological studies exist that support that DEA is a human carcinogen.[4] SUMF No. 27. Absent

[3] Two of three Proposition 65 listed chemicals that have been the subject of judgments by this Court barring enforcement were listed using this "Labor Code listing mechanism." *NAWG*, 85 F.4th at 1267 (acrylamide); *PCPC*, 799 F. Supp. 3d at 1081(titanium dioxide).

[4] In 2011, when IARC re-evaluated DEA, it considered epidemiology studies evaluating worker exposure to metalworking fluids containing DEA as an additive and follow-up evaluations for different cancer outcomes. SUMF No. 24-25. However, these metalworking fluid studies cannot inform on DEA-specific cancer risks because not all the fluids contained DEA,

epidemiological data, the evaluation of DEA's potential carcinogenicity necessarily relies on experimental animal studies. SUMF No. 28.

Traditional rodent bioassays employ high-dose testing conditions that differ sharply from realistic human exposures. SUMF No. 48. These studies often employ doses far exceeding any plausible human exposure and exposure routes that alter systemic toxicological responses, making it inappropriate to assume that tumors in experimental animals indicate a human cancer hazard. UMF No. 49. Scientists have long recognized that many compounds produce tumors in rodents when tested at maximally tolerated doses, yet research shows that cancer findings at such extreme doses lack quantitative relevance to humans because they overwhelm detoxification pathways and DNA-repair systems in ways that do not occur at real-world human exposure levels. SUMF Nos. 49, 51.

Rodents also differ fundamentally from humans in their susceptibility to tumors, particularly in the liver, which is the most common spontaneous tumor site in mice and rats, but not even among the top ten cancer sites in humans. SUMF Nos. 42-43. Moreover, many liver-tumor pathways in rodents are not operative or relevant in humans. SUMF No. 44. For this reason, the FDA cautions that mouse liver tumors, especially those arising from nongenotoxic mechanisms, such as the choline-deficiency mode of action identified in the B6C3F1 mouse study, may not predict human carcinogenicity and can be misleading. SUMF No. 41. As of 2022, the FDA expressly recommends short-term transgenic mouse models, precisely because conventional mice are overly susceptible to liver tumor formation. SUMF No. 64.

Including the B6C3F1 mouse study, five cancer bioassays evaluating DEA exposure in rats and mice have been published. SUMF No. 52. Four of the five reported no evidence of carcinogenicity in either species. SUMF No. 53. Two of the five were conducted in rats—a two-year NTP dermal-exposure bioassay in F344/N rats and a two-year FDA oral-exposure bioassay in Sprague-Dawley rats—both of which reported no DEA exposure-related increase in tumors. SUMF Nos. 62-63. Of the three reported studies in mice, two were conducted using transgenic strains. SUMF No. 66. The first involved the same route of exposure (dermal) as the B6C3F1 mouse study though at higher dosages—

use of different metalworking fluids changed over time, and even if DEA was potentially present, it was frequently present in a mixture with other chemicals, including nitrites, which are known human carcinogens. *Id*. Indeed, even IARC determined these studies are insufficient for determination of cancer risk from DEA exposure and did not rely on them in its formal evaluation of DEA. *Id.*

and used the Tg.AC mouse strain, designed and validated for evaluating topically applied products like cosmetics. SUMF No. 67. The second involved the FDA-endorsed Tg.RasH2 mouse strain, used to assess systemic (non-dermal) cancer risks. SUMF Nos. 69-70. Neither study reported a positive association between DEA exposure and cancer. SUMF Nos. 68-69.

The NTP's 1999 B6C3F1 mouse study is the only reported cancer bioassay to show positive results. SUMF No. 54. However, because the strain is inherently prone to developing liver tumors at extremely high background rates, even compared to other rodents, its use in human carcinogenicity testing is particularly controversial. SUMF Nos. 55-56. Compounding this concern, B6C3F1 mice possess genetically controlled deficiencies in maintaining DNA methylation, a key protective mechanism for resisting tumors. SUMF No. 57. Dietary changes alone, such as choline or methionine deprivation, can trigger DNA instability and liver tumor development. SUMF No. 58. Regulatory bodies, including the NTP's predecessor organization, the National Cancer Institute, and the European Chemicals Agency ("ECHA"), have questioned the B6C3F1 mouse strain's suitability. SUMF Nos. 59-60. The Organization for Economic and Cooperative Development ("OECD") has specifically noted that B6C3F1 mice have limited usefulness in carcinogenicity testing. SUMF No. 61. Moreover, human skin absorbs DEA far less efficiently than rodent skin, meaning the internal dose reaching human liver tissue from dermal exposure is dramatically lower than in mice and rats. SUMF No. 46. Thus, under "any human scenario of DEA exposure . . . even if humans were chronically exposed up to their maximally tolerated DEA dose . . . this would be insufficient to induce liver tumors[.]" Bus Decl. ¶ 70(d); SUMF No. 47.

Nor is there any other evidence that DEA possesses the chemical characteristics of substances capable of carcinogenic effect. SUMF Nos. 71-73. A key characteristic of many carcinogens is genotoxicity, meaning they injure DNA, causing genetic mutations and ultimately cancer. SUMF No. 72. DNA genotoxicity could be an explanation for the B6C3F1 mice liver tumors, but repeated assessments of mutagenicity, clastogenicity, aneugenicity, and DNA damage have produced negative results. SUMF No. 73.

C. No Governmental Authority Supports OEHHA's Listing DEA as a Human Carcinogen.

Governmental authorities across the globe that have evaluated DEA have concluded that the

mouse study relied on by IARC is not a reliable indicator of any cancer risk to humans from DEA. SUMF Nos. 79, 85, 88. Even the NTP, which conducted the B6C3F1 mouse study, decided not to classify DEA as a human carcinogen because, among other points, its review found no evidence that DEA is mutagenic or metabolized to a mutagen and the DEA choline-deficiency mode of action observed in B6C3F1 mouse strains is not relevant to humans. SUMF Nos. 80-81. Ultimately, it declined to designate DEA as either "Known to be a Human Carcinogen" or "Reasonably Anticipated to be a Human Carcinogen." SUMF No. 81. EPA likewise found the evidence insufficient to classify DEA as a known or likely human carcinogen. SUMF No. 82. EPA instead categorized DEA as showing "Suggestive Evidence of Carcinogenic Potential," meaning, "a concern for potential carcinogenic effects is raised, but the data are judged not sufficient for a stronger conclusion." SUMF No. 83. As there is no known or even probable hazard to humans from exposure to DEA, the EPA's designation means the agency need not even attempt a cancer dose-response and risk assessment for DEA. SUMF No. 84.

Multiple public-health and regulatory agencies applying the United Nations Globally Harmonized System of Classification ("GHS")[5] have reached the same conclusion: the evidence does not support classifying DEA as a known or presumed human carcinogen. SUMF Nos. 86-89. Based on a review of the same DEA carcinogenicity studies, both ECHA and the Australian Industrial Chemicals Introduction Scheme ("AICIS") agreed that the available data were insufficient for a Category 1A or 1B carcinogenicity designation. SUMF Nos. 84, 85. AICIS went further by declining even a Category 2 "suspected" classification. SUMF No. 87. Even ECHA's limited Category 2 proposal did not rely on any new scientific evidence and expressly acknowledged unresolved questions about the relevance of the mouse tumors to humans. SUMF No. 89.

The FDA, meanwhile, has, through multiple administrations, accepted DEA as safe and appropriate for use in cosmetics and other products. SUMF No. 76. The agency approved an oral pharmaceutical, treprostinil diolamine, which contains approximately 21 percent DEA, and does not require a cancer warning label on the product. SUMF No. 77. The FDA inactive ingredient website also lists approved uses of DEA in intravenous injections up to 1.5% and in topical creams at up to 0.3%.

[5] There are three levels of carcinogen classification under GHS: Category 1A chemicals are "Known to have carcinogenic potential for humans…largely based on human evidence"; Category 1B chemicals are "Presumed to have carcinogenic potential for humans...largely based on animal evidence"; and Category 2 chemicals are "Suspected human carcinogens." SUMF No. 86.

SUMF No. 78. In reference to DEA carcinogenicity data, the FDA provides public guidance stating that "[t]he NTP study did not establish a link between DEA and the risk of cancer in humans," and "that at the present time there is no reason for consumers to be alarmed based on the use of these substances in cosmetics." SUMF No. 79.

D. Proposition 65.

Businesses whose products contain a Proposition 65 substance must provide a "clear and reasonable warning" before "expos[ing] any individual" to the substance. Cal. Health & Safety Code § 25249.6. OEHHA's regulations deem cancer warnings for consumer products containing DEA, including cosmetic and personal care products, to be "clear and reasonable" if they state:

> ⚠ **WARNING**: This product can expose you to chemicals including diethanolamine, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov.

27 Cal. Code Regs. § 25603(a)(2)(A). Alternatively, the warning can be provided in a short form:

> ⚠ **WARNING**: Cancer – www.P65Warnings.ca.gov.

27 Cal. Code Regs. § 25603(b)(2)(A). These are known as "safe harbor warnings" because they are approved by the State as compliant with Proposition 65 and protect businesses from liability if they use these warnings. Although other forms of warnings are technically permitted, "only the safe harbor warning is actually useable in practice." *CERT*, 29 F.4th at 479.

Proposition 65 provides an affirmative defense if a business "can show that the exposure poses no significant risk assuming lifetime exposure at the level in question." Cal. Health & Safety Code § 25249.10(c). This threshold is referred to as the "No Significant Risk Level," or "NSRL." For some substances, OEHHA has published a "safe harbor" NSRL, a presumptive limit below which a business is not obligated to warn. Cal. Code Regs. tit. 27, § 25705. For DEA and other chemicals, however, OEHHA has not set a "safe harbor" NSRL.[6] In those circumstances, a defendant must establish the appropriate NSRL in litigation and prove that its product exposes average consumers to a level of the chemical below that level. *Id.* §§ 25703 *et seq*. Because these showings are very expensive and expert-intensive and bear inherent litigation risk, they are rarely undertaken.

[6] While OEHHA recently proposed a safe harbor NSRL for DEA, it is unclear at present whether OEHHA will move forward with, or issue a new, proposal. Either way, such process could consume more than 1-2 years. And even if OEHHA finalizes its proposed NSRL safe harbor, Defendants retain the right to prove a higher NSRL in litigation. *See* Cal. Code of Regs., tit. 27, § 25701(a).

The Attorney General, district attorneys, and certain city attorneys may bring an enforcement action under Health & Safety Code § 25249.7(c). Proposition 65 imposes penalties of up to $2,500 *per day* for *each* failure to provide an adequate warning. *Id.* § 25249.7(b). It also authorizes courts to enjoin any person who "threatens to violate" the warning requirement. *Id.* § 25249.7(c). The statute also permits private citizens (or organizations) to bring enforcement actions. *Id.* § 25249.7(d). Private enforcers recover a "bounty" of 25 percent of the civil penalty (*id*. § 25249.12(d)), as well as their attorneys' fees (Cal. Code Civ. Proc. § 1021.5), creating strong incentives for private enforcement.[7]

Since 2013, private enforcers have issued over 1,500 DEA notices. SUMF No. 90. These notices have resulted in at least 171 lawsuits. SUMF No. 91. On April 7, 2025, defendants in several of these lawsuits filed a petition with the statewide Judicial Council to coordinate 33 such lawsuits and refer them to one judge for resolution of pre-trial issues, including the controversial technical and scientific issues. The petition was granted and assigned to Judge Chatterjee of Department 21 of the Alameda Superior Court. *See* Ex. S, at 13, 21. There are now approximately twice as many cases in the coordinated proceeding. *See* Ex. T, at 13-14.

More than 800 companies, including many of PCPC's members that sell cosmetic and personal care products, have been targeted with 60-day pre-litigation notices in connection with alleged exposures to DEA in their products. SUMF No. 93. Many of PCPC's members, including board members, also have been sued in connection with these 60-day notices. SUMF Nos. 94, 95.

III. LEGAL STANDARD

The Court "shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Thus, "[s]ummary judgment is appropriate when, viewing the evidence in the light most favorable to the nonmoving party, there is no genuine dispute as to any material fact." *Italian Colors Rest. v. Becerra*, 878 F.3d 1165, 1171 (9th Cir. 2018) (citation omitted). Further, because this action

[7] Courts have long recognized how onerous and ripe for abuse these private enforcement suits under Proposition 65 can be on businesses. *See, e.g.*, *B&G Foods N. Am., Inc. v. Embry*, 29 F.4th 527, 533 (9th Cir. 2022) (observing that "businesses often choose to settle Prop. 65 cases" because establishing a safe harbor defense is "very burdensome"); *Consumer Def. Grp. v. Rental Hous. Indus. Members*, 137 Cal. App. 4th 1185, 1214 (2006) (describing how provisions make it "virtually impossible" for defendants "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 an actual trial"); *Consumer Cause, Inc. v. SmileCare*, 91 Cal. App. 4th 454, 477-78 (2001) (Vogel, J., dissenting) (describing Proposition 65 lawsuits as "judicial extortion").

challenges a government-compelled disclosure, the government "has the burden" to establish that the law passes First Amendment scrutiny. *Am. Beverage Ass'n v. City & Cnty. of S.F.*, 916 F.3d 749, 756 (9th Cir. 2019) ("*ABA*") (en banc).

IV. ARGUMENT

The undisputed record establishes that a Proposition 65 warning for DEA in cosmetic products violates the First Amendment because it is not "purely factual and uncontroversial." Because the State cannot carry its burden, summary judgment should be entered in favor of PCPC, along with a declaration and a permanent injunction against enforcement of the warning requirement.

A. Compelled Cancer Warnings for DEA Violate the First Amendment.

Regulations of commercial speech are generally subject to intermediate scrutiny—that is, the State must show that the regulation "directly advances" a "substantial" government interest and is "not more extensive than is necessary to serve that interest." *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 566 (1980). There is a narrow exception to this rule under which courts "appl[y] a lower level of scrutiny to laws that compel disclosures," but only "in certain contexts." *Nat'l Inst. of Family & Life Advocs. v. Becerra*, 585 U.S. 755, 768 (2018) ("*NIFLA*") (citing *Zauderer v. Off. of Disc. Counsel*, 471 U.S. 626, 651 (1985)). Under that exception, "the government may compel commercial speech so long as it is reasonably related to a substantial governmental interest, and the compelled speech is (1) purely factual, (2) noncontroversial, and (3) not unjustified or unduly burdensome." *PCPC*, 799 F. Supp. 3d at 1083 (*citing ABA*, 916 F.3d at 756).

There is no presumption that State-mandated disclosures meet this standard. Instead, "[t]he State has the burden of demonstrating that" each element is satisfied. *Wheat Growers II*, 468 F. Supp. 3d at 1258. The Attorney General cannot meet its burden to make any of these showings here, let alone all three. And because "the warning does not meet [this] lower standard [under *Zauderer*], it necessarily does not meet [the] higher standard" under *Central Hudson*. *ABA*, 916 F.3d at 756 n.5. The Proposition 65 warning requirement for DEA in cosmetics and personal care products therefore is unconstitutional.

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B. The Compelled Cancer Warning Does Not Meet the *Zauderer* Requirements.

1. The Warning Is Not "Purely Factual."

"When the government takes the momentous step of mandating that its message be delivered by private parties, it is exceptionally important that the compelled speech be purely factual." *ABA*, 916 F.3d at 767 (Christen, J., concurring). Courts applying *Zauderer*, therefore, only uphold compelled disclosures of purely factual information, the accuracy of which cannot be reasonably disputed. *See, e.g.*, *Am. Meat Inst. v. Dep't of Agric.*, 760 F.3d 18, 27 (D.C. Cir. 2014) (product's country of origin); *New York State Rest. Ass'n v. New York City Bd. of Health*, 556 F.3d 114, 134 (2d Cir. 2009) (calorie counts on food menus).

A "factually accurate" disclosure, however, "is not enough to qualify for the *Zauderer* exception." *NAWG,* 85 F.4th at 1276 (2023). "[A] statement may be literally true but nonetheless misleading and, in that sense, untrue." *CTIA-The Wireless Ass'n v. City of Berkeley*, 928 F.3d 832, 847 (9th Cir. 2019) ("*CTIA II*"). In determining whether a public health warning is misleading, courts must consider how that speech will be understood "not just [by] those with sophisticated levels of health literacy," but by "unsophisticated consumers" too. *ABA*, 916 F.3d at 766 (Christen, J., concurring); *cf. Nat'l Ass'n of Wheat Growers v. Zeise*, 309 F. Supp. 3d 842, 851 (E.D. Cal. 2018) ("Ordinary consumers do not interpret warnings in accordance with a complex web of statutes, regulations, and court decisions.").

Here, the Proposition 65 warning provides the message that a product containing DEA will increase consumers' risk of cancer. There is no reliable scientific support for this message.

a) Proposition 65 Requires a Message that Products Containing DEA Will Increase Consumers' Risk of Cancer.

"At its core, the function of Prop 65 is to inform consumers of *risks*, not *hazards*." *NAWG*, 85 F.4th at 1269 (emphasis added); *cf.* Cal. Code Regs. tit. 27, § 25701 (explaining that a chemical need not include the statutory warning if it "pose[s] no significant risk"). The ballot argument that swayed California voters to adopt the law assured them that Proposition 65's focus would be on "chemicals that are scientifically known—not merely suspected but known—to cause cancer and birth defects." *People ex rel. Lungren v. Super. Ct.*, 14 Cal. 4th 294, 307 (1996) (quoting Proposition 65 ballot

pamphlet).

To determine whether a Proposition 65 warning meets *Zauderer*'s "purely factual" requirement, courts consider "the overall impression delivered by a compelled warning," as opposed to a sentence-by-sentence analysis. *PCPC*, 799 F. Supp. 3d at 1085. Here, the plain meaning of any warning for DEA must convey that the product will increase consumers' risk of developing cancer. Indeed, the statute's "clear and reasonable" warning requirement compels businesses to convey to consumers that their product "can expose [them] to chemicals including [DEA], which is known to the State of California to cause cancer," or "words to that effect." *See Dowhal v. SmithKline Beecham Cons. Healthcare*, 32 Cal. 4th 910, 918 (2004). Defendant's own regulations also expressly preclude "use of the adverb 'may' to modify whether the chemical causes cancer," as well as any other language that "obfuscates" the core warning. *See* Cal. Code Regs. tit. 11, § 3202(b). As such, "it is reasonable for the average consumer to read the warning requirement and conclude that [DEA] may cause them cancer or increase their chances of obtaining cancer." *PCPC*, 799 F. Supp. 3d at 1086.

Moreover, the phrase "known to the State of California to cause cancer" is simply untrue. California does not "know" DEA causes cancer—never having made any such conclusion—and thus compelling a Proposition 65 warning is forcing delivery of a false statement.

The Ninth Circuit in *NAWG* considered a similar warning for glyphosate and held it did not qualify for *Zauderer* review despite being factually true because it still "convey[ed] the overall message that glyphosate is unsafe which is, at best, disputed" and "elevate[d] one side of a legitimately unresolved scientific debate." 85 F.4th at 1280-81. Even accepting "that each sentence [of the warning] is entirely and literally true, that is not enough," as "the totality of the warning may [] be nonetheless misleading." *Id.* at 1279. This Court came to a similar conclusion when considering a Proposition 65 warning for dietary acrylamide, noting that the warning "conveys the one-sided message that people who consume dietary acrylamide will increase their risk of cancer without sufficient scientific consensus to support that message." *CalChamber,* 781 F. Supp. 3d at 1088. Most recently this Court in *PCPC* also found that "even though each sentence on its own may be factually true, 'the totality of the warning' is nonetheless misleading and Defendant's argument 'ignores the reality that it conveys the 'core message' that using a cosmetic or personal care product containing

Listed Titanium Dioxide poses a risk of cancer in *humans*." 799 F. Supp. 3d at 1086 (*citing NAWG*, 85 F.4th at 1279). The same is true here.

Accordingly, to meet its "purely factual" burden, the State must show the warning is supported by scientific evidence that DEA causes cancer in humans. The State cannot do so.

b) The Proposition 65 Message Is Supported Neither by the IARC Classification, Nor by OEHHA's Independent Review.

OEHHA's 2012 decision to list DEA and compel warnings that it is *"*known to the State of California to cause cancer*"* relied exclusively on IARC's 2011 decision to classify DEA in Group 2B, which—without explanation—reversed IARC's 2000 decision to the contrary. Despite earlier concluding in 2003 that DEA did not merit listing, OEHHA did not independently review the scientific data and blindly followed IARC. And IARC's 2B classification reflects only a *possible* carcinogenic hazard rather than a demonstrated cancer risk in humans. SUMF Nos. 8-9, 11; *see also CTIA-The Wireless Ass'n v. City & Cnty. of S.F.*, 827 F. Supp. 2d 1054, 1063 (N.D. Cal. 2011), *aff'd,* 494 F. App'x 752 (9th Cir. 2012) (noting that "[t]he uninitiated will tend to misunderstand" a cancer warning for a Group 2B 'possible carcinogen'" "as more dangerous than it really is"). IARC explicitly found inadequate evidence of carcinogenicity in humans and instead based its classification on a single, controversial 1999 mouse study. SUMF Nos. 23-26, 29. In short, IARC's 2B classification, even on its own terms, cannot support OEHHA's decision to compel warnings that DEA is "known" to cause cancer in humans. *See PCPC*, 799 F. Supp. at 1090. ("The Prop 65 warning does not indicate anything about cancer in 'experimental animals'[,] . . . the warning is reasonably understood to mean that it does in fact cause cancer in humans.").[8]

In line with IARC's 2011 determination that the evidence of carcinogenicity in humans is "inadequate," as well as its 2003 determination that DEA is "not classifiable as to carcinogenicity in humans," PCPC's expert, toxicologist James Bus, Ph.D., concluded that the "available animal toxicology and mode of action information support that DEA is not a human carcinogen, and therefore

[8] Indeed, of the three chemicals for which the Proposition 65 warning requirement has been declared to violate the First Amendment, two were classified by IARC as Category 2A (*probable* human carcinogen), a stronger finding than Category 2B (*possible* human carcinogen). The third chemical for which the warning requirement was struck down, titanium dioxide, like DEA, was classified as Category 2B.

a Proposition 65 warning for DEA as a compound '*known*' to cause cancer is scientifically indefensible." Bus Decl. ¶ 13. The basis for this conclusion is laid out in Dr. Bus's 31-page expert report, in which he critically assesses dozens of animal studies and meta-analyses published since 1965.

Critically, at no point did either the IARC classification or the evidence underlying it ever support a conclusion that DEA is "known" to cause cancer. SUMF No. 27. In fact, no scientific body has found it to be a "probable" or "likely" carcinogen. SUMF Nos. 74-75, 79-85, 87-89. Only OEHHA, acting pursuant to a state statute it believes requires adding Group 2B substances to the Proposition 65 list, has decided to mandate warnings that DEA is a "known" human carcinogen. *Id*; SUMF No. 3.

c) NTP's Single Positive Bioassay Is Defective, and No Other Epidemiological or Toxicological Study Supports Its Findings.

IARC's decision to classify DEA as a Group 2B carcinogen, the sole ground for the Proposition 65 listing, becomes even more head-scratching when the other scientific data concerning DEA are considered. The weight of evidence strongly supports that DEA is not a carcinogen in humans. No epidemiological studies exist that show exposures to DEA increase human cancer risk.

Absent epidemiological data, the evaluation of DEA's potential carcinogenicity is based on the single, 1999 unreliable mouse study. In comparison, titanium dioxide's 2B designation by IARC was based on three studies that linked the chemical to cancer in rodents, none of which included the controversial B6C3F1 mouse strain. *PCPC*, 799 F. Supp. 3d at 1087-91. Here, the strain of mice in NTP's 1999 study is inherently prone to developing liver tumors at extremely high background rates, even compared to other rodents, and its use in human carcinogenicity testing is particularly controversial. SUMF Nos. 55-56. Indeed, the FDA cautions that mouse liver tumors, especially those arising from nongenotoxic mechanisms, such as the choline-deficiency mode of action identified in the B6C3F1 mouse study, may not predict human carcinogenicity and can be misleading. SUMF No. 41.

Ultimately, the only plausible explanation for the tumors in the B6C3F1 mice NTP studied is that strain's own unique susceptibility to liver tumors. This conclusion is consistent with a liver tumorigenesis rate greater than 60% in the mice in control groups. SUMF No. 56. Far from demonstrating human carcinogenicity, the NTP study underlying IARC's "possible carcinogen" classification can only be said to underscore the controversy surrounding the use of liver tumors in

B6C3F1 mice in carcinogenicity evaluations.

Moreover, even if a rodent study provided positive results for increased tumors, it would be scientifically inappropriate to assume that tumors in experimental animals indicate a human cancer hazard. SUMF Nos. 48-50. Even considering this methodological problem, the two other mice studies of DEA did not show positive results for cancer. SUMF Nos. 54, 66. As this Court has held, "the key issue is whether there is a scientific consensus around [the chemical's] carcinogenicity in *humans"* and not in rodents. *PCPC*, 799 F. Supp. 3d at 1090 (emphasis in original). In short, the scientific evidence from animal studies does not support that DEA presents, let alone increases cancer risk in humans.

d) No Government Body Has Concluded that DEA Causes Cancer in Humans.

If there is any scientific consensus, it is that NTP's 1999 study is not a reliable indicator of DEA's potential carcinogenicity in humans. Given the substantial scientific skepticism surrounding this study and the absence of any corroborating evidence, it is hardly surprising that "[n]o agency that has reviewed DEA's carcinogenicity experimental data has identified DEA as a known human carcinogen or presumed (or probable) human carcinogen." Bus Decl. ¶ 37.

In the United States, several governmental agencies have evaluated the same data underlying IARC's classification and have concluded that they are not reliable indicators of any cancer risk to humans from DEA. The NTP itself, which conducted the B6C3F1 mouse study, determined not to classify DEA as a human carcinogen. SUMF Nos. 80-81. Similarly, EPA found the evidence insufficient to classify DEA as a known or likely human carcinogen. SUMF No. 82. And European and Australian agencies have arrived at the same conclusion; ECHA and AICIS agree that the available data was insufficient to classify DEA as a human carcinogen. SUMF Nos. 85-89.

FDA, meanwhile, has long accepted DEA in cosmetics and other products. Bus Decl. ¶ 50. FDA has approved drugs, intravenous injections, and topical creams containing DEA. SUMF Nos. 77-78. FDA's position is that "[t]he NTP study did not establish a link between DEA and the risk of cancer in humans," and "that at the present time there is no reason for consumers to be alarmed based on the use of these substances in cosmetics." SUMF No. 79.

Based on the foregoing, the consensus among American and global health agencies is that DEA

is not a human carcinogen. Even if Defendant were (somehow) to present an expert who disagrees and brings forward a different interpretation of the scientific evidence, the strength of the scientific assessments detailed above shows that, at minimum, there is a controversy—however one-sided—over whether DEA causes cancer in humans.

2. The Warning is Controversial.

Zauderer also requires the information in commercial speech to be uncontroversial. The Ninth Circuit has stated that "an objective evaluation of 'controversy' is also an important consideration." *Id.* On two occasions, the Ninth Circuit has held that a Proposition 65 cancer warning was "controversial" where there was "robust disagreement by reputable scientific sources." *NAWG,* 85 F.4th at 1277-78 (finding a Proposition 65 glyphosate warning was controversial where the IARC and EPA were "on opposite sides of the scientific debate" and "scientific consensus is much less evenly distributed"); *CERT*, 29 F.4th at 478 (finding a Proposition 65 acrylamide warning was controversial where the EPA, IARC, and U.S. National Toxicology Program each classified acrylamide as some level of carcinogen, while the American Cancer Society, National Cancer Institute, and an epidemiologist who reviewed 56 studies concluded it was not carcinogenic).

Here, IARC classified DEA as only a "possible" carcinogen, and many other agencies besides the EPA have found DEA not to be a carcinogen. In *PCPC,* the court found that there "was a clear debate over whether Listed Titanium Dioxide causes cancer in humans" because, similarly to here, government authorities analyzed the same data as IARC but came to a different conclusion about the cancer risk to humans. *PCPC,* 799 F. Supp. 3d at 1094. The court therefore held that "the Proposition 65 warning would likely improperly elevate one side of a legitimately unresolved scientific debate." *Id.* (citing *CERT*, 29 F.4th at 478).

The State cannot show that the warning is uncontroversial, *i.e.*, that there is a "strong scientific consensus" that DEA is a known human carcinogen, because no such consensus exists. *See NAWG*, 85 F.4th at 1278. In fact, there is no evidence—from IARC, any scientist, or any government authority—that DEA in fact causes cancer in humans. This alone is "sufficient to place [the] Prop 65 warning outside the realm of the lower level of review under *Zauderer*." *Id.* at 1282. Even if Defendant's expert were to argue that there is some scientific evidence that DEA is a possible carcinogen, at an absolute

minimum there would be a debate over whether DEA causes cancer in humans. That is sufficient to hold that the Proposition 65 warning is "objectively controversial." *PCPC*, 799 F. Supp. 3d at 1089.

Moreover, the warning requirement is also controversial because PCPC's members are "forced to convey a message fundamentally at odds with their businesses." NAWG, 85 F.4th at 1278. In this way, the compelled warning is both objectively and subjectively controversial. Because the cancer warning requirement for DEA compels businesses to disparage their products with a highly misleading and even false message, the State cannot show that it is entitled to the more relaxed standard of review under *Zauderer*, and the warning requirement as applied here must be held unconstitutional.

3. The Warning Requirement is "Unjustified [and] Unduly Burdensome."

Finally, the undisputed factual record shows that the compelled warning requirement as applied to DEA cannot satisfy *Zauderer*'s third element. *See NIFLA*, 585 U.S. at 776 ("Even under *Zauderer*, a disclosure requirement cannot be 'unjustified or unduly burdensome.'"). The State must prove that the compelled disclosures "remedy a harm that is potentially real not purely hypothetical" and "extend no broader than reasonably necessary." *Id.* (internal quotations omitted). Otherwise, they are unjustified and must fail.

Proposition 65's warning mandate for DEA is unjustified because it addresses a purely hypothetical harm. The State's purported interest in Proposition 65's required warnings is in informing Californians about exposures to "chemicals that are scientifically known—not merely suspected but known—to cause cancer" in humans. *Lungren*, 14 Cal. 4th at 306-07. But the message that exposure to DEA causes or even increases the risk of cancer in *humans* is far from settled science. Indeed, it is an outlier position. The State cannot demonstrate that a cancer warning for DEA informs consumers about a chemical that is "scientifically known" to pose a risk of cancer in humans—at best, the State can show only that it causes liver tumors in one already susceptible strain of mice studied in 1999. Indeed, the very authority that triggered the chemical's listing under Proposition 65 concluded that there is "inadequate evidence" of human carcinogenicity. Bus Decl. ¶ 14. In other words, the alleged "harm" that California wants consumers to be warned of is not only "hypothetical"—it is entirely unproven.

But "[e]ven if California had presented a nonhypothetical justification," the warning

requirement here imposes an undue burden and fails independently on that basis. *NIFLA*, 585 U.S. at 777. The Court need not linger on this point, for the Ninth Circuit's decision in *CERT* is dispositive. *See CERT,* 29 F.4th at 479-80 (citing "heavy litigation burden" as reason the compelled warning for acrylamide was unduly burdensome). Here, even more so than in *CERT* (where businesses had the benefit of a governmental published "No Significant Risk Level"), PCPC's members whose products contain DEA are heavily burdened by Proposition 65 enforcement actions. The State cannot refute this. "[A] government-compelled disclosure that imposes an undue burden" such as this "fails for that reason alone." *ABA*, 916 F.3d at 757.

C. Under *Central Hudson,* the Compelled Cancer Warning for DEA is Unconstitutional.

Because "the warning does not meet [the] lower standard [under *Zauderer*], it necessarily does not meet [the] higher standard" under *Central Hudson*. *ABA*, 916 F.3d at 756 n.5. To satisfy its burden under *Central Hudson*, the State must show that the law "directly and materially advances a substantial government interest" and is "no more extensive than necessary." *Junior Sports Mags. Inc. v. Bonta*, 80 F.4th 1109, 1117 (9th Cir. 2023). Said differently, California "must provide evidence establishing 'that the harms it recites are real,'" and that the law "will '*significantly*' alleviate those harms." *Id*. (emphasis in original). "California's burden under this test is 'heavy.'" *See Italian Colors*, 878 F.3d at 1176.

While California may have a substantial interest in public health, "simply having a substantial interest does not validate the state's [compelled speech]." *Junior Sports Mags. Inc.*, 80 F.4th at 1117. However, "compelling businesses 'to warn consumers of a potential 'risk' never confirmed by any regulatory body . . . does not advance that interest.'" *PCPC*, 799 F. Supp. 3d at 1095 (*citing NAWG*, 85 F.4th at 1283; *see also Wheat Growers II*, 468 F. Supp. 3d at 1264 ("[M]isleading statements about [chemical]'s carcinogenicity . . . do not directly advance [California's] interest."). The same is true here. Proposition 65 warnings for DEA are misleading, if not outright false. Ninth Circuit precedent is clear: Compelling unsubstantiated cancer warnings on cosmetics for DEA does not directly advance the State's interest. *See NAWG*, 85 F.4th at 1283; *cf. Video Software Dealers Ass'n v. Schwarzenegger*, 556 F.3d 950, 967 (9th Cir. 2009) ("[T]he State has no legitimate reason to force retailers to affix false information on their products.").

To the contrary, enforcing the safe harbor regulations for "speculative, conjectural, or tentative" risks "inevitably dilut[es] the force of any specific warning given." *Dowhal*, 32 Cal. 4th at 932-33. California jurists considering Proposition 65 have repeatedly explained that inundating consumers with cancer warnings is counterproductive. *See, e.g.*, *id.* at 932 (cautioning of the "dangers of overwarning and of less meaningful warnings crowding out" those that are actually "necessary"); *Env't Health Advocs., Inc. v. Sream, Inc.*, 83 Cal. App. 5th 721, 733 (2022) (explaining that Proposition 65's purpose "would be stymied" by the "proliferation of unnecessary warnings [that] distract the public from other important warnings on consumer products").

The compelled cancer warnings in this case also fail intermediate scrutiny for the independent reason that California has "more narrowly tailored" options to inform the public about cancer risks, "such as posting information about the chemical on its website, funding scientific research, and pursuing public awareness campaigns." *PCPC*, 799 F. Supp. 3d at 1095; *see also Italian Colors*, 878 F.3d at 1178 (availability of "numerous and obvious less-burdensome alternatives" informs whether the compelled speech is narrowly drawn to achieving the State's interest). As the Ninth Circuit has observed in upholding challenges to Proposition 65 warnings for another chemical, "California could employ various other means to promote its (minority) view that [the chemical] puts humans at risk of cancer 'without burdening [businesses] with unwanted speech.'" *NAWG*, 85 F.4th at 1283.

In the end, if the State truly believes that DEA causes cancer in humans (and it is far from clear that the State has this belief), the State is free to "advance its own side of [the] debate" on the possible carcinogenic effects of DEA "through its own speech." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 578-80 (2011). But the "State's failure to persuade" or refusal to explore these options "does not allow it to hamstring" businesses by forcing them to disparage their own products and parrot the State's misleading message. *See id.* at 578. After all, "the First Amendment does not permit the State to sacrifice speech for efficiency." *Riley v. Nat'l Fed'n of the Blind of N.C.*, 487 U.S. 781, 795 (1988).

D. A Permanent Injunction Should Issue.

A plaintiff seeking permanent injunctive relief must show "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and

defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391 (2006).

"Irreparable harm is relatively easy to establish in a First Amendment case." *CTIA II*, 928 F.3d at 851. Indeed, "[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury." *Id.* (citing *Elrod v. Burns*, 427 U.S. 347, 373 (1976)). And unlike monetary injuries, "constitutional violations cannot be adequately remedied through damages." *Stormans, Inc. v. Selecky*, 586 F.3d 1109, 1138 (9th Cir. 2009); *see also CERT*, 29 F.4th at 479 (recognizing that labeling products with Proposition 65 warnings damages a business's "reputation and goodwill").

The final two factors—balance of equities and public interest—"merge when the Government is the opposing party." *Nken v. Holder*, 556 U.S. 418, 435 (2009). Both favor granting a permanent injunction. The Ninth Circuit has "consistently recognized the significant public interest in upholding First Amendment principles." *Wheat Growers II*, 468 F. Supp. 3d at 1266 (quoting *Doe v. Harris*, 772 F.3d 563, 583 (9th Cir. 2014)). The State "has no legitimate interest in enforcing an unconstitutional" law. *Id*. And, although California has an interest in accurately informing its citizens of possible health risks, "[p]roviding misleading or false labels to consumers also undermines [that] interest . . . at the expense of [PCPC's] First Amendment rights." *Id*. Therefore, just as in *Wheat Growers II*, "the balance of equities and public interest weigh in favor of permanently enjoining Proposition 65's warning requirement" for DEA in cosmetics and personal care products. *See id.*, *aff'd NAWG*, 85 F.4th at 1283; *see also CERT*, 29 F.4th at 481-82 (finding this Court had "sufficient reason to enjoin Prop. 65 acrylamide litigation").

E. Declaratory Relief Is Appropriate.

PCPC is entitled to a declaration pursuant to 28 U.S.C. § 2201 that the Proposition 65 warning requirement for cancer as applied to DEA in cosmetic and personal care products violates the First Amendment. The procedural requirements for such a declaration are met: (1) "there is a case of actual controversy"; and (2) the Court should exercise its jurisdiction to decide that controversy. *Am. States Ins. Co. v. Kearns*, 15 F.3d 142, 143-44 (9th Cir. 1994).

The first requirement is "identical" to establishing Article III standing. *Id*. at 143. The

undisputed factual record shows that many of PCPC's members have for years faced enforcement actions alleging they are required to provide warnings for DEA. SUMF Nos. 90-93. For purposes of standing, "[i]t is well settled that evidence of past instances of enforcement is important." *LSO, Ltd. v. Stroh*, 205 F.3d 1146, 1155 (9th Cir. 2000). "[T]he Government's failure to disavow application of the challenged provision"—as here—is another factor in favor of finding standing. *Id.* And "when the threatened enforcement effort[s] implicate[] First Amendment rights," as they do here, "the inquiry tilts dramatically toward a finding of standing." *Id*. Absent a declaration from this Court, PCPC members currently embroiled in the dozens of lawsuits alleging failure to warn of DEA with additional claims will continue to incur expenses and damages for litigation, reformulation and testing, and/or unwarranted warnings. SUMF Nos. 90-96.

As to the second requirement, declaratory relief is appropriate "(1) when the judgment will serve a useful purpose in clarifying and settling the legal relations in issue, and (2) when it will terminate and afford relief from the uncertainty, insecurity, and controversy giving rise to the proceeding." *Bilbrey by Bilbrey v. Brown*, 738 F.2d 1462, 1470 (9th Cir. 1984); *see also PCPC*, 799 F. Supp. 3d at 1096. Here, declaratory relief would provide needed clarity as to the constitutionality of a misleading and controversial warning requirement. It would "serve to delineate important [constitutional] rights" of PCPC's members who wish to lawfully do business. *See id.* at 1471. And it would put private enforcers on notice that they may no longer enforce this controversial application of Proposition 65.

V. CONCLUSION

For the reasons stated above, and consistent with the Eastern District's decisions in the three prior lawsuits challenging Proposition 65 cancer warnings for chemicals whose listings were based on questionable science, the Court should grant summary judgment in favor of Plaintiff, permanently enjoin enforcement of Proposition 65's warning requirement as to DEA in cosmetics and personal care products, and declare that any such enforcement is unconstitutional.

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Respectfully submitted,

DATED: April 27, 2026

HOGAN LOVELLS US LLP

By: */s/ Trenton H. Norris*
Trenton Norris

Attorneys for Plaintiff
THE PERSONAL CARE PRODUCTS COUNCIL

CERTIFICATE OF SERVICE

I am a citizen of the United States and employed in the City and County of San Francisco, California. I am over the age of eighteen years and not a party to the within-entitled action. My business address is Hogan Lovells US LLP, Four Embarcadero Center, Suite 3500; San Francisco, California 94111.

On April 27, 2026, I served a true copy of the following document(s):

- **NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT;**
- **DECLARATION OF WILLIS WAGNER;**
- **DECLARATION OF EMILY MANOSO;**
- **DECLARATION OF DR. JAMES BUS; APPENDICES TO DECLARATION OF DR. JAMES BUS;**
- **SEPARATE STATEMENT OF UNDISPUTED MATERIAL FACTS;**
- **REQUEST FOR JUDICIAL NOTICE;**
- **EXHIBITS A-T;**
- **PROPOSED ORDER GRANTING MOTION FOR SUMMARY JUDGMENT**

by Electronic Submission. I served the above listed document(s) described via the United States District Court's Electronic Filing Program on the designated recipients via electronic transmission through the CM/ECF system on the Court's website. The Court's CM/ECF system will generate a Notice of Electronic Filing (NEF) to the filing party, the assigned judge, and any registered users in the case. The NEF will constitute service of the document(s). Registration as a CM/ECF user constitutes consent to electronic service through the court's transmission facilities.

Laura J. Zuckerman Megan K. Hey Mary Haley Ousley Department of Justice Office of the Attorney General 1515 Clay Street, 20th Floor Oakland, California 94612 Telephone: 510-879-3957 maryhaley.ousley@doj.ca.gov	Attorneys for Defendant Rob Bonta, Attorney General of the State of California

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I declare under penalty of perjury that the foregoing is true and correct. Executed on April 27, 2026, at San Francisco, California.

Jim Brossard