No._____

IN THE SUPREME COURT OF CALIFORNIA

AMERICAN CHEMISTRY COUNCIL,

Plaintiff and Petitioner,

v.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, ET AL.,

Defendants and Respondents.

After a decision of the Court of Appeal of the State of California,
Third Appellate District, Case No. C079260

The Superior Court Sacramento County, Case No. 34-2014-80001868
The Honorable Christopher Krueger, Judge Presiding

PETITION FOR REVIEW

GIBSON, DUNN & CRUTCHER LLP
*THEODORE J. BOUTROUS JR., SBN 132099
TBOUTROUS@GIBSONDUNN.COM
333 SOUTH GRAND AVENUE
LOS ANGELES, CA 90071-3197
TELEPHONE: 213.229.7000
FACSIMILE: 213.229.7520

EIMER STAHL LLP
ROBERT E. DUNN., SBN 275600
RDUNN@EIMERSTAHL.COM
99 S. ALMADEN BLVD.,
SUITE 662
SAN JOSE, CA 95113
TELEPHONE: 669.231.8755
FACSIMILE: 312.692.1718

ATTORNEYS FOR PETITIONER
AMERICAN CHEMISTRY COUNCIL

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes

Regulations

Publications

I. ISSUES PRESENTED

(1) Should an agency's decision be set aside when it violates its own published rules in order to reach a decision that would have been prohibited by a faithful application of those rules?

(2) Was the Office of Environmental Health Hazard Assessment's decision to list diisononyl phthalate on the Proposition 65 list of "chemicals known to the state to cause cancer," which was based solely on a vote of the Carcinogen Identification Committee, arbitrary and capricious where every other health agency that has studied the chemical has concluded that it is *not* a human carcinogen and where the Chairman of the Committee instructed the other members to ignore the Committee's published Guidance Criteria and instead apply a new standard of his own invention moments before the vote?

II. WHY REVIEW SHOULD BE GRANTED

In the opinion below, the Court of Appeal upheld a decision by Respondent Office of Environmental Health Hazard Assessment ("OEHHA) to add diisononyl phthalate ("DINP") to the Proposition 65 list of chemicals known to the state to cause cancer. OEHHA's decision was based on a vote of the "state's qualified experts" (Cal. Health & Safety Code §25249.8, subd. (b))[1]—the Carcinogen Identification Committee ("CIC"). The CIC's published Guidance Criteria allow the Committee to vote to list a chemical based on evidence that the chemical causes cancer in animals—due to the rebuttable presumption that animal carcinogens are hazardous to humans—but the Criteria specifically provide that listing is

[1] All references are to the Health and Safety Code unless otherwise noted.

inappropriate where "the mechanism of action has been shown not to be relevant to humans." (AR 8889 ¶1.D.)

Although studies have found that DINP causes cancer in laboratory rodents, there is overwhelming scientific evidence that DINP is not a cancer hazard to humans. The CIC's own Guidance Criteria thus required the Committee to vote *against* listing DINP. But at the hearing where the Committee evaluated the scientific evidence, the Chairman of the Committee directed the other members to ignore the text of the Guidance Criteria and instead apply a new standard he invented on the spot that effectively *required* the Committee to vote in favor of listing. This Court's review is urgently needed for three primary reasons.

First, in upholding OEHHA's decision, the Court of Appeal set a dangerous precedent that gives the CIC unfettered discretion to change the Guidance Criteria at will to reach a desired result. In describing the standard of review, the court stated that it would "uphold the decision" if the agency "considered all relevant factors and demonstrated a rational connection between those factors, the choice made, and the purposes of the statute." (Ex.A at 8 [citing *Exxon Mobil Corp. v. Office of Environmental Health Hazard Assessment* (2009) 169 Cal.App.4th 1264, 1277].) But although the CIC's published Guidance Criteria are presumably "relevant factors" in the decision-making process, the court held that the CIC was *not* required to "slavishly follow[]" the Criteria. (Ex.A at 4.) And rather than holding the agency's feet to the fire, the court simply "assume[d]" that the Committee followed its Criteria. (Ex.A at 13.)

As OEHHA conceded in seeking publication of the opinion below, this case involves "a legal issue of continuing public interest," and the Court of Appeal issued "the first appellate decision" addressing "the

'state's qualified experts' mechanism for listing chemicals as carcinogens or reproductive toxins under [Proposition 65]." (OEHHA Request for Publication, Attached hereto as Exhibit B [quoting §25249.8, subd. (b)].) The agency apparently intends to take full advantage of the limitless discretion authorized by the court's opinion. In urging the court to publish, OEHHA indicated that it sought to enshrine into law the principle that the "guidance criteria 'are not intended to be binding regulations or slavishly followed.'" (Ex.B.) This case thus squarely presents the question whether, as a matter of California administrative law, an agency's decision should be set aside when it fails to follow its own internal rules.

Federal law provides a useful roadmap for resolving this question. The United States Supreme Court has long held that the decision of a federal administrative agency should be set aside where the agency failed to follow its own internal rules or operating procedures. (See *Accardi v. Shaughnessy* (1954) 347 U.S. 260, superseded by statute.) "*Accardi* has come to stand for the proposition that agencies may not violate their own rules and regulations to the prejudice of others." (*Battle v. Federal Aviation Administration* (D.C. Cir. 2005) 393 F.3d 1330, 1336.) By requiring federal agencies to follow their own procedures, the doctrine upholds the rule of law and engenders public confidence in agency decisions. Although it has often been noted that "[m]en must turn square corners when they deal with the Government" (*Rock Island, A& L. R. Co. v. United States* (1920) 254 U.S. 141, 143), it is equally true that "the Government should turn square corners in dealing with the people" (*Department of Homeland Security v. Regents of University of California* (2020) 140 S.Ct. 1891, 1909). State agencies, including OEHHA, should likewise be required to follow their internal rules, especially when making decisions that have wide-ranging consequences for businesses and

consumers across the state. This case affords the Court an opportunity to issue a clear statement on this important issue of administrative law.

Second, the Court of Appeal erred in upholding the agency's decision to list DINP on the Proposition 65 list. Although the CIC's Guidance Criteria authorize it to list a chemical based on studies showing that the chemical causes cancer in animals, the Criteria state that a chemical should *not* be listed when the "mechanism of action has been shown not to be relevant to humans." (AR 8889 ¶1.D.) This provision is consistent with the text of Proposition 65, which "clearly was intended to protect people and not household pets or livestock." (*AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, 435.) Here, although studies have shown that DINP causes various cancers in laboratory rodents, there is overwhelming scientific evidence that the mechanisms of action are not relevant to humans. In other words, because of the differences in physiology between humans and rodents, DINP does not pose a cancer hazard to humans. Every other public health agency that has studied DINP—including the Environmental Protection Agency, the European Chemicals Bureau, and the Australian public health agency—has reached the same conclusion.

Yet at the CIC hearing to review DINP, the Chairman of the Committee directed the other members to ignore the text of the Guidance Criteria, erroneously asserting that human relevance is "not the question," and that the Committee should vote to list based on animal studies unless there is "good epidemiologic data suggesting that there is no effect on humans." (AR 9523:2-9524:1.) But in addition to departing from the text of the Criteria, the Chairman's new standard makes little sense as a scientific matter, because human epidemiologic data—*i.e.*, data comparing the incidence of cancer in exposed populations to unexposed populations—is almost *never* available. Under Chairman Mack's erroneous new standard,

a chemical that causes cancer in animals could be listed even if every member of the CIC *knew* it was harmless to humans. That result is at odds with the statute, which voters passed to protect *people* not animals.

Given the Chairman's erroneous instructions, the Committee unsurprisingly voted to list DINP on the Proposition 65 list. The Court of Appeal upheld the agency's action based on a gross misreading of the transcript, concluding that it was ambiguous whether the Committee properly applied the Guidance Criteria. But a comprehensive review of the hearing transcript—the only evidence of the Committee's decision-making process—removes all ambiguity and confirms that the CIC applied the wrong standard. This Court should grant review to correct the Court of Appeal's error and set aside the erroneous listing decision.

Third, this case presents an issue of extreme importance. The listing of a substance under Proposition 65 has wide-ranging and serious consequences. Businesses must warn the public about all listed chemicals present in their products and facilities. As a result, businesses routinely attach unnecessary warnings on thousands of everyday products, leaving Californians "overwarned, underinformed, and potentially unprotected."[2] Yet because there are now over 900 chemicals and elements on the Proposition 65 list, many small businesses inadvertently fail to provide the required warnings, exposing them to lawyer-driven "bounty-hunter" lawsuits that are almost always cheaper to settle than to fight because Proposition 65 imposes civil penalties of $2,500 per violation *per day*. As a result, Proposition 65 "has funneled hundreds of millions of dollars to a

[2] Geoffrey Mohan, *You see the warnings everywhere. But does Prop. 65 really protect you?* THE LOS ANGELES TIMES (July 23, 2020) (hereinafter "*Warnings everywhere*"), https://www.latimes.com/business/story/2020-07-23/prop-65-product-warnings.

handful of attorneys and their repeat clients." (*Ibid.*) Given the potential for frivolous shakedowns of small businesses, the process for adding chemicals to the Proposition 65 list should be rigorous, and courts should closely examine whether the agency faithfully applied its own rules before upholding a listing decision.

III. STATEMENT OF THE CASE

A. The Statutory Scheme

Proposition 65, which was enacted via ballot initiative in 1986 (§25249.5 et seq), directs the Governor to publish, and revise annually, "a list of those chemicals known to the state to cause cancer or reproductive toxicity." (§25249.8, subd. (a).) Once a chemical is listed, no person "in the course of doing business" in the State of California shall "knowingly and intentionally expose any individual" to the chemical without first issuing "clear and reasonable" warnings about the exposure. (§25249.6.) Proposition 65 is enforced by the Attorney General's office, local law enforcement, and via a "citizen attorney general" provision that permits private plaintiffs to bring claims against alleged violators so long as those actions are "in the public interest." (§25249.7, subd. (d).) Any person that violates Proposition 65 is liable for civil penalties of up to $2,500 per violation, per day, and may also be liable for the enforcer's attorney's fees. (§25249.7, subd. (b)(1); CCP, §1021.5.)

OEHHA is the "lead agency" designated by the Governor to publish and maintain this list. (§25249.12, subd. (a); see also Cal. Code Regs., tit. 27 ("27 CCR"), §25102 subd. (o).) As relevant here, OEHHA may list a chemical if "in the opinion of the state's qualified experts [the chemical] has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity."

(§25249.8, subd. (b).) The state's "qualified experts" for the purpose of identifying carcinogens are the members of the Carcinogen Identification Committee ("CIC"). (27 CCR, §25302.) The CIC is authorized to "render an opinion, pursuant to subdivision (b) of Section 25249.8 of the Act, as to whether specific chemicals have been clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer." (27 CCR, §25305, subd. (a)(1).)

The CIC does not conduct independent scientific studies or experiments on the carcinogenicity or toxicity of chemicals. Rather, OEHHA's staff scientists prepare a summary of the scientific evidence on the chemicals' carcinogenicity for the CIC, called a Hazard Identification Document ("HID"). (CT 75.) In preparing the HID, OEHHA reviews the scientific literature on the chemical's carcinogenicity and solicits information from the public. (*Ibid.*) Once prepared, OEHHA releases the HID and the supporting materials to the members of the CIC and to the public for a 45-day comment period. (*Ibid.*) After the close of the comment period, OEHHA provides each CIC member with a copy of all comments and supporting documents for review prior to the meeting at which the CIC discusses the evidence and votes whether to recommend listing the chemical. (*Ibid.*)

The CIC reviews the research studies and other information presented according to the *Guidance Criteria for Identifying Chemicals for Listing as "Known to the State to Cause Cancer*" ("Guidance Criteria"), which the Committee adopted in 2001. (AR 8889-8893.) The Guidance Criteria specify that the CIC shall utilize a "'weight-of evidence' approach" to evaluate the body of information available for any given chemical, including "all evidence bearing on the issue of carcinogenicity shown

through scientifically valid testing according to generally accepted principles" of scientific inquiry. (AR 8889 ¶1.C.)

The Guidance Criteria specify that the CIC will "normally identify [a] chemical for listing" if "the weight of the scientific evidence clearly shows that [the] chemical causes invasive cancer in humans, or that it causes invasive cancer in animals (*unless the mechanism of action has been shown not to be relevant to humans*)[.]" (AR 8889 ¶1.D, italics added.) Unlike epidemiological studies, which compare the incidence of cancer in human populations exposed to a chemical with the incidence of cancer in unexposed populations, mechanistic evidence focuses on the "actual biochemical processes by which a substance causes cancer." (*Tozzi v. HHS* (D.C. Cir. 2001) 271 F.3d 301, 305.) The Guidance Criteria thus recognize the possibility that a chemical may cause cancer in laboratory animals by a mechanism of action—i.e., a biochemical process—that does not operate in humans.

B. No Regulatory Body Has Determined That DINP Should Be Classified As A Carcinogen

DINP is an important commercial chemical used to soften or "plasticize" polyvinyl chloride ("PVC"), commonly referred to as flexible vinyl. DINP is used "to improve the flexibility, pliability, and elasticity of a variety" of important products, "including vinyl flooring, wire and cable insulation, stationery, coated fabrics, gloves, tubing, garden hoses, artificial leather, footwear, automobile undercoatings, and roofing materials." (AR 1577.) DINP is also used as a softener "in the production of non-PVC products, such as rubbers, inks, pigments, paints, lacquers, adhesives, and sealants." (*Ibid.*)

"DINP and phthalates in general as a class are some of the most widely studied industrial chemicals in commerce today." (AR 9466:7-9.)

In the 1990s, several studies were published showing that rodents exposed to DINP in extremely high doses—orders of magnitude higher than any human would ever be exposed to the chemical—tended to develop more cancers than unexposed rodents. (AR 8975-8976.) However, the overwhelming weight of scientific evidence shows that the mechanisms of action by which DINP causes cancer in laboratory rodents do not operate in humans. (AR 708, 1401, 8975-8976.) Based on this scientific evidence, numerous government agencies and public health organizations around the world have declined to list DINP as a known human carcinogen.

In 2001, the Consumer Product Safety Commission's Chronic Hazard Advisory Panel ("CPSC CHAP"), consisting of seven independent experts, concluded that DINP was unlikely to pose a cancer risk to humans. (AR 2150, 217.) A workgroup of the International Life Sciences Institute reached a similar conclusion in 2003. (AR 217-218, 3057.) The European Union Risk Assessment Report produced by the European Chemicals Bureau in 2003 likewise concluded that DINP was unlikely to pose a cancer risk to humans, and the European Commission determined that DINP should not be classified as a carcinogen. (AR 9847-9848, 217.) A 2004 review conducted by several CPSC scientists and published in Regulatory Toxicology and Pharmacology discussed the mechanistic evidence and concluded that "DINP is not likely to present a cancer risk to humans[.]" (AR 60, 52-53.)

More recent reviews by other health agencies have likewise declined to classify DINP as a human carcinogen. In 2012, the Australian NICNAS confirmed that the incidences of cancers observed in rodent carcinogenicity studies "are regarded to be species specific and *not relevant to humans*." (AR 9923, italics added.) In 2013, the European Chemicals Agency concluded that "the carcinogenic responses … in rodents are of little or

unclear relevance to humans." (AR 10105.) OEHHA has never identified a single authoritative body that has concluded that DINP is carcinogenic to humans.

C. OEHHA Issues a Hazard Identification Document for DINP

On October 16, 2009, OEHHA issued a "Request for Relevant Information" on DINP's carcinogenicity. (AR 611-663).) ExxonMobil submitted a response to OEHHA's request, which summarized and attached numerous scientific studies conducted over the prior two decades showing that DINP does not pose a cancer hazard to humans. (AR 725-1534.) ExxonMobil's submission explained that "there is a very robust data base for DINP demonstrating that [the] tumors [observed] in rodents are not relevant to a human cancer hazard assessment and that DINP is unlikely to cause cancer in humans." (AR 1401.) ACC also submitted comments, explaining that "listing DINP as a carcinogen under Proposition 65 would be contrary to California law as no evidence exists that DINP is a human carcinogen[.]" (AR 708.)

Three and a half years later, on October 4, 2013, OEHHA finally released the HID to the public and initiated a 45-day public comment period. (AR 1539-1540, 1565.) The HID largely focused on the studies conducted on rodents (AR 1570-1572, 1580-1617), and concluded that DINP has "positive carcinogenicity data in rats and mice" (AR 1613).

ACC and ExxonMobil submitted comments on November 18, 2013 that pointed out many glaring deficiencies in OEHHA's summary of the scientific evidence relating to DINP. (AR 8907-9302.) ExxonMobil's comments explained that the HID failed to "provide a balanced and complete summary" of evidence, "consistently fail[ed] to recognize the breadth and depth of available scientific literature that exhaustively shows

the lack of human relevance and/or biological significance of the rodent observations[,] … [and] engage[d] in speculation about possible alternative mechanisms of action in rodents." (AR 8908.)

D. The CIC Chairman Directs the Committee to Ignore the Guidance Criteria and Shuts Down Debate about the Mechanistic Evidence

At the CIC meeting on December 5, 2013, two OEHHA scientists presented evidence that DINP causes cancer in rodents. (AR 9433:25-9461:3.) Following OEHHA's presentation, three scientists presenting on behalf of ACC discussed evidence showing that the mechanisms of action by which DINP causes various cancers in rodents are not relevant to humans. (AR 9461:17-9486:17.) These presentations made an impact on the committee members. In the brief discussion that followed, several members questioned whether the evidence showed that the mechanisms of action were relevant in humans. (AR 9512:21-9512:23 [Landolph: "I struggle with the issue of the relevance to human tumors"], 9513:8-9513:10 [Zhang: "Dr. Landolph already … expressed the most things I needed to say"], 9514:16-20 [Reynolds: "I really would like to hear more … about this issue that seems very key, which is really whether the mechanism of action has been shown to be relevant in humans"], 9518:6-9 [Eastmond: "I don't feel real confident listing on that given the human relevance that there's real questions about. I mean, these are very significant questions about whether this data is relevant to humans"], 9520:3-4 [Bush: "what I'm wrestling with is whether this is meaningful for humans"].)

Chairman Mack, who was the last member to share his reactions to the presentation, offered his "own view" that because Proposition 65 does not ask whether a chemical causes cancer *in humans*, "the question to me is does this stuff cause cancer?" (AR 9520:8-17.) He then attempted to bring

the committee to a vote. (AR 9521:8.) However, his statement understandably created confusion about the standard for listing, and one of the other Committee members interjected to seek clarification as to whether the committee "could vote or list based on animal data." (AR 9521:13-14 [Zhang].) Although paragraph 1.D says nothing about epidemiologic data, Chairman Mack responded that "in the absence of epidemiologic information, we're stuck making decisions about animal data." (AR 9521:21-23.)

Another Committee member noted that paragraph 1.D directs the Committee to consider whether "the *mechanism of action* has been shown not to be relevant in humans," and attempted to engage OEHHA's staff scientist in a discussion about the mechanistic evidence. (AR 9522:14-17 [Thomas], italics added.) However, Chairman Mack interrupted that discussion, asserting that because he was "the person who wrote those guidelines" he wanted to "try and describe to [the Committee] why that verbiage was put in there." (AR 9522:25-9523:2.) Once again shifting the focus from the "mechanism of action" to "epidemiologic" data, Chairman Mack stated that paragraph 1.D. was drafted for the "circumstance where there's extremely good epidemiologic data suggesting that there is no effect on humans" but there are "one or two animal studies with liver cancers in rats, in which there is a marginally increased effect." (AR 9523:2-12.) Because there "is no epidemiologic data" for DINP, Chairman Mack declared that "[*w*]e *have to go solely on the animal data*." (AD 9523:10-12, italics added.)

Counsel for ACC member BASF, Stanley Landfair, attempted to clarify that because "everyone concedes . . . that the animal data do show different cancers in different animals," "the question before the Committee is whether those data are relevant to humans[.]" (AR 9523:20-24.) But

Chairman Mack abruptly cut him off and insisted that "[*t*]*hat's not the question*. That's the whole problem. *The question is not whether or [not] they're relevant to humans*." (AR 9524:1-6, italics added.)

Mr. Landfair made one last attempt to refocus the Committee's attention on the actual Guidance Criteria (AR 9524:11-12), but Chairman Mack again cut him off, reiterated that the Criteria were written "for the circumstance in which there was a conflict between human epidemiologic data and information from animals," and pressed the committee to vote. (AR 9524:13-20.)

Six members of the CIC voted to recommend listing DINP, one member voted against listing, and one member abstained. (AR 9526:20-9527:4.) OEHHA added DINP to the Proposition 65 list, effective December 20, 2013, in accordance with the CIC's recommendation. (AR 9611.)

E. The Trial Court Denies ACC's Petition for Writ of Mandate, and the Court of Appeal Affirms

ACC filed a petition for a writ of mandate on June 9, 2014, asserting that OEHHA's decision to list DINP was arbitrary and capricious because the CIC's vote was tainted by Chairman Mack's erroneous instructions. (CT 1.) The trial court recognized that ACC "would be entitled to a writ of mandate if it could prove the CIC's decision was based on an incorrect interpretation of the law," but it concluded that ACC failed "to make that showing." (CT 180.)

On June 10, 2020, the Court of Appeal affirmed the trial court's decision in an unpublished opinion. (*See* Ex.A.) Although Paragraph 1.A of the Guidance Criteria states that "[t]he criteria included herein *shall be utilized* by the [OEHHA] Science Advisory Board [CIC] to identify those

chemicals which are to be recommended for listing as known to the State to cause cancer" (AR 8889 ¶1.A), the court began its analysis by asserting that the "Guidance criteria are not intended to be binding regulations or to be slavishly followed." (Ex.A at 4.) The court asserted that the Criteria "are intended neither to limit the scope of the Committee's consideration of all appropriate cumulated scientific information, nor to limit the use of best scientific judgment available at the time." (*Ibid.* [quoting AR 8889, ¶1.B].)

Turning to ACC's claim that the CIC's vote was tainted by Chairman Mack's erroneous instructions, the court stated that, "absent evidence to the contrary, [it] must presume the [Committee] properly performed its duties." (Ex.A at 9 [citing Evid. Code, § 664].) Because the CIC does not "make findings or explain how the evidence supports its decision," the court recognized that the hearing transcript is the "primary evidence" supporting ACC's arbitrary-and-capricious claim. (Ex.A. at 9.)

Yet the court inexplicably failed to discuss the most relevant portion of the transcript—namely, Chairman Mack's exchange with Mr. Landfair in which Mack unequivocally (and erroneously) told the other members of the Committee that human relevance was *not* the question. The court instead focused on two of Chairman Mack's other erroneous statements and, concluding they were ambiguous, declined to "assume" that the other "Committee members failed to follow the criteria they were instructed to follow." (Ex.A at 10-13.)

ACC filed a petition for rehearing on June 25, 2020, alerting the court to its failure to address the critical portion of the hearing transcript. As ACC explained, any "ambiguity" in the transcript "disappears when Chairman Mack's erroneous discussion of epidemiologic data is viewed in

the context of his exchange with Mr. Landfair." (Pet. at 12.) The court denied ACC's petition for rehearing on July 8, 2020.

Meanwhile, on June 26, 2020, while ACC's petition for rehearing was pending, OEHHA filed a letter asking the court to order publication of its opinion. (*See* Ex.C.) As OEHHA's letter correctly noted, this is "the first appellate decision to address the 'state's qualified experts' mechanism for listing chemicals as carcinogens or reproductive toxins under [Proposition 65]." (Ex.C. at 1.) OEHHA asserted that the court's "observation that the guidance criteria 'are not intended to be binding regulations or to be slavishly followed' clarifies the role the criteria are to play in listing decisions, which is an issue that arises frequently in public comments and during the Committee's proceedings." (Ex.C. at 1-2.) OEHHA also contended that the opinion helpfully "clarifies" that arguments related to the adverse "*consequences*" of a listing decision "do not implicate the propriety of the listing decision itself, because "'consequences do not bear on OEHHA's discretion to list' a chemical." (Ex.C at 2 [quoting Ex.A at 17].)

The Court of Appeal ordered publication on July 8, 2020. (*See* Ex.B.) The court's opinion thus became final on August 7, 2020.

IV. ARGUMENT

As OEHHA argued, and the Court of Appeal agreed, this case presents a matter of first impression and "involves an issue of continuing public interest." (Ex.C. at 2.) This is the first case in which the courts have been asked to review a decision by the CIC to list a chemical on the Proposition 65 list. It thus provides the Court a valuable opportunity to clarify the standard for reviewing the CIC's decisions, an extremely important issue given the immense consequences resulting from a

chemical's placement on the Proposition 65 list. This case is also an excellent vehicle for addressing, more broadly, whether an agency's quasi-legislative action must be set aside when the agency violates its own internal rules, especially in situations where the public has relied on those rules for many years. Because OEHHA's decision to list DINP on the Proposition 65 list was fatally tainted by Chairman Mack's erroneous instructions directing the CIC to ignore the mechanistic evidence and vote solely based on animal carcinogen studies, this Court should grant review and reverse the judgment of the Court of Appeal.

A. This Case Presents A Novel Question as To Whether the Carcinogen Identification Committee Must Follow Its Published Guidance Criteria When Voting to List Chemicals on the Proposition 65 List

The Guidance Criteria utilized by the CIC are not codified in Proposition 65 or published in the California Code of Regulations. Nevertheless, the CIC produced the Guidance Criteria in 2001 after a thorough 14-month process in which it solicited comments and held several public hearings. The public input focused closely on the language of paragraph 1.D, which describes the circumstances in which the CIC can list a chemical based on studies showing that a chemical causes cancer in animals. (AR 8889 ¶1.D.) Because of the reasonable "*inference* that carcinogenicity in other animals means carcinogenicity in humans," chemicals can be listed solely on the basis of animal studies. (*Western Crop Protection Association v. Davis* (2000) 80 Cal.App.4th 741, 749, italics added.) But the inference of human carcinogenicity is rebuttable because animals and humans are not physiologically identical. And as several trade associations, including ACC, stressed to the CIC when it was drafting the Criteria, the presumption most often will be rebutted through *mechanistic* evidence. (See ACC Opening Br. at 38-40.)

By adopting the current version of Paragraph 1.D, the CIC led the public to believe that it would *not* vote to list a chemical based on animal studies if it could be shown that the "mechanism of action [is] not relevant to humans." (AR 8889 ¶1.D.) After all, the very first paragraph of the Guidance Criteria plainly states that the Criteria "shall be utilized" by the CIC to identify chemicals for listing. (AR 8889 ¶1.A.)

Relying on the Guidance Criteria as a faithful guide to the CIC's decision-making process, ACC and its member companies devoted substantial time and resources to showing that the mechanisms of action by which DINP causes various cancers in rodents are not relevant to humans. (AR 725-1534, 8903-9340.) Indeed, ACC brought several of the world's foremost experts on phthalates—and DINP in particular—to the CIC hearing to testify exclusively about the compelling mechanistic evidence. (See 9468:1-9486:17.)

And yet, when Petitioner challenged the CIC's decision in this case, OEHHA argued that the criteria were simply "general statements of policy" designed to "advise the public prospectively as to how the agency intends to exercise its discretion, and are not intended to be binding regulations." (OEHHA Resp. Br. at 15.) The Court of Appeal adopted OEHHA's position and upheld the decision to list DINP even though the Chairman of the Committee jettisoned the key provision of the Criteria during the hearing and informed the other members to vote solely based on animal studies. (See *infra* IV.B.) In so doing, the Court of Appeal effectively granted the CIC boundless discretion to ignore or amend the Guidance Criteria without notice.

If the CIC is not constrained by the written Criteria, it can list chemicals based on whatever evidence it deems relevant without *any*

possibility of meaningful judicial review. Indeed, as OEHHA's request for publication indicates, the agency hopes to rely on the Court of Appeal's decision to ward off future challenges to listing decisions.

Review is warranted because the decision below is at odds with this Court's well-established precedent holding that when dealing with "quasi-legislative" agency decisions—such as OEHHA's decision to add DINP to the Proposition 65 list—courts must ask whether the agency's action was "arbitrary, capricious, or entirely lacking in evidentiary support, or whether [the agency] has *failed to follow the procedure* and given the notices required by law." (*Pitts v. Perluss* (1962) 58 Cal.2d 824, 833, emphasis added.) Lower courts have similarly held that where such agency action is challenged in court, the "relevant inquiry" is whether the agency "failed to comply with the requirements of [the] regulatory program." (*City of Sacramento v. State Water Resources Control Bd.* (1992) 2 Cal.App.4th 960, 976; see also *Schenley Affiliated Brands Corp. v. Kirby* (1971) 21 Cal.App.3d 177, 196-97 [noting that while "courts are precluded from fresh evidentiary inquiry," they are obliged to determine whether the agency "failed to follow procedures established by law"].) This case provides the Court its first opportunity to apply these principles of administrative law to listing decisions predicated on the vote of the CIC.

In addressing that novel issue, this Court may find it helpful to look to federal precedent. It is a bedrock principle of federal administrative law that an agency is bound to follow its own rules "even when the administrative action under review is discretionary in nature." (*Service v. Dulles* (1957) 354 U.S. 363, 372 [citing *Accardi*, *supra*, 347 U.S. 260]; see also *Vitarelli v. Seaton* (1959) 359 U.S. 535, 539-40 [Secretary of Interior was "bound by the regulations which he himself had promulgated for dealing with [employee discharge] cases"].) The so-called "*Accardi*

doctrine" stands for the proposition that "[a]n agency of the government must scrupulously observe rules, regulations, or procedures which it has established. When it fails to do so, its action cannot stand and courts will strike it down." (*United States v. Heffner* (4th Cir. 1969) 420 F.2d 809, 811; *see also Battle v. Federal Aviation Administration* (D.C. Cir. 2005) 393 F.3d 1330, 1336 ["*Accardi* has come to stand for the proposition that agencies may not violate their own rules and regulations to the prejudice of others."]; 32 Fed. Prac. & Proc. Judicial Review §8165 ["One of the most firmly established principles in administrative law is that an agency must obey its own rules."].)

Courts have recognized that the *Accardi* doctrine "extends beyond formal regulations." (*Alcaraz v. I.N.S.* (9th Cir. 2004) 384 F.3d 1150, 1162.) For example, the Ninth Circuit has held that, "[p]ursuant to the *Accardi* doctrine, an administrative agency is required to adhere to its own internal operating procedures." (*Church of Scientology of California v. United States* (9th Cir. 1990) 920 F.2d 1481, 1487; see also *Romeiro de Silva v. Smith* (9th Cir. 1985) 773 F.2d 1021, 1024 [noting that INS could be bound by its own "operating instructions"]; *United States v. 1996 Freightliner Fld. Tractor VIN 1FUYDXYBoTP822291* (9th Cir. 2011) 634 F.3d 1113, 1116 ["Generally, the government is bound by the regulations it imposes on itself."].)

The theoretical basis for the doctrine is self-evident: "*Ad hoc* departures from [an agency's] rules, even to achieve laudable aims, cannot be sanctioned, for therein lie the seeds of destruction of the orderliness and predictability which are the hallmarks of lawful administrative action." (*Reuters Limited v. Federal Communications Commission* (D.C. Cir. 1986) 781 F.2d 946, 950-51 (citation omitted).) The *Accardi* doctrine thus "prevent[s] the arbitrariness which is inherently characteristic of an

agency's violation of its own procedures." (*Heffner*, *supra*, 420 F.2d at p. 812.) As the Chief Justice reminded a federal agency earlier this year, "the Government should turn square corners in dealing with the people." (*Department of Homeland Security*, *supra*, 140 S.Ct. at p. 1909.)

This rationale applies with equal force to state agencies, and the Court of Appeal's decision upholding OEHHA's lawless decision threatens to introduce further unpredictability into the Proposition 65 regulatory regime. To prevent these "seeds of destruction" from taking root, this Court should grant review and make clear that an agency cannot "deviate from its rules in order to achieve what it deems to be justice in the individual case" by "walking away from the metes and bounds which otherwise constrain" the agency's conduct. (*Reuters Limited*, *supra*, 781 F.2d at p. 951.)

B. The Court of Appeal Erred in Holding that OEHHA's Listing Decision Was Not Arbitrary and Capricious

This is an ideal vehicle for addressing the proper standard for reviewing CIC decisions because the transcript of the Committee's hearing reveals that the Chairman flatly contradicted the text of the Guidance Criteria and instructed the other members to ignore the compelling mechanistic evidence showing that DINP is not a human carcinogen. The Court of Appeal rejected ACC's arbitrary-and-capricious challenge on the ground that Chairman Mack's statements were ambiguous, and that the Committee members were not misled in any event because they had the written criteria in front of them and are "independent experts." (Ex.A at 12-13.) Neither of these grounds for affirmance withstands scrutiny.

1. When Chairman Mack's statements are viewed collectively, there is nothing ambiguous about them. In the short discussion that followed the scientific presentations, the Committee members shared their views about

the evidence and whether they were leaning for or against voting to list DINP. Because all sides agreed that DINP causes various cancers in rodents, the discussion understandably focused on the evidence showing that the mechanisms of action are not relevant to humans. (AR 9512:21-9512:23; 9513:8-9513:10; 9514:16-20; 9518:6-9; 9520:3-4.) But instead of encouraging the Committee to explore this mechanistic evidence further—which would have been helpful given the Chairman's earlier decision to limit the presentation given by scientists on behalf of ACC to 30 minutes total (AR 9461:11-13)—Chairman Mack stated that because Proposition 65 does not ask whether a chemical causes cancer *in humans*, the question whether "this stuff cause[s] cancer." (AR 9520:8-17.) The Chairman thus loaded the dice in favor of listing because there is no dispute that DINP is an animal carcinogen.

After one of the new Committee members asked for clarification as to whether they "could vote or list based on animal data" (AR 9521:13-14), Chairman Mack further confused matters by asserting that, "in the absence of epidemiologic information, we're stuck making decisions about animal data." (AR 9521:21-23.) That is incorrect. Paragraph 1.D of the Guidance Criteria, which the Committee hammered out over 14 months with substantial public input, says nothing about epidemiologic information. Nor would such a reference make sense, because scientists employ "studies of toxicokinetics and mechanisms"—not epidemiologic studies—to "answer questions about the similarity of response between animals and humans." (Cogliano, et al., *The Science and Practice of Carcinogen Identification and Evaluation* (Sept. 2004) 112 Envtl. Health Persp. 1269, 1270.[3]) "Mechanistic studies aim to eventually elucidate the chemical species and cellular processes involved in cancer initiation and

[3] Available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1247515.

development." (*Id.* at p. 1270.) Indeed, epidemiologic data is rarely available, especially for chemicals like DINP where human exposure is limited, because "it is unethical to test humans" and there is a "20-to 30-year latency period of many human cancers." (*AFL-CIO*, *supra*, 212 Cal.App.3d at p. 438 n. 7.) Also, epidemiological studies "often are not sufficiently sensitive to identify a carcinogenic hazard except when the risk is high or involves an unusual form of cancer." (Cogliano, 112 Envt. Health Persp. at p. 1270.) For this reason, the CIC has previously voted *not to list* animal carcinogens when the animal studies were "not relevant to humans." (AR 9599:20-23 [CIC declined to list trichloroacetic acid despite six positive animal studies].) Chairman Mack's assertion that animal carcinogens must be listed absent epidemiologic information thus had no foundation in the text of the Guidance Criteria, the relevant scientific literature, or the CIC's past practice.

Recognizing the discrepancy between Chairman Mack's statement and the written Criteria, another Committee member interjected: "As I read the guidelines that says that if it causes invasive cancer in animals parenthesis, unless the mechanism of action has been shown not to be relevant in humans." (AR 9522:14-17.) But instead of acknowledging his mistake, the Chairman doubled down, asserting that he was the "person who wrote those guidelines" and therefore had authority to explain "why that verbiage was put in there." (AR 9522:25-9523:2.) Repeating his erroneous interpretation of Paragraph 1.D, Chairman Mack asserted that it referred to "a circumstance where there's extremely good epidemiologic data suggesting that there is no effect on humans" and "at the same time, there is one or two animal studies with liver cancers in rats, in which there is a marginally increased effect." (AR 9523:2-6.) That makes no sense. As noted, such epidemiologic data almost *never* exists, and the Committee

would not be asked to review a chemical where only a study or two shows a marginal increase in carcinogenic response in rats. In Chairman Mack's view, the key "unless" clause in Paragraph 1.D, which was the focus of so many public comments, is essentially meaningless. Chairman Mack then concluded that because "[h]ere we're in a situation where there is no epidemiologic data," the CIC "has to go solely on the animal data." (AR 9523:10-12.)

At that point, the attorney representing ACC member BASF, Stanley Landfair, attempted to clarify the proper listing standard. Acknowledging that all sides agreed DINP causes cancer in animals, Mr. Landfair clarified that "the question before the Committee is whether those data [showing cancers in rodents] are relevant to humans[.]" (AR 9523:22-24.) Although that statement was 100% accurate, Chairman Mack abruptly cut off Mr. Landfair and asserted:

> *That's not the question*. That's the whole problem. *The question is not whether or [not] they're relevant to humans*. That's not what the law says. The law says that the regulation, which comes from the Proposition 65, says does it cause cancer? It does not say[,] does it cause cancer in humans?

(AR 9524:1-6, italics and underline added.) Chairman Mack thus told the members of the CIC they should vote to list DINP based on the animal studies, *irrespective* of whether those studies are "relevant to humans." That is precisely the opposite of the actual standard established in the Guidance Criteria. The Court of Appeal completely ignored this key portion of the transcript. And although ACC pointed out this omission in its petition for rehearing, the court did not grant the petition or amend the opinion.

Mr. Landfair made one final attempt to refocus the committee on the actual language of paragraph 1.D (AR 9524:11-12 ["Well, with all respect,

these criteria that the Panel has authored and adopted—"]), but Chairman Mack interrupted to insist that the Criteria were written "for the circumstance in which there was a conflict between human epidemiologic data and information from animals." (AR 9524:13-20.) He then promptly ended all discussion, saying "I don't think we can discuss it any further. We have to take a vote now." (AR 9524:17-18.)

As Mr. Landfair correctly recognized, because there is no dispute that DINP causes cancers in rodents, the only question for the CIC was whether the scientific evidence—which in this case consisted of toxicokinetics and other mechanistic studies—demonstrated that the mechanisms of action by which DINP causes cancers in rats and mice are relevant to humans. But instead of agreeing with Mr. Landfair's statement and focusing the discussion on the mechanistic evidence, Chairman Mack expressly *disputed* Mr. Landfair's assertion that human relevance was the key issue for the Committee. Indeed, the Chairman said that Mr. Landfair was "mistaken" in saying that the sole question for the Committee was whether the animal data is relevant to humans. If Chairman Mack is correct, the CIC could (and presumably should) vote to list chemicals that cause cancer in animals even when the mechanistic evidence proves beyond all doubt that the chemicals are not human cancer hazards. That result cannot be reconciled with the text and purpose of Proposition 65, which the voters passed to protect *people*, not animals. (See *AFL-CIO*, *supra*, 212 Cal.App.3d at p. 435.)

In short, contrary to the Court of Appeal's assertion that the Chairman's statements were ambiguous (Ex.A at 12), there is only one reasonable interpretation of the transcript: by publicly repudiating Mr. Landfair's attempted clarification, Chairman Mack fundamentally altered the standard the CIC spent two years drafting—and which industry had

relied on for over a decade—and directed the Committee to ignore the mechanistic evidence showing that DINP is not a human cancer hazard.

2. The Court of Appeal also concluded that any "ambiguity" in Chairman Mack's comments "cannot be considered in isolation" because the Committee had the printed Guidance Criteria and the "Committee members, made up of independent experts, were twice instructed to follow the criteria." (Ex.A at 12-13.) But those instructions were worthless because the Chairman purported to offer a definitive interpretation of the Criteria based on his supposed authorship. And while the Committee members are all highly trained scientists, they are not legal experts. As the hearing transcript makes clear, there was considerable confusion as to the meaning and application of paragraph 1.D. Moreover, the Committee meets only once or twice a year, so there is no basis for assuming that the CIC members—several of whom were new—were familiar with the Criteria or understood how to apply them.

The Court of Appeal apparently required conclusive proof that each Committee member's vote was influenced by Chairman Mack's erroneous instructions. But that cannot be the standard because the CIC does not issue opinions setting forth the reasons for its vote, and individual members are not required to explain or justify their votes on the record. Instead, like a jury, the CIC simply votes on the relevant question and reports the result of that vote to OEHHA. When deciding whether an erroneous jury instruction was prejudicial, courts do not require conclusive proof that each juror's vote was influenced by the instruction. Rather, courts conduct an "examination of the entire cause" to determine whether it is "'reasonably probable the jury would have returned a more favorable verdict'" had it not been given an incorrect instruction. (*Adams v. MHC Colony Park, L.P.* (2014) 224 Cal.App.4th 601, 614 [quoting *Holmes v. Petrovich Dev. Co.,*

LLC (2011) 191 Cal.App.4th 1047, 1073]; see also *Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 574 [the prejudice assessment "requires evaluation of several factors, including the evidence, counsel's arguments, the effect of other instructions, and any indication by the jury itself that it was misled."].) Here, the totality of the evidence demonstrates that it is reasonably probable the CIC would have voted differently absent Chairman Mack's erroneous statements.

If the Court of Appeal's decision is allowed to stand, it is unclear how a petitioner could *ever* successfully challenge a decision by the CIC. By embracing OEHHA's argument that the Guidance Criteria do no more than inform the public about how the CIC will normally exercise its discretion—while leaving the Committee free to depart from the Criteria on a case-by-case basis—the Court of Appeal has given the Committee *carte blanche* to apply whatever criteria the Chairman invents at the next hearing, irrespective of the published Criteria the Committee is required to utilize.

C. The Petition Raises Questions of Great Importance Because Proposition 65 Listings Entail Substantial Economic Consequences For Businesses Across The State

Proposition 65 is one of the most consequential laws ever enacted through the initiative process. The ubiquitous warning signs posted on businesses across the state, and the cottage industry of private bounty hunters, attest to the Proposition's far-reaching consequences. Expanding the Proposition 65 list to include chemicals that, like DINP, are not hazardous to humans, will cause a proliferation of needless Proposition 65 warnings and expose the state's already beleaguered business owners to an avalanche of frivolous lawsuits that provide no public benefit.

1. Because of the OEHHA's decision to list DINP, thousands of businesses around the state must warn customers about potential exposure

to a harmless chemical. Such warnings provide no benefit, and in fact dilute the efficacy of warnings for hazardous chemicals. "Policymakers have long recognized the dilemma of overwarning in other contexts, such as over-the-counter drugs." Barsa, *California's Proposition 65 and the Limits of Information Economics* (1997) 49 Stan. L. Rev. 1223, 1237.) In the products liability context, this Court has explained that "[r]equiring manufacturers to warn their products' users in all instances would place an onerous burden on them and would invite mass consumer disregard and ultimate contempt for the warning process." (*Johnson v. American Standard, Inc.* (2008) 43 Cal.4th 56, 70 (quotation omitted).)

Gratuitous warnings are also costly. The California Chamber of Commerce estimates that "[n]ew labeling requirements alone are expected to cost California companies between $410 million and $818 million over the next decade." (Mohan, *Warnings Everywhere*, *supra*.) These costs are inevitably passed on to consumers. Requiring manufacturers to add warnings for harmless chemicals, such as DINP, will thus dilute the impact of Proposition 65 warnings and raise prices for all Californians.

2. Erroneous listings also unleash a barrage of litigation against retailers and landlords. As courts have recognized, "instigation of Proposition 65 litigation [is] . . . almost absurdly easy at the pleading and pretrial stages." (*Consumer Defense Group v. Rental Housing Industry Members* (2006) 137 Cal.App.4th 1185, 1215.) Because Proposition 65 authorizes monetary penalties of up to $2,500 per violation *per day* and allows plaintiffs to recover attorneys' fees and 25 percent of penalties assessed (§ 25249.7, subds. (b)(1), (f)), defendants are nearly always forced to settle. (See *Consumer Defense Group*, 137 Cal.App.4th, *supra*, at p. 1216 [explaining how plaintiffs' attorneys can force "any small, ma and pa business" into a settlement by using threat of civil penalties as a

"bargaining chip"].) These "'shakedown' lawsuits," often "brought by 'self-proclaimed bounty hunters,'" "'represent a needless expense imposed on businesses in California without any corresponding genuine public benefit.'" (*Starbucks Corp. v. Superior Court* (2008) 168 Cal.App.4th 1436, 1451 [quoting *Consumer Defense Group*, 137 Cal.App.4th at p. 1189].) As The Los Angeles Times recently reported, "[l]itigating Proposition 65 enforcement has cost businesses more than $370 million in settlements since 2000," and "[a]ttorney fees account for nearly *three-quarters*" of that amount. (Mohan, *Warnings Everywhere*, *supra*.)

This problem is especially acute for DINP, which is used as a plasticizer in all sorts of useful products. Since OEHHA listed DINP in 2013, bounty hunters have filed nearly *1,400* 60-day notices with the California Attorney General's office alleging that businesses have violated Proposition 65 by selling hundreds of everyday products—including vinyl gloves, vinyl flooring, coaxial cable, and roofing tiles—without adequate warnings. (See *60-Day Notice Search: diisononyl phthalate (DINP)*, State of California Department of Justice Office of the Attorney General, available at https://goo.gl/nemcwX.) Plaintiffs have filed hundreds of actions based on these notices, the vast majority of which have resulted in settlements that provide no benefit to the public.

3. The Court of Appeal brushed aside these concerns, observing that "a business can avoid providing a warning if it can prove that the exposure caused by its product is below the level that will have 'no significant risk.'" (Ex.A at 17 [quoting §25249.10, subd. (c)].) But even if a retailer could prove that its products contained concentrations of a listed chemical below the safe harbor established by OEHHA (see CCR 27 §25705), "plaintiffs would still have no reasonable assurance that they would not be subject to enforcement actions." (*Nat'l Assoc. of Wheat Growers v. Becerra* (E.D.

Cal. June 22, 2020) 2020 WL 3412732, at *4.) This is because the statute places the burden on the defendant to "show[] that their product's [chemical] exposure falls below the no significant risk level in a Proposition 65 enforcement action," and a plaintiff can "bring suit and avoid sanctions" so long as he "credibly allege[s] that th[e] product has some amount of the chemical at issue, not that the amount of the chemical is harmful or that it exceeds the safe harbor level." (*Ibid*. [citing §25249.7(h)(2)].) The statute thus empowers plaintiffs to file frivolous lawsuits and then offer to settle for less than the amount it would cost the defendants to prove their innocence. The Court of Appeal's assertion that erroneous listings are harmless because most defendants can successfully defend themselves blinks reality.

OEHHA made a related argument in its request for publication, contending that the "*consequences* of a listing decision . . . 'do not bear on OEHHA's discretion to list' a chemical." (Ex.C at 2 [citing Ex.A at 17].) To be sure, neither the statute nor the Guidance Criteria require the CIC to consider the consequences of listing when evaluating the scientific evidence of a chemical's carcinogenicity. But that does not mean that *courts* should blind themselves to the severe consequences of an erroneous listing decision when reviewing the CIC's conduct. Because an erroneous listing decision imposes massive costs on businesses and consumers, with no corresponding public benefit, this Court should require OEHHA, and by extension the CIC, to adhere closely to its own published rules. Allowing agencies to ignore or change the rules governing their conduct would undermine the rule of law and create substantial due process concerns.

V. CONCLUSION

For the foregoing reasons, ACC respectfully asks the Court to grant the petition for review.

Dated: August 17, 2020

GIBSON, DUNN & CRUTCHER LLP
Theodore J. Boutrous, Jr.

EIMER STAHL LLP
Robert E. Dunn

By: /s/ *Robert E. Dunn*
Robert E. Dunn

Attorneys for Appellant
American Chemistry Council

CERTIFICATE OF WORD COUNT

The undersigned certifies that pursuant to the word count feature of the word processing program used to prepare this brief, it contains 8,398 words, exclusive of the matters that may be omitted under Rule 8.204(c)(3).

Dated: August 17, 2020

GIBSON, DUNN & CRUTCHER LLP
Theodore J. Boutrous, Jr.

EIMER STAHL LLP
Robert E. Dunn

By: /s/ *Robert E. Dunn*
Robert E. Dunn

Attorneys for Appellant American Chemistry Council

Exhibit A

NOT TO BE PUBLISHED

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

THIRD APPELLATE DISTRICT

(Sacramento)

AMERICAN CHEMISTRY COUNCIL, Plaintiff and Appellant, v. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT et al., Defendants and Respondents.	C079260 (Super. Ct. No. 34-2014-80001868-CU-WM-GDS)

Proposition 65, also known as the Safe Drinking Water and Toxic Enforcement Act of 1986 (Health & Saf. Code, §§ 25249.5-25249.13), requires the Governor to publish a "list of those chemicals known to the state to cause cancer or reproductive toxicity." (Health & Saf. Code, § 25249.8.) In 2013 the Carcinogen Identification Committee (Committee) voted to list the chemical diisononyl phthalate (DINP) as a cancer causing chemical. DINP is used to soften vinyl for use in flooring, wire insulation, gloves, garden hoses, artificial leather, and roofing materials. The Committee concluded DINP causes various types of cancer in animals and that the mechanisms by

which DINP causes cancer in animals are relevant to humans. Subsequently, the Office of Environmental Health Hazard Assessment (OEHHA) added DINP to the Proposition 65 list. Plaintiff American Chemistry Council (Chemistry) challenged the action, arguing it was arbitrary and capricious. The Chamber of Commerce of the United States filed an amicus curiae brief in support of Chemistry. Chemistry appeals the trial court's denial of its petition for writ of mandate, arguing there is insufficient evidence that DINP causes cancer in humans. We shall affirm the judgment.

FACTUAL AND PROCEDURAL BACKGROUND

Proposition 65 Process

Proposition 65 involves a two-step process. First, chemicals are placed on a list of substances known to cause cancer or reproductive toxicity. (Health & Saf. Code, § 25249.8, subd. (a).)[1] Second, the statute prohibits businesses from exposing individuals to listed chemicals without providing a warning and from discharging listed chemicals into sources of drinking water unless the business can establish that the exposure or the discharge to drinking water is below the level that will pose no significant risk. (§§ 25249.5, 25249.6, 25249.9, 25249.10, subd. (c).)

Chemicals must be listed under Proposition 65 if they are identified as causing cancer or reproductive toxicity on the basis of animal studies. Proposition 65 "applies to those chemicals which respected scientific agencies have already determined cause cancer or reproductive toxicity in humans or animals." (*AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, 441.) Human testing is unethical, and because of the long latency period of human cancers, waiting for human studies cannot adequately protect humans from the risk of cancer. As a consequence, the principle of extrapolating from evidence

[1] All further statutory references are to the Health and Safety Code unless otherwise noted.

of cancer in animals to humans " 'has been accepted by all health and regulatory agencies, and is regarded widely by scientists in industry and academia as a justifiable and necessary inference.' " (*Id.* at p. 438, fn. 7.)

OEHHA must list a chemical: (1) if the chemical is identified by reference in certain Labor Code sections; (2) if a body considered authoritative by the group of independent scientists known as the state's qualified experts has formally identified the chemical as causing cancer; (3) if a state or federal agency has formally required the chemical to be labeled or identified as causing cancer (§ 25249.8, subds. (a), (b)); or (4) upon review by the state's qualified experts who, in their opinion, determine "the chemical has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer" (§ 25249.8, subd. (b)). This case involves the fourth mechanism for identifying cancer causing chemicals.

Committee Composition and Guidance Criteria

Independent experts with degrees and research experience in various scientific fields comprise the Committee. (Cal. Code Regs., tit. 27, § 25302, subd. (b)(1)(i), (ii).) The Governor appoints the committee chairperson, who calls and presides over meetings, designates an executive secretary, and designates subcommittees. (Cal. Code Regs., tit. 27, § 25302, subd. (c).) The chairperson possesses no special authority apart from these administrative duties. The state's qualified experts for the purpose of identifying carcinogens are members of the Committee. (Cal. Code Regs., tit. 27, § 25302, subd. (a).)

The Committee's guidance criteria govern the review of a given chemical. Under the criteria, the Committee uses a weight of evidence approach to evaluate the information on any given chemical, including "all evidence bearing on the issue of carcinogenicity shown through scientifically valid testing according to generally accepted principles" of scientific inquiry.

At issue in the case before us is criterion No. 1D, which states the Committee will "normally identify a chemical for listing" if "the weight of scientific evidence clearly shows that [the] chemical causes invasive cancer in humans, or that it causes invasive cancer in animals (unless the mechanism of action has been shown not to be relevant to humans)." As the trial court aptly noted "This case is about that 'unless.' "

Guidance criteria are not intended to be binding regulations or to be slavishly followed. Instead, "these criteria are intended to give the Committee maximal flexibility in evaluating all pertinent scientific information" and "are intended neither to limit the scope of the Committee's consideration of all appropriate cumulated scientific information, nor to limit the use of best scientific judgment available at the time." The criteria require "scientific judgments which can only be based on experience . . . Thus, few of the criteria are amenable to the use of absolute restrictions of either a quantitative or qualitative nature."

The Committee does not conduct independent scientific studies or experiments on the carcinogenicity or toxicity of chemicals. Instead, OEHHA prepares a summary of the current state the scientific evidence on the chemicals' carcinogenicity, a hazard identification document (HID). To prepare the HID, OEHHA reviews scientific literature on the chemical and solicits information from the public. Once prepared, the HID is released to the Committee and the public for a 45-day comment period. At the close of the comment period, OEHHA provides the Committee with a copy of all comments and supporting documents for review.

Consideration of DINP by the Committee

In 2009 the Committee began reviewing DINP when OEHHA asked it to rank a set of chemicals for review. Chemistry and other entities submitted over 200 pages of comments to support the argument that DINP should be ranked as no or low priority for review. They argued the mechanism of carcinogenesis does not operate in humans.

However, the Committee voted on May 29, 2009, to rank DINP as a high priority chemical for its review.

OEHHA issued a notice to interested parties on October 16, 2009, soliciting information on the carcinogenicity of DINP. The public comment period lasted 60 days. OEHHA, after reviewing the submitted material, prepared a 77-page HID. The HID included the most current and pertinent information on the carcinogenicity of DINP, including research and evidence on the mechanisms of action by which DINP operates. The HID was not intended to be a comprehensive document citing every study, but a "look at new more recent literature and thinking on those hypotheses."

Although there were no human studies of the carcinogenicity of DINP, the HID discussed 12 dietary carcinogenicity studies on laboratory animals. OEHHA provided the studies to the Committee. No known carcinogenicity studies were omitted. The HID referenced 114 documents and provided the documents to the Committee. Among the documents were 32 referenced by Chemistry and others in response to the notice to interested parties.

The HID summarized the 12 animal studies and noted three cancers seen at statistically significantly levels: liver tumors, mononuclear cell leukemia, and kidney tumors. Other rare or noncommon tumors were seen, but not at statistically significant levels.

In addition, the HID noted that the mechanisms by which DINP induces tumors are unknown. However, several studies identified possible mechanisms of action. These include: activation of peroxisome proliferator activated receptors (PPAR), activation of constitutive androstane receptor and pregnane X receptor, effects on steroidogenesis and androgen-responsive tissues, tumor necrosis factor-alpha induction, and alpha 2u-globulin nephropathy.

OEHHA released the HID to the Committee on October 7, 2013, along with the supporting documents. Concurrently, OEHHA released the HID to the public for a 45-

day comment period. When the comment period ended, OEHHA provided all public comments and supporting documents to the Committee on November 20, 2013.

Meeting and Vote

On December 5, 2013, the Committee met to discuss and vote on DINP. Staff counsel for OEHHA told the Committee that "there are certain criteria for listing chemicals. And you have those criteria in front of you. You're [*sic*] listing decisions should be based on those criteria, and the discussions you have on those criteria." In addition, counsel stated the Committee was not obligated to render a decision that day, and could ask OEHHA to provide further information.

As the meeting continued, the Committee heard testimony from OEHHA scientists about DINP. The Committee also heard testimony from four people representing Chemistry and others opposing listing DINP.

Following the presentations, the Committee questioned the presenters and discussed the evidence before it. Members also discussed Chemistry's argument that the mechanism operating in animals is not relevant to humans.

At the conclusion of the presentation and discussion, the chairperson, Thomas Mack, called for a vote by the Committee. Six members voted to identify DINP as known to the state to cause cancer, one voted against, and one abstained. Following the Committee's vote, OEHHA added DINP to the Proposition 65 list on December 20, 2013.

Trial Court's Decision

Chemistry filed suit against OEHHA, challenging the listing of DINP. In denying Chemistry's petition for writ of mandate, the court stated Chemistry would be entitled to a writ if it "could prove the [Committee's] decision was based on an incorrect interpretation of the law. [Chemistry] fails to make this showing."

The court rejected Chemistry's argument that the HID was incomplete, noting the document discussed a number of studies relied on by Chemistry in support of its argument that animal cancers were not relevant to humans. In addition, OEHHA accompanied submission of the HID with voluminous materials relating to DINP's carcinogenicity. These documents included studies in support of Chemistry's argument that the mechanism operative in rats did not apply to humans. Chemistry members also spoke at length at the public meeting, arguing against the listing.

Chemistry also claimed the Committee lacked adequate time to review this voluminous information. The court found "absent evidence to the contrary, the court will assume the [Committee] reviewed sufficient evidence to come to an informed decision. (Evid. Code, § 664.)"

Chemistry argued the studies demonstrated that the mechanisms that cause cancer in rodents, such as PPAR, do not operate in humans. The court disagreed: "[S]ome of the studies [Chemistry] cites are less categorical than it suggests. For example, the ILSA Health and Environmental Sciences Institute concluded 'it is unlikely that peroxisome proliferators are carcinogenic to humans under anticipated conditions and levels of exposure, although their carcinogenic potential cannot be ruled out under extreme conditions of exposure.' " The court found it clear that the Committee considered the very evidence Chemistry accused it of disregarding. Committee members discussed the issue of mechanistic data and its relevance to humans, stated they understood the issue, and "considered, and wrestled with" the evidence of mechanism.

Finally, the court addressed Chemistry's contention that Mack incorrectly outlined the guidance criteria, invalidating the entire Committee review process. After carefully reviewing the comments Chemistry posits as incorrect interpretations of the law, the court determined Mack's statements were susceptible to several alternative interpretations.

More importantly, the court noted, the Committee members had the guidance criteria in front of them and were twice instructed to follow those criteria. In order to find the Committee's decision arbitrary and capricious, "the court would have to assume the remaining [Committee] members followed Mack's rather garbled and possibly erroneous interpretation of the law rather than the guidance criteria they were instructed to follow. The court cannot make this assumption." The court denied the petition.

DISCUSSION

Standard of Review

In order to overturn OEHHA's listing of DINP, Chemistry must show OEHHA's action is "inconsistent with the governing statute, section 25249.8." (*Western Crop Protection Assn. v. Davis* (2000) 80 Cal.App.4th 741, 757.) A review of OEHHA's scientific analysis regarding a chemical's listing under Proposition 65 requires deference: " ' "[I]n technical matters requiring the assistance of experts and the study of marshaled scientific data as reflected herein, courts will permit administrative agencies to work out their problems with as little judicial interference as possible." ' " (*Exxon Mobil Corp. v. Office of Environmental Health Hazard Assessment* (2009) 169 Cal.App.4th 1264, 1277 (*Exxon*).)

We defer to the agency's authority and presumed expertise and do not reweigh the evidence or substitute our judgment for that of the agency. If the agency has adequately considered all relevant factors and demonstrated a rational connection between those factors, the choice made, and the purposes of the statute, we will uphold the decision. We set aside the decision only if it was arbitrary, capricious, or entirely lacking in evidentiary support. (*Exxon, supra*, 169 Cal.App.4th at p. 1277.)

The Committee's Decision

At the conclusion of the review process, six of the Committee's eight scientists found DINP causes several types of invasive cancers in laboratory animals and the

evidence was not sufficient to show that all of the possible mechanisms underlying these cancers are not relevant to humans. Consequently, OEHHA added DINP to the list of chemicals known to the state to cause cancer.

On appeal, Chemistry challenges the decisionmaking process, focusing on several comments made by the chairperson, Mack. Chemistry contends Mack incorrectly instructed the Committee that the evidence of mechanism was irrelevant and directed the Committee to apply a different standard of his own creation. According to Chemistry, "it is clear that the instructions so infected the [Committee's] deliberations that the decision to list DINP was arbitrary and capricious."

Preliminarily we note, as the trial court observed, the Committee never explained the basis for its determination, and never explained how it evaluated the evidence on whether animal studies were relevant to humans. An administrative body making a quasi-legislative decision such as the one before us is not generally required to either make findings or explain how the evidence supports its decision. (*Fullerton Joint Union High School Dist. v. State Bd. of Education* (1982) 32 Cal.3d 779, 787.) As a consequence the trial court found: "[T]he lack of findings or an explanation may make it difficult for [Chemistry] to show the [Committee's] decision was arbitrary or capricious. This difficulty is then compounded by the fact that, absent evidence to the contrary, the court must presume the [Committee] properly performed its duties. (Evid. Code, § 664.) Here, the primary evidence to the contrary consists of the transcript of the public hearing. But at no point during that hearing did the [Committee] clearly explain its views on the evidence on human relevance." As the trial court recognized, we are left with the presumption that the Committee properly performed its duties and the burden is on Chemistry to show the Committee's decision is arbitrary, capricious, or without evidentiary support.

At the hearing, OEHHA's staff counsel informed the Committee that its listing decision should be based on the published criteria for listing, a copy of which was

provided to each member. Counsel stated, "you have those criteria in front of you. You're [*sic*] listing decisions should be based on those criteria." Under the criteria provided to the Committee, they were directed to identify a chemical for listing if the weight of scientific evidence shows it causes invasive cancer in animals "unless the mechanism of action has been shown not to be relevant to humans." Subsequently, counsel reminded the Committee "if the weight of scientific evidence clearly shows that certain chemicals cause invasive cancer . . . in animals, unless a mechanism of action has been shown not to be relevant to humans, the Committee will normally identify the chemical for listing."

Juxtaposed against these correct statements of the decisionmaking process are comments by chairperson Mack, which Chemistry argues directed the Committee to "ignore the mechanistic data, contrary to the published Criteria," advice which tainted the voting process.

The parties focus on two statements made by Mack towards the end of the hearing. In the first Mack stated:

"My own view is that I wish the proposition had been worded a little bit better. I wish it had said in humans, but it didn't say in humans. And that means that we're left either pretending that we're the Supreme Court, and we can interpret and make law, or we can simply be technologists and apply the rules that we're given. And I think we're -- my own position is we're stuck with the latter.

"So the question to me is does this stuff cause cancer? And I have to rely upon the dose response relationships. And I actually am moved by the number of cancers which pop up, in an unusual circumstance, including the kidney, the pancreatic islet cell and the leukemia. I understand completely points that [Committee member] David [Eastmond]

has made about – and that the regulated community has made about the mechanism issue.[2]

"And I wouldn't be a bit surprised to find in the long run that each of these tumor frequencies can be explained by mechanisms that are not pertinent in humans.

"But my gut response right now is that that can't be an assumption I can make. And so my inclination is to make the judgment on the basis of whether or not the cancers that are caused in mice are invasive and truly malignant. And I presume that that's -- not presume. I know that that's the case."

We read Mack's comments as acknowledging that listing might not be appropriate in the "long run" (the future) if the scientific evidence reveals DINP-caused tumors can be explained by mechanisms not relevant to humans. However, "right now" (presently) Mack cannot assume "the number" of "invasive and truly malignant" cancers which "pop up, in unusual circumstances" were caused by a mechanism that is not relevant to humans. Mack did not misstate the law in his comment.

After Mack's statement, Committee member Duncan Thomas quoted from the guidelines: "As I read the guidelines that says that if it causes invasive cancer in animals parenthesis, unless the mechanism of action has been shown not to be relevant in humans." He continued: "[W]e clearly show that the PPAR alpha mechanism is not relevant in humans, but that's not the only possible mechanism, that there are others about which we are simply unsure. And so the possibility that it's relevant [in humans] still stands . . . ."

Mack then made the second statement:

---

2 David Eastmond discussed the evidence concerning the relevance of animal studies to humans. Eastmond concluded "When you get this many [tumor types], it really is very difficult not to list it." But he also stated: "I'm right now not convinced to list, just simply because I see enough weaknesses on each of these that I don't feel real confident."

"Having -- being the person who wrote those guidelines, I have to try and describe to you the reason why that verbiage was put in there. Can you picture a circumstance where there's extremely good epidemiologic data suggesting that there is no effect on humans, a carcinogenic effect? And, at the same time, there is one or two animal studies with liver cancer in rates, in which there is a marginally increased effect.

"And I think the point of that mechanistic inclusion in the criteria document is thinking about that rather than this. Here we're in a situation where there is no epidemiologic data. We have to go solely on the animal data."

Shortly afterward Mack reiterated: "Did you hear what I said about why the panel -- why we wrote those criteria? We wrote them for the circumstance in which there is a conflict between human epidemiologic data and information from animals. And, in any case, I don't think we can discuss it any further. We have to take a vote now.

"So if you'll permit me, we'll go ahead and do that."

Chemistry argues Mack's statement again misstated the law to the Committee. We agree Mack's statement is confusing enough to be susceptible to several interpretations. It might be interpreted to state that the guidance criteria require listing based on animal studies alone, even if epidemiological studies show no effect on humans, unless there is additional evidence showing the mechanism of action in animals has no relevance to humans. This would allow a chemical to be listed even though studies on humans showed it did not cause cancer in humans, which runs afoul of the criteria. However, Mack's comments can also be read to state that, in the absence of human studies, the Committee must rely on animal studies. Mack earlier told the Committee "in the absence of epidemiologic information, we're stuck making decisions about animal data." This is not an incorrect statement of the law.

Mack's comments lacked clarity, but any ambiguity cannot be considered in isolation. The Committee had before it the guidance criteria, which Chemistry does not dispute state the law accurately. Committee members, made up of independent experts,

were twice instructed to follow the criteria. Based on the totality of the circumstances surrounding the decision, we cannot find the Committee's decision was arbitrary and capricious. We cannot assume Committee members failed to follow the criteria they were instructed to follow and instead were led astray by Mack's somewhat confusing and possibly erroneous interpretation.

In the absence of evidence to the contrary, we must presume the Committee properly carried out its obligation and followed its own guidance criteria. Again, the question before us is not whether the record establishes the Committee complied with requirements, but whether the evidence establishes the agency failed to comply. (Evid. Code, § 664; *City of Sacramento v. State Water Resources Control Bd.* (1992) 2 Cal.App.4th 960, 976.)

Adequacy of the HID

Chemistry acknowledges OEHHA based its decision to list DINP on the Committee's recommendation, but argues OEHHA preluded the Committee from considering all relevant factors by issuing a "biased, incomplete and misleading HID." Chemistry also faults OEHHA's allowing only two weeks for the Committee to consider opposing comments and 7,000 pages of scientific studies. After painstakingly setting forth the alleged omissions, Chemistry states the "only plausible explanation for the HID's many inaccuracies is agency bias in favor of listing."

The scientific evidence collected by OEHHA revealed DINP causes three types of cancer in rodents: kidney tumors, liver tumors, and mononuclear cell leukemia. Some evidence suggests the mechanism of action of these three cancers is not relevant to humans because the cancers occur in rodents through a mechanism that does not occur in humans or because of physiological differences between rodents and humans.

Chemistry cites authority stating we must ensure that the agency has " ' " ' "adequately considered all relevant factors." ' " ' " (*Exxon, supra*,

169 Cal.App.4th at p. 1277.) Chemistry also notes the Committee's own guidance criteria require it to consider "all evidence bearing on the issue of carcinogenicity shown through scientifically valid testing according to generally accepted principles" of scientific inquiry. Since the Committee failed to consider the evidence showing DINP was not a human carcinogen, Chemistry argues its decision to list DINP is arbitrary and capricious.

Chemistry mounts a multiprong attack on the alleged HID failures: omission of primate studies; omission and mischaracterization of critical toxicity reviews; mischaracterization of evidence regarding kidney tumors; mischaracterization of evidence regarding liver tumors; mischaracterization of evidence regarding mononuclear cell leukemia; and mischaracterization of evidence of pancreatic, testicular, and uterine tumors. According to Chemistry, the record is clear that the HID presented a misleading picture of the science and biased the Committee in favor of listing DINP.

However, our review of the record reveals the Committee considered much of the evidence Chemistry accuses it of ignoring. Chemistry faults the HID for failing to adequately discuss studies showing that kidney tumors, liver tumors, and leukemia observed in rodents are not relevant in humans. However, one of Chemistry's members submitted extensive comments to OEHHA reviewing and discussing these other studies. This critique explained in great detail the studies Chemistry claims reveal DINP caused animal cancers are not relevant to humans. The additional materials were provided to the Committee prior to the meeting. Chemistry addressed the Committee at the public meeting and provided a detailed explanation of their view that the rodent studies were not relevant to humans.

The HID itself does discuss some of the issues Chemistry claims it ignores. The HID discusses a study that reported no human counterpart to rodent leukemia. Regarding another study cited, HID stated: "It has also been suggested that rat and mouse liver tumors induced by PPARα agonists are not relevant to human cancer risk

assessment because of differences in activation characteristics between rodent and human PPARα." The HID discussed another study that found "The protein α2u-globulin is specific to male rats, and some renal tubule cell tumors induced by agents that induce α2u-globulin accumulation in male rat renal tubules have been suggested to be not relevant to human cancer risk assessment."

Nor did the subsequent discussion of the HID by Committee members reveal a monolithic approach to the conflicting evidence. Committee members acknowledged struggling with the question of whether the evidence that DINP caused cancer in animals was relevant to humans. Committee member Joseph Landolph stated "I struggle with the issue of the relevance to human tumors." The key issue, according to Committee member Peggy Reynolds, "is really whether the mechanism of action has been shown to be relevant in humans." Committee member Eastmond agreed, stating, "The key question now becomes are those [cancers] relevant to humans?" Committee member Jason Bush revealed: "I guess what I'm wrestling with is whether this is meaningful for humans?" Chairperson Mack summed up the members concerns: "I understand completely the points . . . the regulated community has made about the mechanism issue."

The Committee did not disregard evidence presented by Chemistry regarding mechanism. Chemistry submitted studies and offered arguments disputing the relevance of rodent studies to humans. The HID included studies cited by Chemistry and members of the Committee admitted struggling over the issue. We cannot find the HID presented a biased view of the relevant data.

In a related argument, Chemistry contends the time period allowed for the Committee to review the voluminous underlying toxicity reviews and scientific studies "was patently inadequate" and as a result the Committee's understanding of the state of the science regarding DINP was shaped by the HID's inaccurate summary of the evidence. The trial court rejected this argument: "Absent evidence to the contrary, the

court will assume the [Committee] reviewed sufficient evidence to come to an informed decision. (Evid. Code, § 664.)"

OEHHA provided the HID to the Committee on October 7, 2013, along with references cited in the document and including 32 documents submitted by the industry. On November 20, 2013, OEHHA gave additional documents submitted by the industry in response to the HID to the Committee. The meeting took place two weeks later on December 5, 2013.

At the beginning of the meeting, OEHHA's staff counsel informed the Committee they did not have to vote that day and could request additional time. Four industry members were given 30 minutes to present arguments against listing DINP. Committee members followed up with questions for the presenters. At the conclusion of the questioning, Mack allowed industry members to provide further comment. The record reveals the Committee review was not rushed and did not render the Committee's decision arbitrary and capricious.

Negative Consequences of Listing

Finally, Chemistry contends the Committee's decision to list DINP carries with it serious consequences. The listing may cause manufacturers to replace DINP with other chemicals that are less safe, not as well studied, and less effective. In addition, "The listing will lead to an increase in unnecessary warnings on consumer products, because manufacturers can insulate themselves from enforcement litigation by applying warnings to any product containing DINP. (§ 25249.6.) The overuse of Proposition 65 warnings will cause individuals to become desensitized to legitimate warnings that *are* supported by scientific evidence, completely undermining Proposition 65's value and purpose." Amicus curiae Chamber of Commerce of the United States of America echoes this argument in its brief. Chemistry also warns of "a barrage of harmful and costly litigation" filed by "bounty hunters" against manufacturers who use DINP.

We note these objections to the consequences of the Committee's decision do not address the propriety of the decision itself. Consequences do not bear on OEHHA's discretion to list DINP.

In addition, the decision to list a chemical does not determine whether or not a warning is required. Under Proposition 65, a business can avoid providing a warning if it can prove that the exposure caused by its product is below the level that will have "no significant risk." (§ 25249.10, subd. (c).) OEHHA's decision requires listing DINP. Subsequently, Chemistry will have the opportunity to prove it is exempt from the Proposition 65 requirements because a specific exposure that it causes is below the level that will have no significant risk. (*Exxon, supra*, 169 Cal.App.4th at p. 1291.)

DISPOSITION

The judgment is affirmed. OEHHA shall recover costs on appeal. (Cal. Rules of Court, rule 8.278(a)(1) & (2).)

RAYE, P. J.

We concur:

ROBIE, J.

DUARTE, J.

IN THE

Court of Appeal of the State of California

IN AND FOR THE

THIRD APPELLATE DISTRICT

MAILING LIST

Re: American Chemistry Council v. Office of Environmental Health Hazard Assessment et al.
C079260
Sacramento County
No. 34201480001868CUWMGDS

Copies of this document have been sent by mail to the parties checked below unless they were noticed electronically. If a party does not appear on the TrueFiling Servicing Notification and is not checked below, service was not required.

Theodore Joseph Boutrous Jr
Gibson Dunn & Crutcher LLP
333 South Grand Ave.
Los Angeles, CA 90071-3197

Robert Edward Dunn
Eimer Stahl LLP
99 S. Almaden Blvd., Suite 662
San Jose, CA 95113

Susan Sabina Fiering
Office of the Attorney General
1515 Clay Street, 20th Floor
Oakland, CA 94612-0550

Fred A. Rowley Jr.
Munger, Tolles & Olson LLP
355 South Grand Avenue, 35th Floor
Los Angeles, CA 90071

Janet Y. Galeria
U.S. Chamber Litigation Center
1615 H. Street, NW
Washington, DC 20062

✓ Honorable Christopher E. Krueger
Judge of the Sacramento County Superior Court
720 Ninth Street
Sacramento, CA 95814

Exhibit B

CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

THIRD APPELLATE DISTRICT

(Sacramento)

AMERICAN CHEMISTRY COUNCIL, Plaintiff and Appellant, v. OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT et al., Defendants and Respondents.	C079260 (Super. Ct. No. 34-2014-80001868-CU-WM-GDS) ORDER CERTIFYING OPINION FOR PUBLICATION

APPEAL from a judgment of the Superior Court of Sacramento County, Christopher E. Krueger, Judge. Affirmed.

Gibson Dunn & Crutcher, Theodore J. Boutrous, Jr., Vanessa C. Adriance, Robert E. Dunn and Julia L. Reese for Plaintiff and Appellant.

Kamala D. Harris and Xavier Becerra, Attorneys General, Sally Magnani, Assistant Attorney General, Susan S. Fiering and Harrison M. Pollak, Deputy Attorneys General, for Defendants and Respondents.

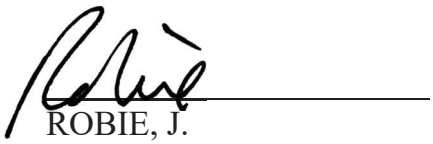
U.S. Chamber Litigation Center, Janet Galeria; Munger, Tolles & Olson, Fred A. Rowley, Jr., Patrick J. Cafferty, Jr., Jeffrey Y. Wu and David J. Feder as Amicus Curiae on behalf of Plaintiff and Appellant.

THE COURT:

The opinion in the above-entitled matter filed June 10, 2020, was not certified for publication in the Official Reports. For good cause it appears now that the opinion should be published in the Official Reports and it is so ordered.

BY THE COURT:

RAYE, P. J.



ROBIE, J.

DUARTE, J.

IN THE

Court of Appeal of the State of California

IN AND FOR THE

THIRD APPELLATE DISTRICT

MAILING LIST

Re: American Chemistry Council v. Office of Environmental Health Hazard Assessment et al.
C079260
Sacramento County
No. 34201480001868CUWMGDS

Copies of this document have been sent by mail to the parties checked below unless they were noticed electronically. If a party does not appear on the TrueFiling Servicing Notification and is not checked below, service was not required.

Theodore Joseph Boutrous Jr
Gibson Dunn & Crutcher LLP
333 South Grand Ave.
Los Angeles, CA 90071-3197

Robert Edward Dunn
Eimer Stahl LLP
99 S. Almaden Blvd., Suite 662
San Jose, CA 95113

Harrison M. Pollak
Office of the State Attorney General
P.O. Box 70550
1515 Clay Street, 20th Floor
Oakland, CA 94612-0500

Fred A. Rowley Jr.
Munger, Tolles & Olson LLP
355 South Grand Avenue, 35th Floor
Los Angeles, CA 90071

Janet Y. Galeria
U.S. Chamber Litigation Center
1615 H. Street, NW
Washington, DC 20062

✓ Honorable Christopher E. Krueger
Judge of the Sacramento County Superior Court
720 Ninth Street
Sacramento, CA 95814

Exhibit C

XAVIER BECERRA
Attorney General

State of California
DEPARTMENT OF JUSTICE

1515 CLAY STREET, 20TH FLOOR
P.O. BOX 70550
OAKLAND, CA 94612-0550

Public: (510) 879-1300
Telephone: (510) 879-0853
Facsimile: (510) 622-2270
E-Mail: Harrison.Pollak@doj.ca.gov

June 26, 2020

Honorable Vance W. Raye
Honorable Elena J. Duarte
Honorable Ronald B. Robie
California Court of Appeal
Third Appellate District
914 Capitol Mall, 4th Floor
Sacramento, CA 95814-4814

RE: Request for Publication (California Rules of Court, rule 8.1120(a))
American Chemistry Council v. Office of Environmental Health Hazard Assessment et al. (C079260)

Dear Presiding Justice Raye and Justices Duarte and Robie:

We write on behalf of Respondents Office of Environmental Health Hazard Assessment and Dr. Lauren Zeise, Director ("OEHHA"), to respectfully request that the Court order publication of the opinion it filed in the captioned matter on June 10, 2020. (Cal. Rules of Court, rule 8.1120, subd. (a).) The opinion applies an existing rule of law to a set of facts significantly different from those stated in published opinions, and it involves a legal issue of continuing public interest. (*Id.*, rule 8.1105, subd. (c)((2) and (6).) A copy of the opinion is attached as Exhibit A.

If published, this would be the first appellate decision to address the "state's qualified experts" mechanism for listing chemicals as carcinogens or reproductive toxins under the Safe Water and Toxic Enforcement Act of 1986, commonly known as "Proposition 65." (Health & Saf. Code, § 25249.8, subd. (b).) The opinion confirms that the qualified experts – in this case, the Cancer Identification Committee ("Committee") – can properly apply to listing decisions the "weight of evidence" approach set forth in the Committee's guidelines. The observation that the guidance criteria "are not intended to be binding regulations or to be slavishly followed" (Opinion, at p. 4) clarifies the role the criteria are to play in listing

decisions, which is an issue that arises frequently in public comments and during the Committee's proceedings.

Additionally, the opinion affects an issue of continuing public interest because it succinctly draws the distinction between objections to a listing decision, which are governed by the applicable rules and legal standards, and objections to the alleged *consequences* of a listing decision. Appellant American Chemistry Council, supported by amicus curiae Chamber of Commerce, argued here that affirming the listing of DINP as a carcinogen will have serious consequences for several reasons. Entities often make similar arguments pertaining to Proposition 65 listing decisions about other chemicals as well. The opinion clarifies that these arguments do not implicate the propriety of the listing decision itself, because "[c]onsequences do not bear on OEHHA's discretion to list" a chemical. (Opinion, at p. 17.) The opinion also recognizes that listing a chemical will not necessarily lead to warnings, because businesses that have a valid defense under the statute do not need to warn. (*Ibid.*) Both observations will assist litigants and the courts when faced with future challenges to listing decisions.

For these reasons, publication is warranted under California Rules of Court, rule 8.1105, subdivision (c)(2), because this would be the first published decision to consider the qualified experts listing mechanism under Proposition 65, and under subdivision (c)(6), because the opinion involves an issue of continuing public interest. The agency and the public will both benefit from the additional guidance this opinion provides.[1]

Thank you for your consideration.

[1] In the event the Court grants this request to publish the opinion, we note two minor typographic errors for correction. In the second paragraph on page 4, there is a missing period in the ellipses after "based on experience," and in the third full paragraph on page 5, "statistically significantly" should be "statistically significant."

Sincerely,

/s/ Harrison Pollak

HARRISON M. POLLAK
Supervising Deputy Attorney General

For XAVIER BECERRA
Attorney General
Counsel for Respondents

SF1986IN1847
DINP Request for publication26Jun20.docx

DECLARATION OF ELECTRONIC SERVICE

Case Name: American Chemistry Council v. Office of Environmental Health Hazard Assessment et al.

Case No.: C079260

I declare:

I am employed in the Office of the Attorney General, which is the office of a member of the California State Bar, at which member's direction this service is made. I am 18 years of age or older and not a party to this matter. I am familiar with the business practice at the Office of the Attorney General for collecting and processing electronic and physical correspondence. In accordance with that practice, correspondence placed in the internal mail collection system at the Office of the Attorney General is deposited with the United States Postal Service with postage thereon fully prepaid that same day in the ordinary course of business. Correspondence that is submitted electronically is transmitted using the TrueFiling electronic filing system. Participants who are registered with TrueFiling will be served electronically. Participants in this case who are not registered with TrueFiling will receive hard copies of said correspondence through the mail via the United States Postal Service or a commercial carrier.

On June 26, 2020, I electronically served the attached **REQUEST FOR PUBLICATION** by transmitting a true copy via this Court's TrueFiling system:

I declare under penalty of perjury under the laws of the State of California the foregoing is true and correct and that this declaration was executed on June 26, 2020, at Oakland, California.

Jennifer Merino	/s/ Jennifer Merino
Declarant	Signature

SF1986IN1847
91261399.docx