No. C079260

IN THE COURT OF APPEAL
OF THE STATE OF CALIFORNIA

THIRD APPELLATE DISTRICT

AMERICAN CHEMISTRY COUNCIL,

Petitioner and Appellant,

v.

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT, ET AL.,

Respondents and Appellees.

Appeal from the Superior Court of the State of California
for the County of Sacramento
The Honorable Christopher Krueger, Judge Presiding
Superior Court Case No. 34-2014-80001868

APPELLANT AMERICAN CHEMISTRY COUNCIL'S OPENING BRIEF

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TO BE FILED IN THE COURT OF APPEAL

APP-008

COURT OF APPEAL, Third **APPELLATE DISTRICT, DIVISION**	Court of Appeal Case Number: C079260
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APPELLANT/PETITIONER: American Chemistry Council RESPONDENT/REAL PARTY IN INTEREST: Office of Environmental Health Hazard	
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I. INTRODUCTION

This case involves an arbitrary and capricious agency action in which the Chairman of the key decision-making body expressly directed the other members to disregard the controlling legal standard and to apply instead an erroneous legal standard to the single question before them. They did just that, resulting in a flagrant violation of core administrative law principles. In addition to being misled about the proper legal standard, the members of the committee were prevented from rationally considering all of the relevant factors essential to their decision because the agency's staff presented them with a biased and incomplete summary of the relevant scientific evidence, and because the committee was given an unrealistically short period of time to review the sizeable scientific record. The agency's decision was thus arbitrary and capricious, and this Court should reverse the Superior Court's denial of Appellant American Chemistry Council's ("ACC") petition for writ of mandate.

This case concerns Proposition 65, which requires the Governor to publish "a list of those chemicals known to the state to cause cancer or reproductive toxicity."[1] The chemical at issue here, diisononyl phthalate ("DINP"), does not pose a cancer hazard to humans. In fact, DINP is a common and useful chemical that has been used for decades to soften vinyl

[1] The Safe Drinking Water and Toxic Enforcement Act of 1986, Health & Safety Code §§25249.5-.13, is commonly referred to as Proposition 65.

and thus enhance the functionality of everyday products such as vinyl flooring, wire and cable insulation, gloves, garden hoses, artificial leather, and roofing materials.

DINP has been exhaustively studied for possible health effects, and there is zero epidemiologic evidence that DINP causes cancer in humans. Laboratory studies on non-human primates have also found that DINP does not cause effects indicative of a carcinogenic response, even when administered in large doses. Although it has been well known since the 1990s that DINP causes certain cancers in laboratory rodents, there is a large body of reliable scientific evidence demonstrating that these cancers are not relevant to humans because they are caused by mechanisms of action (i.e., biochemical processes) that do not occur in humans. Nevertheless, relying on the evidence of carcinogenicity in rodents, the Carcinogen Identification Committee ("CIC")—the state-appointed panel of experts established by Proposition 65 to make carcinogenicity determinations—voted to list DINP as a chemical "known to the state to cause cancer." On the basis of this vote, Appellee Office of Environmental Health Hazard Assessment ("OEHHA") added DINP to the Proposition 65 list effective December 20, 2013. OEHHA's arbitrary and capricious decision to list DINP should be overturned for several reasons.

First, it is predicated on a clearly incorrect legal standard. The CIC's own published guidance criteria provides that a chemical that causes invasive cancer in animals will *not* be listed if the "mechanism of action [by which the chemical causes cancer in animals] has been shown not to be relevant to humans[.]" (AR 8889 ¶ 1.D.) But, as the transcript of the CIC hearing evaluating DINP makes clear, the CIC voted to list DINP because the Chairman of the committee misled the committee members about the governing standard. During the crucial discussion about how to apply the guidance criteria, the Chairman inexplicably declared that, with respect to animal cancers, "[t]he question is *not* whether … they're relevant to humans. That's not what the law says." (AR 9524:2-3, italics added.) To the contrary, human relevance is the *only* question that matters where, as here, the evidence of carcinogenicity comes exclusively from animal studies. (AR 8889 ¶ 1.D.)

Immediately after misinforming the committee as to the relevant legal standard, the Chairman ended discussion and directed the committee to vote. Applying the Chairman's erroneous standard, and thus precluding consideration of the scientific evidence that the mechanisms of action by which DINP causes cancers in rodents *do not occur in humans*, the committee voted to list DINP. This is a textbook example of arbitrary and capricious agency action—the Chairman literally replaced the committee's

published guidance criteria with his own invented legal standard for listing chemicals under Proposition 65.

Second, the arbitrary and capricious nature of this action is confirmed by the fact that it flies in the face of two decades of analysis by health agencies around the world. These agencies have rigorously reviewed DINP and concluded that it does not pose a cancer risk to humans. Agencies and organizations such as the Consumer Product Safety Commission ("CPSC"), the International Life Sciences Institute ("ILSI"), the European Chemicals Agency ("ECHA"), and the Australian National Industrial Chemicals Notification and Assessment Scheme ("NICNAS") have all concluded that studies finding that high doses of DINP cause specific cancers in laboratory rodents are unlikely to apply to humans because DINP causes cancers in rodents via mechanisms that are unlikely to be relevant to humans. In short, the worldwide regulatory community has unanimously declined to conclude that DINP is "known" to be a human carcinogen.

OEHHA's decision to list DINP as a chemical "known to the [S]tate [of California] to cause cancer" in spite of this global consensus is an outlier that runs contrary to the purposes and intent of Proposition 65—it is undisputed that Proposition 65 is concerned with *human* carcinogens, not

with chemicals that cause cancers only in animals, as the CIC's own published guidance criteria make abundantly clear.

Third, in a separate and independent error, OEHHA employed defective procedures leading to this listing. The CIC's deliberative process was short-circuited by the biased Hazard Identification Document ("HID") that OEHHA's staff scientists prepared for the CIC, and by the absurdly short time the CIC was given to evaluate both the HID and the comments on it. The HID either ignored or selectively cited portions of the many reviews conducted by other health agencies and instead presented an incomplete and unbalanced summary of the studies showing that the mechanisms by which DINP causes cancers in laboratory rodents are not relevant to humans. Although public commenters sought to correct the gaps, errors, and biases in the HID, OEHHA effectively prevented the CIC from evaluating the comments and scientific studies by limiting the time for evaluation. While OEHHA had over *three and a half years* to evaluate DINP, the CIC, whose members have full-time jobs, was given a mere eight weeks to review the HID and its 7,000 pages of attachments. Even more egregious, stakeholders were given only 45 days to comment on the HID, and the CIC was given a mere *two weeks* to review these voluminous and technical comments. It is thus clear from the record that the CIC members were provided a scientific record that was incomplete to the point

of being misleading and were prevented from meaningfully evaluating the relevant data, rendering their decision to list arbitrary and capricious.

Finally, OEHHA's erroneous listing of DINP will have several harmful consequences. The listing of DINP will incentivize manufacturers to replace DINP, a well-studied chemical with a long-established record of safe use, with unlisted chemicals that may not be as thoroughly tested for safety, and/or that may otherwise undermine the integrity of the products made with them. Additionally, once a chemical is added to the Proposition 65 list, companies using it are exposed to public and private litigation if they fail to warn consumers of the chemical's presence, and thus will often label whether or not the label is warranted, increasing the volume of already-ubiquitous Proposition 65 warnings facing consumers and decreasing their usefulness.

For all of these reasons, this Court should reverse the Superior Court's decision denying ACC's petition for writ of mandate, and vacate OEHHA's decision to list DINP under Proposition 65 as a chemical "known to the state to cause cancer."

II. STATEMENT OF THE CASE

In March of 2009, OEHHA began considering DINP for addition to the Proposition 65 list as a carcinogen. (AR 1-3.) Following public comment and a CIC meeting in May of 2009 to prioritize chemicals for

listing consideration, OEHHA announced that the CIC would review DINP for potential listing under Proposition 65, and issued a "Request for Relevant Information" on DINP's carcinogenicity. (AR at 661-663.) Nearly four years later, on October 4, 2013, OEHHA issued an HID summarizing what it had selected as the "relevant scientific evidence" on DINP's carcinogenicity, and provided the public 45 days to comment. (AR 1565-1646.) On December 5, 2013, just over two weeks after the close of the comment period, the CIC met to consider possible listing of DINP. (AR 9423.) Following presentations by OEHHA's scientists and very limited presentations by ACC's scientists and other commenters, the CIC voted to recommend listing DINP as a chemical known to the State of California to cause cancer. (AR 9526:14-9527:4.) OEHHA added DINP to the Proposition 65 list, effective December 20, 2013. (AR 9611.)

On June 9, 2014, ACC filed a Verified Petition for Writ of Mandate (Code Civ. Proc. ("CCP"), § 1085) and Complaint for Declaratory Relief (CCP, § 1060) in Sacramento Superior Court. (CT 1-25.) The court issued a tentative ruling denying the petition on January 20, 2015. (CT 171-185.) Following a hearing on February 20, 2015 (CT 186), the court adopted its tentative ruling as final and denied ACC's petition (CT 187-188). Defendants served Notice of Entry of Judgment on March 16, 2015. (CT 232.) ACC timely filed this appeal on May 5, 2015. (CT 233-236.)

III. STATEMENT OF FACTS

A. The Statutory Scheme

Proposition 65, which was enacted via ballot initiative in 1986 (Health & Saf. Code, § 25249.5 *et seq*[2]), 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 in the course of doing business that violates Proposition 65 is liable for civil penalties of up to $2,500 per violation, per day, and, in the case of actions brought by private enforcers, 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(o).) As relevant here, OEHHA may list a

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

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 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 current state of the scientific evidence on the chemicals' carcinogenicity for the CIC, called a 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 and evaluates the research studies and other information presented according to a guidance document the committee adopted in 2001 titled *Guidance Criteria for Identifying Chemicals for Listing as "Known to the State to Cause Cancer*" (hereafter, "Guidance Criteria"). (AR 8889-8893.) The Guidance Criteria state the general scientific principles underlying the CIC's evaluative process. (*Ibid.*) They 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 particular 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 Is A Known Human Carcinogen Or Should Be Classified As A Carcinogen

DINP is an important commercial chemical that is used to soften or "plasticize" polyvinyl chloride ("PVC"), commonly referred to as 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, toys, 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.*) Without the ability to increase vinyl's flexibility with well-functioning plasticizers like DINP, products such as reliable, long-life electrical cable insulation and synthetic leather might not exist today.

"DINP and phthalates in general as a class are some of the most widely studied industrial chemicals in commerce today." (AR 9466:7-9.) Since the 1990s, DINP has been thoroughly reviewed by numerous government agencies and public health organizations around the world.

(AR 217, 8975-8976.) None have found that DINP is likely to cause cancer in humans.

Several government organizations undertook thorough reviews of DINP in the early 2000s following the publication of studies conducted in the 1990s finding that rodents exposed to DINP in high doses tended to develop more cancers than unexposed rodents. In 2001, the CPSC Chronic Hazard Advisory Panel ("CHAP") on Diisononyl Phthalate, consisting of seven independent experts, concluded that DINP was unlikely to pose a cancer risk to humans, due to a "lack of confidence in the relevance of the DINP rodent studies to humans." (AR 2150 ["The human risk is therefore seen as negligible"], 217.)[3] A workgroup of the Risk Science Institute of ILSI reached a similar conclusion in 2003. (E.g., AR 217-218, 3057 ["In summary, the weight of the evidence overall currently suggests that the rodent [mode of action] for liver tumors is not likely to occur in humans"].) 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.) These conclusions were echoed by a 2004 review conducted by several CPSC scientists and published in Regulatory Toxicology and

[3] The CHAP also concluded that "humans do not receive DINP doses from current uses of DINP-containing consumer products that are associated with a significant increase in cancer risk" in rodents. (AR 2160.)

Pharmacology, which 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 similarly declined to classify DINP as a human carcinogen or to use cancer as a basis for assessing the risk of DINP. 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.) In 2013, the European Chemicals Agency ("ECHA") concluded that "the carcinogenic responses … in rodents are of little or unclear relevance to humans." (AR 10105.)

Thus, by the time the CIC convened in 2013, many of the world's leading health agencies and organizations had concluded that DINP causes cancers in laboratory rodents at high doses, but no agency had concluded that DINP is a known human carcinogen.[4]

[4] Though the European Union has banned the use of DINP in children's products that can be placed in children's mouths, this ban is based on mild non-cancer liver effects in aged rats and not on a finding that DINP causes cancer. (AR 10021-23.) Likewise, the United States has enacted an interim ban on DINP in mouthable children's toys and child care articles, but this ban also is not based on a finding of carcinogenicity. (15 U.S.C. § 2057c(b)(1).)

C. OEHHA Issues A Defective Hazard Identification Document For DINP

On March 6, 2009, OEHHA announced that the CIC would review DINP and other chemicals to assign priorities for OEHHA preparation of an HID and CIC consideration of listing under Proposition 65. (AR 1-3, 33-39.) Several commenters, including ACC and ExxonMobil Chemical Company ("ExxonMobil"), an ACC member company, recommended that the CIC rank DINP as a "no priority" or "low priority" chemical because of the extensive scientific evidence showing that DINP is unlikely to pose any cancer hazard *to humans*. (AR 211-482, 211 [Dr. Henry I. Miller, of the Hoover Institution: "there is significant scientific evidence … that the mechanisms which show possible carcinogenic effects in rodents at high doses are not present in humans"], 215 [ExxonMobil: "there is a strong body of evidence that the mechanisms for these lesions in rodents are not applicable to humans and therefore they are not relevant for human risk assessment—a finding that has been made by several expert reviewing bodies"], 466 [ACC: although "DINP at high do[s]es produces liver tumors in rats and mice, kidney tumors in male rats, and mononuclear cell leukemia (MNCL) in rats[,] … [t]here is a substantial body of research

providing compelling evidence that these tumors in rodents are not relevant for human health assessment"].)[5]

Notwithstanding the numerous scientific studies showing that DINP does not pose a cancer hazard to humans, the CIC ranked DINP as a "high priority" chemical at its May 29, 2009 meeting. (AR 661-662.) Of the nine chemicals the CIC considered a "high priority," OEHHA selected DINP and four other chemicals for possible listing, and, on October 16, 2009, issued a "Request for Relevant Information" on DINP's carcinogenicity. (*Ibid.*) ExxonMobil submitted a response to OEHHA's request on February 16, 2010, which summarized and attached a number of 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 although the studies showed that some rodents fed large doses of DINP experienced increases in certain cancers, "there is a very robust data base for DINP demonstrating that those tumors 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 on February 16, 2010 (AR 707-724), which explained that DINP "has not been identified by an authoritative body to cause cancer, [and that] no state or federal government has required it to be identified as causing

[5] ExxonMobil also urged that a "no priority" or "low priority" ranking was appropriate because humans are not exposed to DINP at meaningful levels. (AR 221-222.)

cancer[.]" (AR 707.) ACC further explained 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, despite many years of use, and numerous authoritative bodies have concluded that the laboratory evidence suggesting that DINP causes cancer in rodents is not relevant to humans." (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.) Because "[n]o epidemiology studies [have] investigated the risk of cancer associated with documented exposure to DINP" (AR 1570), the HID 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). The HID devoted a mere 14 pages to mechanistic evidence, even though ExxonMobil's 2010 comments had pointed to numerous scientific reviews showing that the mechanisms of action by which DINP causes cancers in rodents are not relevant to humans, and even though the mechanistic evidence was central to the conclusions of every other body that reviewed DINP. (AR 1617-1631.)

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 8907-9268 [ExxonMobil

comments], 9269-9302 [ACC comments].) ExxonMobil's comments explained that the HID failed to "provide a balanced and complete summary by which the CIC may make a weight-of-evidence determination[,] … 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.)

In light of the HID's deficiencies and the massive amount of technical data the CIC needed to review, ExxonMobil "urge[d] that the CIC delay consideration of DINP until a more complete and balanced HID [could] be produced." (AR 8908.)[6] OEHHA declined to revise the HID or delay the CIC meeting, which took place on December 5, 2013, as scheduled. (AR 9423.) As a result, the members of the CIC had only two weeks, including the Thanksgiving holiday, to review and consider the many public comments pointing out the HID's deficiencies.

D. The CIC Chairman Misstates The Guidelines And Shuts Down Debate

At the CIC meeting on December 5, 2013, two OEHHA scientists presented evidence that DINP causes cancer in rodents. (AR 9433:25-

[6] In the cover letter to its 2010 submission, ExxonMobil also urged that the CIC members be given longer than two weeks to review the public comments due to the "complexity of the database for DINP." (AR 1402.)

9461:3.) OEHHA's scientists again devoted much of their presentation to the tumors seen in laboratory rodents. (AR 9436:2-9449:17 [discussion of rodent studies], 9450:15-9455:5 [discussion of mechanistic evidence].) Following OEHHA's presentation, counsel for ACC member BASF Corporation ("BASF"), spoke briefly about Proposition 65's listing standards, after which three scientists 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.)[7]

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

[7] ACC, BASF, and ExxonMobil submitted a joint letter on November 21, 2013, requesting that the CIC alter its normal practice of limiting public comments to five minutes each (AR 9344), and instead "allocate[] one hour for a consolidated presentation" by several prominent scientists (AR 9345). Chairman Mack denied this request and instead allocated only 30 minutes for four presentations, the equivalent of an extra two and a half minutes per person. (AR 9461:11-13.)

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"].)

In response to this discussion, Chairman Mack dismissed the question of human relevance and instead 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 ["I guess now we're ready to take a vote"].) Following Chairman Mack's comments, Committee Member Zhang asked for clarification of the listing criteria and whether the committee "could vote or list based on animal data." (AR 9521:13-14.) Chairman Mack responded that "in the absence of epidemiologic information, we're stuck making decisions about animal data." (AR 9521:21-23.) This instruction contrasts starkly with the CIC's Guidance Criteria, which state that the CIC will not vote to list a chemical that causes cancer in animals if "the mechanism of action has been shown ***not to be relevant to humans***." (AR 8889 ¶ 1.D, emphasis added.) Contrary to Chairman Mack's assertions, the Guidance Criteria do not require "*epidemiologic* information" showing the chemical does not cause cancer in humans.

Committee Member Thomas pointed out the discrepancy between Chairman Mack's statement and the Guidance Criteria: "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.) Instead of acknowledging his mistake, Chairman Mack asserted that he was the "person who wrote those guidelines," and then attempted to explain "why that verbiage was put in there." (AR 9522:25-9523:2.) Once again shifting the focus from the "mechanism of action" to the existence of "epidemiologic" data, Chairman Mack stated:

> 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 cancers in rats, 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*.

(AR 9523:2-12, italics added.) That explanation directly conflicts with Paragraph 1.D of the CIC's Guidance Criteria, which focuses on mechanistic evidence, not epidemiologic data, when the potential listing hinges on evidence of animal carcinogenicity.

Recognizing that Chairman Mack was materially misstating the Guidance Criteria, counsel for ACC member BASF, Stanley Landfair, attempted to clarify that under the CIC's Guidance Criteria, "the question before the Committee is whether those data [showing cancers in rodents]

are relevant to humans[.]" (AR 9523:22-24.) But Chairman Mack abruptly cut off Mr. Landfair, again asserting:

> 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 added.) Chairman Mack thus instructed the members of the CIC that they were required to list chemicals that cause cancer in laboratory animals *irrespective* of whether "they're relevant to humans"—precisely the *opposite* of the actual standard established by the CIC's Guidance Criteria.

Mr. Landfair again attempted to correct Chairman Mack's inaccurate statement and to refocus attention on the actual Guidance Criteria, stating, "with all respect, these criteria that the Panel has authored and adopted –" (AR 9524:11-12), but Chairman Mack cut him off again, reiterated the incorrect standard, and pressed the committee to vote:

> Did you just hear what I said about why the panel—why we wrote those criteria? We wrote them for the circumstance in which there was 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.

(AR 9524:13-20.) Chairman Mack thus left no doubt that, in his view, the CIC should vote to list a chemical shown to cause cancer in animals *unless*

there is epidemiologic evidence showing that the chemical does not cause cancer in humans.

Chairman Mack had the last word regarding the standard for listing. Immediately following his exchange with Mr. Landfair, Chairman Mack called for a vote and asked the committee members whether "diisononyl phthalate [had] been clearly shown, through scientifically valid testing, according to generally accepted principles to cause cancer[.]" (AR 9526:14-17.) 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

ACC filed a petition for a writ of mandate on June 9, 2014. (CT 1.) The court issued a tentative ruling denying the petition on January 20, 2015. (CT 171.) The court correctly noted that three key facts are undisputed: First, it is "undisputed there are no scientific studies that directly show DINP causes cancer in humans"; second, it is "undisputed that the decision to include DINP on the list was based solely on studies showing that it causes cancer in animals"; and, third, it is "undisputed that the animal studies show rodents fed DINP had statistically significant increases in three types of cancers: kidney tumors, liver tumors and

mononuclear cell leukemia." (CT 173.) The court noted that it "also appears undisputed there is at least some evidence suggesting the mechanism of action of these three cancers is not relevant to humans, either because the cancers occur in rodents through a particular mechanism that does not occur in humans or because of physiological differences between rodents and humans." (CT 179.)

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[.]" (CT 180.) The court concluded, however, that ACC failed "to make that showing." (*Ibid.*) The court focused on the fact that prior to the CIC's discussion of DINP, OEHHA's staff counsel "informed the CIC that its listing decision should be based on its own published criteria for listing, a copy of which was provided to each member prior to the hearing." (CT 180-81.) The court noted only that "Mack did make several remarks at the hearing that *may* be based on an incorrect interpretation of the law." (CT 181, original italics.) Notwithstanding Chairman Mack's repeated statements that a chemical causing cancer in animals must be listed even if the mechanism of action is not relevant to humans unless there is epidemiological evidence, the court opined that it was possible "Mack [was] simply making the (uncontroversial) point that, in the absence of human studies, animal studies are all the CIC has to go on[.]" (CT 183-84.)

Finally, despite the committee members' obvious confusion over the proper legal standard, and Chairman Mack's egregious and clear misstatement of the Guidance Criteria, the court declined to "assume [that] the remaining CIC members followed Mack's rather garbled and possibly erroneous interpretation of the law rather than the guidance criteria they were instructed to follow." (CT 184.)

IV. STANDARD OF REVIEW

"In determining whether to grant a petition for traditional mandamus, [courts] review for an abuse of discretion." (*Exxon Mobil Corp. v. Office of Environmental Health Hazard Assessment* (2009) 169 Cal.App.4th 1264, 1276.) Because the "'trial court and the appellate courts essentially perform identical roles'" in determining whether the agency abused its discretion, this Court "'review[s] the record de novo and [is] not bound by the trial court's conclusions.'" (*Ibid.* [quoting *Environmental Protection Information Center v. California Department of Forestry and Fire Protection* (2008) 44 Cal.4th 459, 478]; see also *Golden Drugs Co., Inc. v. Maxwell-Jolly* (2009) 179 Cal.App.4th 1455, 1465 ["Where, as here, the trial court made no new factual findings, our review is the same as that of the trial court"].)

When reviewing quasi-legislative decisions, such as a chemical listing under Proposition 65, the court "may not reweigh the evidence or substitute its judgment for that of the agency." (*Exxon Mobil*, *supra*, 169

Cal.App.4th at p. 1277.) Rather, the court will set aside the agency's decision if it was "arbitrary, capricious, or entirely lacking in evidentiary support." (*Ibid*. [quoting *American Board of Cosmetic Surgery, Inc. v. Medical Board of California* (2008) 162 Cal.App.4th 534, 547-548].) "When making that inquiry, the '"'court must ensure that [the] agency has adequately considered all relevant factors, and has demonstrated a rational connection between those factors, the choice made, and the purpose of the enabling statute.' [Citation.]" [Citation.]'" (*Ibid.* [quoting *American Board of Cosmetic Surgery*, *supra*, 162 Cal.App.4th at pp. 547-548].)

V. ARGUMENT

A. Because Proposition 65 Is Intended To Protect People, Not Household Pets, The Presumption That Carcinogenicity In Animals Applies To Humans Is Rebuttable

As the Superior Court recognized, "[n]o one seriously disputes" that "Proposition 65 is concerned with cancer in humans, not cancer in animals." (CT 197.) For over 25 years, courts have held that Proposition 65 "clearly was intended to *protect people* and not household pets or livestock[.]" (*AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, 435, italics added; see also *Styrene Information and Research Center v. Office of Environmental Health Hazard Assessment* (2012) 210 Cal.App.4th 1082, 1094.) However, because "[i]t is unethical to test humans, and because of the 20-to 30-year latency period of many human cancers," it is difficult to obtain solid evidence of human carcinogenicity. (*Id*. at p. 438, fn. 7; see

also *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th 333, 352 [because of ethical issues with human testing and long latency periods "it would pose an undue risk to the public to require definitive proof that a chemical causes cancer in humans"].)

Epidemiological studies also "often are not sufficiently sensitive to identify a carcinogenic hazard except when the risk is high or involves an unusual form of cancer." (Cogliano, et al., *The Science and Practice of Carcinogen Identification and Evaluation* (Sept. 2004) 112 Envtl. Health Persp. 1269, 1270 (hereafter "Cogliano"), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1247515.) For these reasons, "[t]he most common method for identifying potentially carcinogenic agents is a long-term bioassay in experimental animals." (*Id.* at p. 1271.) Evidence of animal carcinogenicity can then be extrapolated to humans, if appropriate. (See *Deukmejian*, *supra*, 212 Cal.App.3d at p. 438, fn. 7 ["the principle which supports qualitative animal to human extrapolation from carcinogenesis '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' (Rep., Office of Science and Technology Policy (Mar. 14, 1985) 50 Fed. Reg. 10375)"].)

Such extrapolation is based on the reasonable "*inference* that carcinogenicity in other animals means carcinogenicity in humans."

(*Western Crop Protection Association v. Davis* (2000) 80 Cal.App.4th 741, 749, italics added; see also *Exxon Mobil Corp.*, *supra*, 169 Cal.App.4th at p. 1289 ["'In the absence of human data to the contrary, it is *assumed* that the effects observed in laboratory animals are relevant to humans,'" italics added]; Cogliano, *supra*, 112 Envtl. Health Persp. at p. 1271 ["Experimental carcinogenesis research is based on the scientific *assumption* that agents causing cancer in animals will have similar effects in humans," italics added].) Nevertheless, because animals and humans are not physiologically identical, the results of animal studies may not be relevant to humans. "To answer questions about the similarity of response between animals and humans," scientists employ "studies of toxicokinetics and mechanisms[.]" (Cogliano, *supra*, 112 Envtl. Health Persp. at p.1270.) "Mechanistic studies aim to eventually elucidate the chemical species and cellular processes involved in cancer initiation and development." (*Id.* at p. 1271.)

If scientists can discover the biochemical mechanism by which a chemical causes cancer in the tested animal, they can often determine whether "analogous mechanisms may be operative in humans" and thus whether the chemical is likely to also be carcinogenic to humans. (*Ibid.*) If studies show that the mechanism of action does not occur in humans—i.e., is not relevant to humans—the "inference" (or "assumption") of

carcinogenicity arising from the animal studies is rebutted. (See Meek et al., *A Framework for Human Relevance Analysis of Information on Carcinogenic Modes of Action* (2003) 33 Critical Reviews in Toxicology 591, 597 (hereafter "Meek") [noting that "significant and convincing" evidence of irrelevance to humans will support deviation from the inference of human carcinogenicity].) For example, scientists are now confident that the artificial sweetener sodium saccharine, which causes bladder cancer in rats, is not a human carcinogen. (CT 202, fn. 16). This is because, as the International Agency for Research on Cancer ("IARC") explained in 1999, "sodium saccharine produces urothelial bladder tumours in rats by a non-DNA-reactive *mechanism* that … is not relevant to humans because of *critical interspecies differences* in urine composition." (*Saccharin and its Salts*, IARC – Summaries and Evaluations (1999), italics added, available at http://www.inchem.org/documents/iarc/vol73/73-19.html.) In fact, OEHHA removed saccharin from the list of chemicals known to the State to cause cancer on the basis of this same mechanistic evidence. (*Notice to Interested Parties Chemical Delisted Effective January 17, 2003 From the List of Chemicals As Known to the State of California to Cause Cancer,* OEHHA (Jan. 17, 2003), *available at* http://www.oehha.ca.gov/prop65/prop65_list/011703Not.html; see also *Evidence on the Carcinogenicity of Sodium Saccharin*, OEHHA (Oct. 2002) at ii ["Since 1987, considerable scientific information has become

available relevant to the mode of action of sodium saccharin carcinogenicity in the rat"], *available at* http://www.oehha.ca.gov/prop65/hazard_ident/pdf_zip/HIDNaSacc.pdf.) In short, as OEHHA itself has previously recognized, where the inference of human carcinogenicity for a particular chemical has been rebutted by the mechanistic evidence, listing the chemical would not advance Proposition 65's purpose of protecting humans.

The CIC's Guidance Criteria are consistent with this scientific reality and with Proposition 65's purpose of identifying and protecting against *human* carcinogens. According to the Guidance Criteria, listing is appropriate where "the weight of the scientific evidence clearly shows that [the] chemical … 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.) Paragraph 1.D of the Guidance Criteria thus provides a two-step process when the only available evidence comes from animal studies. First, the CIC must ask whether the weight of the scientific evidence clearly shows that the chemical causes invasive cancer in animals. If the answer is no, the chemical should not be listed. If the answer is yes, however, the CIC must then address any evidence presented showing that the mechanism of action by which the chemical causes cancer in animals is not relevant to

humans. If the mechanism is shown not to be relevant, the CIC may not list the chemical.

Significantly, paragraph 1.D does not require *epidemiologic* evidence—i.e., evidence of a correlation between the substance and the disease in the exposed human population (cf. *Tozzi*, *supra*, 271 F.3d at p. 305)—showing that the chemical is not carcinogenic to humans. Rather, it requires a showing only that the *mechanism of action* by which a chemical causes cancer in the studied animals does not apply to humans. (AR 8889 ¶ 1.D; see also Meek, *supra*, at p. 597 ["If the data strongly support a species-specific MOA [mechanism of action] that is not relevant to humans, chemicals producing animal tumors by that MOA would not be expected to pose a cancer hazard to humans"].) The Guidance Criteria's focus on mechanistic evidence makes sense given that human epidemiologic data that could rebut the presumption of human carcinogenicity "may not exist and may be difficult or impossible to obtain." (*Baxter*, *supra*, 120 Cal.App.4th at p. 345.)

Far from being mere "verbiage," as Chairman Mack asserted, the precise language of Paragraph 1.D was hammered out over a 14-month period involving public comments, several revisions, and two separate CIC

hearings.[8] OEHHA first released the guidance criteria drafted by the CIC on September 3, 1999, and sought public comment. (Motion for Judicial Notice ("MJN") at 308.) Paragraph 1.D of the initial draft provided, in relevant part, "if the weight of the scientific evidence indicates that a certain chemical causes cancer in humans, or that it causes invasive cancer in animals (unless the mechanism of action is known not to be relevant to humans), the committee is required to identify that chemical for listing." (MJN at 27.) The CIC discussed the draft criteria at a public meeting on October 7, 1999, and several commenters warned that the proposed language of paragraph 1.D would lead to unnecessary listing of animal carcinogens that pose no threat to humans. (MJN at 275:22-25 [Dr. Jay Murray: "to put [chemicals] on [the list] where you feel they're probably not relevant to humans, I think, is inconsistent with the 'clearly-shown' standard"]; MJN at 270:12-15 [Dr. Gary Williams: "I think it's a good idea to maintain a stringent standard for what is an animal carcinogen that should be construed to be a putative human cancer risk"].) The CIC Chairman subsequently extended the written public comment period to November 2, 1999, and several entities, including ACC, submitted written comments. (MJN at 308.)

[8] "[T]he Carcinogen Identification Committee may … [r]eview or propose standards and procedures for determining carcinogenicity of chemicals." (27 CCR, § 25305, subd. (a)(4).)

The CIC revised the draft criteria in response to these comments and, on September 22, 2000, issued a new Notice to Interested Parties initiating another 30-day public comment period. (*Ibid.*) The revised criteria replaced "is known not to be relevant to humans" in paragraph 1.D with "has been shown not to be relevant," but made no other changes. (MJN at 309.) Several entities, again including ACC, submitted written comments proposing further revisions to paragraph 1.D. All of these comments stressed the importance of *mechanistic* evidence. For example, ACC requested that the "principle [in paragraph 1.D] be more clearly and affirmatively stated to make clear that a chemical shown to cause cancer in experimental animals *shall not* be listed if the weight of the evidence indicates that it does so by a mechanism of action that is not relevant to humans." (MJN at 333-334.) The Cosmetic Toiletry and Fragrance Association likewise urged that the criteria "should allow for positive animal study results to be rejected on the basis of lack of human relevance" because "[c]hemicals which induce tumors via mechanisms which are not relevant to humans do not present a risk to human health." (MJN at 318.) ILSI suggested that "[t]he criteria would benefit from further revisions that clarify and discuss how the relevance of animal and mechanistic data to humans is used for listing a substance." (MJN at 319.) Other commenters urged the CIC to modify paragraph 1.D to say that a chemical causing invasive cancer in animals will not be listed if "the mechanism of action is

probably not relevant to humans." (MJN at 326 [comments of Dr. Jay Murray]; see also MJN at 330 [Gary M. Roberts: "Members of the CIC should be allowed to weigh data concerning the relevance of animal test results to human hazard without being restricted merely to mechanistic data that has 'shown' there is no need for concern."].) These comments confirm that both the CIC and other stakeholders were acutely aware that listing decisions under Proposition 65 would often hinge on mechanistic evidence regarding the relevance to humans of observed cancers in animals.

At the CIC's November 16, 2000 meeting, public comments again focused on paragraph 1.D and the importance of mechanistic evidence. For example, a representative of the American Electronics Association and the Chemical Industry Council urged the committee to change the criteria to say that "if the weight of the scientific evidence clearly shows that a certain chemical … causes invasive cancer in animals through a mechanism appropriate for extrapolation to humans, the Committee will identify the chemical for listing." (MJN at 352; see also MJN at 354-356 [comments of Dr. Murray suggesting changes to paragraph 1.D]; MJN at 363-364 [comments of Gary Roberts addressing paragraph 1.D].) Responding to these comments, Chairman Mack agreed to substitute "*will normally* identify [a chemical for listing]" in place of "*is required to* identify a chemical for listing" in paragraph 1.D. (MJN at 365.) The CIC did not

adopt any other changes to paragraph 1.D and voted to approve the Guidance Criteria at the November 16, 2000 meeting. (MJN at 380.)

The intensive focus on mechanistic evidence leaves no doubt that both the CIC and the public understood that rebutting the inference of human carcinogenicity arising from animal studies involved a "show[ing]" that the "mechanism of action [is] not relevant to humans." (AR 8889 ¶ 1.D.)

In accordance with the Guidance Criteria, ACC, its member companies, and other commenters devoted substantial time and resources to "show[ing]" that the mechanisms of action by which DINP causes various cancers in rodents are not relevant to humans. (AR 725-1534, 8903-9340.) At the CIC hearing on DINP, prominent scientists testifying on behalf of ACC and its members also discussed the mechanistic evidence. For example, Dr. Michael Cunningham, who reviewed DINP in the early 2000s as a member of the CPSC CHAP, explained that the mechanism by which DINP can cause liver cancer in rodents is not relevant to humans. (AR 9468:1-9474:17; see, e.g., AR 9469:18-21 ["the significant quantitative differences in PPAR alpha activator induced effects that related to liver cancer in rodents were ***not operative in humans*** after PPAR activation," emphasis added].) Two other scientists, Dr. Gordon Hard and Dr. Jennifer Foreman, explained why the mechanisms of action leading to kidney

tumors and mononuclear cell leukemia in rodents are not relevant to humans. (AR 9474:22-9486:17.)

In response to these comments, the committee members expressed interest in the scientific evidence regarding whether the results of animal studies on DINP were applicable to humans. Indeed, Committee Member Reynolds specifically stated that he would "really like to hear more" about "whether the mechanism of action [for liver tumors] has been shown to be relevant to humans." (AR 9514:16-20; see also AR 9517:19-20 [Committee Member Eastmond: "The key question now becomes, are those [liver tumors in rodents] relevant to humans?"].)

Assuming arguendo that these scientists are correct and the mechanisms of action causing MNCL and liver and kidney tumors are not relevant to humans, the *inference* that DINP is a human carcinogen would be rebutted. There would thus be no basis for listing DINP under the Guidance Criteria because "it is undisputed there are no scientific studies that directly show DINP causes cancer in humans." (CT 194; AR 1580 [HID: "No carcinogenicity studies in humans were found in the published literature or referenced in government documents."].) Accordingly, the CIC members were obligated under Proposition 65 and the Guidance Criteria to evaluate this scientific evidence and decide whether the mechanisms of action by which DINP causes cancers in rodents are

relevant to humans. They were foreclosed from doing so, however, because (1) Chairman Mack misstated the listing criteria and shut down any cogent discussion regarding the relevance of the animal tumors to humans, and (2) OEHHA's biased and rushed administrative process prevented the CIC from reviewing and analyzing the relevant scientific information.

B. The Chairman's Incorrect Statement Of The Listing Standard And OEHHA's Biased And Rushed Administrative Process Rendered The CIC's Vote And Recommendation Arbitrary And Capricious

The trial court correctly recognized that ACC is "entitled to a writ of mandate if it … prove[s] the CIC's Chairman incorrectly instructed the CIC on the law by stating this [mechanistic] evidence was irrelevant." (CT 200.) As the transcript of the CIC hearing demonstrates, Chairman Mack did precisely that, directing the CIC to ignore the text of paragraph 1.D of the Guidance Criteria and apply a different standard of his own creation. Given the timing and context of these instructions, as well as the reservation and confusion expressed by several committee members, it is clear that the instructions so infected the CIC's deliberations that the decision to list DINP was arbitrary and capricious. OEHHA also precluded the CIC from adequately considering the relevant factors by drafting a grossly defective HID that selectively quoted key toxicity reviews conducted by other health agencies, omitted highly relevant toxicology studies on primates treated with DINP, and mischaracterized the scientific

evidence regarding the relevant mechanisms of action for liver and kidney tumors and MNCL in rodents treated with DINP. OEHHA compounded the HID's errors by giving the CIC a mere two weeks to review and process the public comments that sought to correct the HID's deficiencies, and by wasting valuable time at the CIC hearing discussing the undisputed evidence regarding DINP's carcinogenicity for rodents. Chairman Mack further precluded the CIC from considering the relevant information by limiting the commenters' presentations (primarily on mechanistic evidence) to 30 minutes and by closing down discussion of the evidence and forcing the committee to vote even though several members expressly asked to hear more about the mechanistic evidence. Because the CIC applied the wrong legal standard and was foreclosed from adequately considering the relevant factors, the CIC's recommendation—and thus OEHHA's listing decision—was arbitrary and capricious. This abuse of discretion was highly prejudicial because the evidence strongly suggests that the CIC would have voted not to list DINP had it applied the proper standard and been allowed to adequately consider the relevant information.

1. Because The CIC Applied The Chairman's Erroneous And Prejudicial Standard, OEHHA's Decision To List DINP Was Arbitrary And Capricious

It is a bedrock principle of administrative law that an agency's failure to comply with its own governing regulations is arbitrary and

capricious. (See *Schenley Affiliated Brands Corp. v. Kirby* (1971) 21 Cal.App.3d 177, 196 [courts must invalidate quasi-legislative actions that "fail[] to follow procedures established by law"]; see also *Walker v. County of Los Angeles* (1961) 55 Cal.2d 626, 638; 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"]; *Battle v. Federal Aviation Administration* (D.C. Cir. 2005) 393 F.3d 1330, 1336 ["agencies may not violate their own rules and regulations to the prejudice of others"]; *National Environmental Development Association's Clean Air Project v. EPA* (2014) 752 F.3d 999, 1009 ["It is 'axiomatic' … 'that an agency is bound by its own regulations'"].) Courts will not sanction an agency's "[*a*]*d hoc* departures from [its] rules, even to achieve laudable aims, … 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, 950-951.) The "relevant inquiry" is thus "whether the record contains evidence [the agency] failed to comply with the requirements of [the] regulatory program." (*City of Sacramento v. State Water Resources Control Board* (1992) 2 Cal.App.4th 960, 976, italics omitted.)

Although courts presume that an agency has performed its official duties consistent with the requirements by which it is bound (Evid. Code,

§ 664), that presumption can be overcome with evidence to the contrary. (E.g., *McAllister v. California Coastal Commission* (2008) 169 Cal.App.4th 912, 931.) Where an agency has failed to follow its own rules, "[m]andamus is a proper remedy to compel [an agency] to perform its mandatory duties prescribed by [its internal rules]." (*Leftridge v. City of Sacramento* (1943) 59 Cal.App.2d 516, 525; see also *Common Cause v. Board of Supervisors* (1989) 49 Cal.3d 432, 442 [mandamus may issue to compel agency to exercise its discretion "under a proper interpretation of the applicable law"]; *Walker*, *supra*, 55 Cal.2d at p. 639.) Here, the record is replete with evidence that the CIC, which is authorized to render opinions about whether a particular chemical has been shown to cause cancer within the meaning of Proposition 65, failed to follow its own criteria. (See 27 CCR, §§ 25302(a), 25305(a)(1).)

It requires no technical expertise to recognize the CIC's failure to apply its published decision-making criteria, because the transcript reveals that the final instructions the Chairman provided to the CIC members flatly contradicted paragraph 1.D of the Guidance Criteria. (AR 8889 ¶ 1.D.) Under paragraph 1.D, once a chemical has been shown to cause cancer in animals, the *only* relevant question is whether the "mechanism of action" has been shown to be not relevant to humans. But Chairman Mack deliberately turned the focus away from mechanistic evidence to

epidemiologic evidence, insisting that because "we're in a situation where there is not epidemiologic data[,] [w]e have to go solely on the animal data." (AR 9523:10-12.) But paragraph 1.D of the CIC's Guidance Criteria says nothing about "*epidemiologic* information," and neither the CIC nor the regulated community has ever understood 1.D to require rebuttal evidence in the form of epidemiologic studies. (See Part V.A, *ante*.)

Chairman Mack nevertheless insisted that the committee ignore the mechanistic evidence showing that the cancers observed in rodents had no application to humans, and instead instructed the other members that "in the absence of epidemiologic information, we're stuck making decisions about animal data." (AR 9521:21-23.) When other committee members pointed out that paragraph 1.D focuses on *mechanistic* evidence, not epidemiologic evidence (AR 9522:14-17), Chairman Mack justified his reading of the criteria on the ground that he was the "person who wrote those guidelines." (AR 9522:25; see also AR 9522:25-9523:12.) But Chairman Mack's asserted authorship does not allow him to change the meaning of "mechanism of action"—a term with a defined meaning in the scientific world—and thus force the listing of DINP in contravention of the criteria the CIC has adopted and on which the public has relied for more than a decade.

When challenged by Mr. Landfair, Chairman Mack erased any doubt that he expected the committee members to ignore the mechanistic evidence presented by ACC, its members, and the other commenters. After Mr. Landfair pointed out that "the question before the Committee is whether those data [showing cancers in rodents] are relevant to humans" (AR 9523:22-24), Chairman Mack retorted,

> 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 added.) Chairman Mack thus told the committee that the question of human relevance was irrelevant to the listing decision. This statement is impossible to reconcile with the clear language of paragraph 1.D, which allows the inference of human carcinogenicity to be rebutted by a showing that the mechanism of action is "not … relevant to humans." (AR 8889 ¶ 1.D.)[9] When Mr. Landfair made one final attempt to refocus the committee on the actual language of paragraph 1.D (AR 9524:11-12), Chairman Mack abruptly interrupted and directed the committee to apply

[9] Chairman Mack's statements, on a different topic later in the meeting, confirm that he did not want the CIC to consider human relevance, notwithstanding paragraph 1.D's clear statement to the contrary. When discussing Proposition 65's other methods of listing, Chairman Mack said, "Remember that the … other authoritative bodies don't have quite the same mandate that we have. … [T]hey can consider human pertinence, whereas our law doesn't permit us to do that." (AR 9600:11-16.)

his criteria, not the published criteria (AR 9524:13-20). Chairman Mack's response ended all discussion of the proper legal standard and the scientific evidence.

In the face of the Chairman's numerous misstatements about the committee's duties—statements that directly contradicted the CIC's published decision-making criteria—there can be no doubt that committee members were instructed to apply an improper legal standard. The trial court's contrary conclusion that Appellant "may be reading too much into Mack's statement" (CT 203) cannot be reconciled with the record.

The trial court offered a second flawed reason for not granting the writ: it would not "assume the remaining CIC members followed Mack's rather garbled and possibly erroneous interpretation of the law rather than the guidance criteria they were instructed to follow." (CT 204.) The court opined that "in the absence of evidence to the contrary, [it] must presume the CIC properly carried out its obligations and followed its own guidance criteria." (CT 204.) But there *is* evidence to the contrary. The transcript shows that although several committee members initially pushed back against Chairman Mack's erroneous interpretation of the guidance criteria, they eventually acquiesced to his interpretation and thus did *not* "follow [the CIC's] guidance criteria." (*Ibid.*)

After Chairman Mack expressed his personal views regarding DINP's carcinogenicity (AR 9520:8-9521:9), Dr. Zhang—a new member of the CIC—asked for clarification as to whether they could "list based on animal data" (AR 9521:10-14). Both Chairman Mack and OEHHA's staff counsel confirmed that the CIC could list based on animal data. (AR 9521:15-16.) But Chairman Mack then added that "[t]he only point about humans that Fay mentioned I think was in the criteria document that we produced, which discusses the pertinence to humans. But, of course, in the absence of epidemiologic information, we're stuck making decisions about animal data." (AR 9521:17-23.)[10] That statement was clearly incorrect, and Dr. Thomas asked for "clarification on this relevance question." (AR 9522:13-14.) Dr. Thomas's full comments highlight the discussion that the committee should have (and would have) had if Chairman Mack had not grossly distorted the legal standard:

> Well, I still would like clarification on this relevance question. 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. Now, as I understand, I think it was [S]andy's comment, the – we 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

[10] If that were the correct legal standard, ACC surely would not have brought three of the world's preeminent experts on DINP all the way to California (one traveled all the way from New Zealand) to discuss the mechanistic evidence, given the unanimous agreement that DINP causes cancers in laboratory rodents.

> the possibility that it's relevant still stands, as I read your comments, or whichever of you it was.[11]

(AR 9522:13-23.) As Dr. Thomas recognized, OEHHA's scientists were not convinced that PPAR alpha activation—also called peroxisome proliferation—is the mechanism of action that causes liver cancer in rodents. (See AR 9508:16-24 [Dr. Sandy: "our conclusion is that … PPAR alpha activation may not be involved"].) Because the committee members broadly agreed that DINP causes liver cancer in rodents, their discussion should have focused on the mechanistic evidence presented by ACC's scientists. But the scientific evidence on the mechanism of action for liver cancer was *never* mentioned again because Dr. Mack derailed the discussion by directing the committee to list DINP unless there was "extremely good epidemiologic data suggesting that there is no [carcinogenic] effect on humans." (AR 9522:24-9523:14.)

Instead of evaluating the mechanistic evidence, the discussion continued to focus on the appropriate legal standard. (AR 9523:15-9525:4.) And despite the best efforts of BASF's counsel to refocus the committee on the mechanistic evidence, Chairman Mack insisted that paragraph 1.D of the Guidance Criteria was written "for the circumstance in which there was a conflict between human epidemiologic data and information from

[11] Although the transcript says "Mandy," Dr. Thomas was referring to Dr. Martha Sandy, OEHHA's lead scientist responsible for preparing the HID.

animals." (AR 9524:13-17.) Because all parties conceded that there was no epidemiologic data of any kind, Chairman Mack's erroneous direction eliminated the need for any further discussion, and the CIC promptly voted to list DINP. The transcript thus makes it clear that the committee members applied Chairman Mack's statement of the law. The trial court thus erred in assuming, in the face of clear evidence to the contrary, that the committee members applied the published criteria. (CT 204.) Because the CIC members applied Chairman Mack's erroneous criteria when they voted to list DINP, the CIC's vote—and by extension OEHHA's listing decision—was arbitrary and capricious. (See *No Oil, Inc. v. City of Los Angeles* (1974) 13 Cal.3d 68, 88 ["use of an erroneous legal standard constitutes a failure to proceed in the manner required by law"]; see also *McAllister*, *supra*, 169 Cal.App.4th at p. 954 [citing same principle with approval].)

2. The Decision To List DINP Was Also Arbitrary And Capricious Because OEHHA Precluded The CIC From Adequately Considering All Relevant Factors

It is axiomatic that an agency must "'… adequately consider[] all relevant factors, and … demonstrate[] a rational connection between those factors, the choice made, and the purpose of the enabling statute.'" (*Exxon Mobil*, *supra*, 169 Cal.App.4th at p. 1277 [quoting *American Board of Cosmetic Surgery*, *supra*, 162 Cal.App.4th at pp. 547-548]; *California*

Hotel and Motel Association v. Industrial Welfare Commission (1979) 25 Cal.3d 200, 212.) Failure to do so renders an agency's action arbitrary and capricious. (*Exxon Mobil*, *supra*, 169 Cal.App.4th at p.1277.) Further, the CIC Guidance Criteria require that it utilize a "weight of evidence" approach, including evaluation of "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.)

Here, OEHHA's decision to list DINP was based entirely on the CIC's recommendation (AR 9611), but OEHHA precluded the CIC from considering all relevant factors by issuing a biased, incomplete and misleading HID. OEHHA further prevented the CIC from meaningful consideration of the relevant information by giving the CIC a meager *two weeks* to consider ACC's and ExxonMobil's comments that sought to correct the HID's many deficiencies, along with 7,000 pages of scientific studies. OEHHA's scientists also downplayed the mechanistic evidence at the December 5, 2013 CIC hearing, and Chairman Mack ensured that the CIC would not consider the relevant scientific information by closing down debate on the key question of whether the mechanisms of action causing cancers in rodents are relevant to humans. Because the CIC was foreclosed from adequate consideration of all of the relevant factors, its listing recommendation (and OEHHA's subsequent listing decision) was arbitrary and capricious, and should be vacated.

ExxonMobil submitted extensive information in early 2010 explaining in detail why the rodent bioassays did not establish human carcinogenicity. (AR 725-1534.) OEHHA had over three years to process the studies cited in ExxonMobil's comments and incorporate them into the HID. Nevertheless, when OEHHA released the HID in late 2013, it was riddled with inaccuracies, failed to cite relevant studies, and mischaracterized much of the relevant scientific evidence. Some of the most glaring examples are set forth below.

Omission of Primate Studies. As ExxonMobil explained, "there is an unusually large amount of data from *in vivo* studies in non-human primates as well as some *in vitro* data for humans and non-human primates." (AR 1409.) This scientific evidence is particularly relevant "[b]ecause monkeys are more closely related to humans than are rodents," and thus "primate data provides the best basis for determining whether chronic effects seen in rodents can reasonably be anticipated to occur in humans." (*Ibid.*, underscoring omitted.) None of the primate studies showed any "evidence of potential carcinogenicity, even under conditions that unquestionably would in rodents provoke responses that are part of the progression to cancer in those rodent species." (*Ibid.*; see also AR 1410 [discussing studies involving cynomolgus monkeys and marmosets, and noting that "[i]n both of these primate studies, there was no evidence of

those types of treatment-related effects which occur in rodents, even at the very high levels of treatment" (underscoring omitted)].) Thus, "the primate studies—studies in species much more closely related to human[s] than rodents—indicate that DINP is unlikely to be a human carcinogen." (AR 1410.) Astonishingly, the HID made no mention of these highly relevant studies. The HID's focus on traditional cancer bioassays, which are predominantly conducted in rodents, and incomplete summary of mechanistic studies, such as those conducted in primates, gives only a partial picture and a false impression that no such studies had ever been conducted.

Omission and Mischaracterization of Critical Toxicity Reviews. ACC and other commenters submitted multiple toxicity reviews concluding that DINP is not carcinogenic to humans. (AR at 725-1534.) However, in its section titled "Reviews by Other Agencies," the HID did not even cite several of these studies and reviews. (AR 1631-1632.) The HID also cherry-picked language from those reports it did mention, giving the erroneous impression that regulators maintained a greater degree of certainty pertaining to DINP's carcinogenicity in humans than the full documentation suggests. For example, the HID cites to statements in an EPA review of DINP regarding liver tumors and MNCL (upon which EPA reserved judgment) (AR 1632), but "leaves out a critical conclusion of the

EPA technical review—that the DINP kidney tumors meet both the EPA and IARC criteria for the alpha-2u-globulin mechanism and therefore are not relevant to humans" (in contradiction of the HID conclusion). (AR 8975-8976; see also AR 8917-8918.)

Mischaracterization of Evidence Regarding Kidney Tumors. Although kidney tumors have been observed in male rats exposed to high doses of DINP over a long period of time (AR 9036), scientific studies show that these tumors occur through a mechanism of action—the accumulation of alpha2u-globulin in the rat's kidneys—that is not relevant to humans because humans do not produce alpha2u-globulin. (*Ibid.*) Every other health agency that has reviewed DINP has concluded there is substantial evidence that kidney tumors in rats treated with DINP are due to this mechanism and not relevant to humans. (See AR 8975-8976 [citing several government toxicity reviews].)

Contrary to the strong health-agency consensus and the clear scientific evidence showing that alpha2u-globulin is the mechanism that causes kidney tumors in rodents, the HID concluded that "[alpha]2u-globulin accumulation in the renal tubules of male rats do[es] not explain the renal tubule carcinomas observed in DINP-exposed rats." (AR 1631.) The HID failed to mention that DINP satisfies the three EPA criteria for determining whether tumors result from alpha2u-globulin accumulation

(AR 1629-1631), and declined to mention a number of studies demonstrating that DINP meets all of the IARC's criteria as well. (Compare AR 1629-1631 with AR 9041-9042 [citing AR 1353, 1743-1754, 2039-2046, 3285-3291, 3316-3369].) It even ignored the conclusion of Dr. James Swenberg, an expert in the alpha2u-globulin mechanism and a co-author of the IARC scientific publication on the alpha2u-globulin mechanism, which stated that the data "'clearly demonstrate that DINP causes [alpha2u-globulin nephropathy]'" and that "'the data on [rat] kidney tumors is not relevant for human risk assessment.'" (AR 9037 [quoting AR 1527], second bracketed insertion added.) The HID's discussion of kidney tumors thus presented the CIC with a biased and inaccurate summary of the scientific evidence.

Mischaracterization of Evidence Regarding Liver Tumors.

Studies show that "DINP at high doses produces liver tumors in rats and mice" (AR 9008), but there is a large body of scientific evidence showing that DINP causes liver cancer through a mechanism of action—peroxisome proliferation—that is not relevant to humans. (AR 9008-9009, 9011-9016.)[12] Numerous studies agree that peroxisome proliferation is almost certainly the cause of liver tumors in rodents exposed to high levels of

[12] A peroxisome proliferator is a chemical that increases the number and size of peroxisomes, which are subcellular structures in the liver. (AR 9009.)

DINP (AR 9016-9023), and there is substantial scientific evidence that peroxisome proliferation is not relevant to humans. (AR 9025-9030.)

The HID hypothesized that rodent liver tumors may nevertheless be relevant to humans because other mechanisms could be involved in causing rodent tumors, and those mechanisms may be relevant to humans. (AR 1621-1625.) But the HID ignored the evidence that the proposed "alternative" mechanisms are consistent with downstream events following peroxisome proliferation, that peroxisome proliferation is necessary for these alternative events to occur, and that peroxisome proliferation mechanism is not relevant for humans. (AR 9009-9034.) The HID thus suggested a much greater degree of uncertainty about the role of peroxisome proliferation in rodent liver tumors than is warranted by the scientific evidence. (See AR 9032-9034 [citing findings of the CPSC CHAP, the ILSI workgroup, the EU risk assessment, and several prominent scientists who have conducted significant research on peroxisome proliferation].)

Mischaracterization of Evidence Regarding Mononuclear Cell Leukemia. Researchers have found that one particular strain of rat—the Fischer 344—develops mononuclear cell leukemia ("MNCL") at a higher rate when exposed to large doses of DINP. (AR 9008, 9034.) But it is widely recognized that MNCL occurs spontaneously at variable incidence

and a high level in Fischer 344 rats, making determinations of treatment-related increases difficult to evaluate and suggesting that the increase in MNCL is species- and strain-specific, and not relevant to people. (AR 9034-9036.) In fact, the National Toxicology Program ("NTP") has even "decided to stop use of the [Fischer 344] strain, in part because of the high spontaneous incidence of MNCL i[n] that strain." (AR 9035.) A second strain of rats, Sprague-Dawley, and mice both showed no increase in MNCL rates, which also supports that the effect is limited to Fischer 344 rats, and thus does not have any relevance to humans. (See AR 9034.) One of the pre-eminent researchers in the field of leukemogenesis, Dr. Richard Irons, has concluded that "MNCL in the F344 rat is not a useful model for the direct study of human disease and is certainly not an appropriate endpoint for predicting or extrapolating carcinogenic risk in humans." (AR 9035.) The National Institutes of Health has likewise noted the "obvious lack of significance of MNCL to human disease." (*Ibid*.)[13]

Once again dealing selectively with the evidence, the HID omitted any reference to the many expert bodies that have considered MNCL in Fischer 344 rats and found it irrelevant to humans. For example, the HID ignored the conclusion of Australia's NICNAS in 2012 that because "'[MNCL] is a common neoplasm in Fischer 344 rats with no comparable

[13] The National Research Council has also questioned the human significance of MNCL in Fischer 344 rats. (AR 8941 [citing AR 10557].)

tumour type in humans and its increased incidence after chronic exposure to some substances is considered to be a strain-specific effect … [MNCL] observed in Fischer 344 rats is not regarded as relevant to humans.'" (AR 8941.)

Mischaracterization of Evidence of Pancreatic, Testicular, and Uterine Tumors. The HID included a highly misleading discussion of pancreatic, uterine, and testicular tumors caused by DINP. (AR 1570-1573, 1588-1594, 1622-1626.) Although these tumors were not statistically significant, the HID characterized them as being "considered rare," based on a limited review of the literature for historical control values. (AR 1626.) The HID erroneously stated that these three types of tumors were outside the range of historical controls (AR 1588-1590), even though "[t]he incidence of these three tumor types in each case was within historical control levels" (AR 8914; see also AR 8917, 8923, 8925, 8938-8940). The HID also failed to explain that the testicular and uterine tumor types were observed only in a single study of one strain of rat (Sprague-Dawley rats) but were not elevated in mice or in another strain of rat (Fischer 344). (AR 8925.) Nor did the HID disclose that pancreatic tumors were observed in male Sprague-Dawley rats in the same study but not in female Sprague-Dawley rats or in Fischer 344 rats of either sex, or that a statistically insignificant increase in pancreatic tumors was observed in female mice in one study but not in male mice or Fischer 344 rats. (AR 8925.)

* * *

In short, OEHHA biased the CIC in favor of listing by drafting an HID that omitted significant primate studies, ignored comprehensive government toxicity reviews from around the world, misconstrued those studies and toxicity reviews it did mention, focused myopically on DINP's effects on rodents, and misrepresented or failed to adequately discuss many of the scientific studies addressing mechanistic evidence.

ACC, ExxonMobil, and others submitted comments in November 2013 in an attempt to correct the HID's inaccuracies and omissions. (AR 8907-9340.) OEHHA should have revised the HID at that point to correct the problems highlighted by the comments. At a minimum, it should have delayed the CIC deliberations on DINP, providing a substantial period of time for the CIC to review the critiques of the HID and the underlying scientific studies and toxicity reviews. Instead, OEHHA simply provided the comments to the CIC on November 20, 2013. (AR 8895-8903.) The CIC thus had two weeks to review more than one thousand pages of comments (in addition to only eight weeks for review of the 7,200 pages attached to the HID itself) before the meeting. This time period was patently inadequate given the volume of material, and in light of the intervening Thanksgiving holiday. It is simply not plausible that the committee members, most of whom have full-time jobs, were able to digest

the public comments by December 5, 2013. As a result, the committee members' understanding of the state of the science regarding DINP was shaped by the HID's inaccurate 67-page summary of the evidence.

OEHHA persisted in obscuring the relevant mechanistic evidence at the CIC hearing. Even though none of the commenters disputed that DINP is carcinogenic to rodents, OEHHA's staff scientists spent most of their presentation describing the results of the rodent studies. (AR 9436:2-9449:17 [discussion of rodent studies]; AR 9450:15-9455:5 [discussion of mechanistic evidence].) By needlessly focusing on the uncontroversial rodent studies, OEHHA reduced the time available to discuss the critical mechanistic evidence. Chairman Mack further curtailed discussion when he denied ACC's request to allocate one hour to presentations by several prominent scientists who are experts on the mechanistic evidence. (AR 9345-9349 [joint letter from ACC and member companies requesting one hour presentation]; AR 9461-9463 [allowing scientists to present for only 30 minutes].) It was impossible for the four scientists who presented on behalf of ACC and its member companies to adequately convey all of the mechanistic evidence to the committee members, much less correct all of the HID's errors, in 30 minutes.

ACC's scientists did manage to pique the committee members' interest, and several members expressed interest in "hear[ing] more" about

the mechanistic evidence. (AR 9514:16-20; see also AR 9512:21-9513:5, 9518:8-9, 9520:3-4.) But Chairman Mack curtailed any further discussion of the mechanistic evidence by embroiling the committee in an unnecessary debate over the meaning of paragraph 1.D of the Guidance Criteria (see Part V.B.1, *ante*), and by insisting that the CIC come to an immediate vote (AR 9524:13-20 ["I don't think we can discuss it any further. We have to take a vote now. So if you'll permit, we'll go ahead and do that."].) The Chairman's haste prevented the CIC from taking even 30 additional minutes to discuss the mechanistic evidence with some of the world's leading scientists on DINP. Thus, more than four years after OEHHA first initiated the review process for DINP, the CIC's decision came down to a rushed vote based on incomplete and inaccurate information in which the committee applied the wrong criteria. Because these errors prevented the CIC from adequately considering the relevant factors, the CIC's decision was arbitrary and capricious.

3. The Agency's Abuse Of Discretion Was Highly Prejudicial

The CIC's failure to apply its published Guidance Criteria, and OEHHA's conduct in foreclosing the CIC from adequately considering the relevant factors, were manifestly prejudicial. As the hearing transcript demonstrates, the vote likely would have been different had the CIC applied the published Guidance Criteria and been provided an opportunity

to review and consider the compelling evidence showing that the mechanisms of action by which DINP causes cancer in laboratory rodents are not relevant to humans. Before Chairman Mack changed the listing standard, six of the eight members of the committee (Landolph, Zhang, Reynolds, Eastmond, Bush, and Thomas) expressed significant reservations about listing DINP. (See Part III.D, *ante*; AR 9512:21-9513:5, 9513:8-9514:8, 9514:14-20, 9518:2-9, 9520:3-4, 9522:17-23.) Had even four of these members ultimately concluded that the mechanisms of action are not relevant to humans, the vote would not have yielded a majority in favor of listing DINP.

Given the state of the scientific evidence, it is highly likely that at least four of the members would have reached such a conclusion. DINP is one of "the most widely studied industrial chemicals in commerce today" (AR 9466:7-9), and every health agency that has reviewed DINP—including the CPSC CHAP, the Risk Science Institute of ILSI, the European Chemicals Bureau, and the Australian NICNAS—has declined to find that it is a human carcinogen. (AR 217, 2150, 2160, 3057, 9847-9848, 9923, 10105.) And neither IARC nor the NTP has classified DINP as a human carcinogen. (AR 217, 9269.) In light of the overwhelming scientific evidence indicating that the various mechanisms of action by which DINP causes cancers in rodents are not relevant to humans (see AR

8905-9340), the CIC would likely have reached the same conclusion as the world's other leading health organizations had the committee members been directed to apply the proper criteria and been allowed to adequately consider the relevant mechanistic information. Because the agency's abuse of discretion was prejudicial, this Court should order OEHHA to remove DINP from the Proposition 65 list.

C. OEHHA's Erroneous Decision To List DINP Will Have Severe Negative Consequences

OEHHA's decision to list DINP has serious consequences. The listing may cause manufacturers to replace DINP with other chemicals that may not have been as well studied, may be less safe, and may be less effective. The listing will also 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. Indeed, when product risks are exaggerated and "important safety information is drowned in a sea of trivia," safety may actually suffer. (Owen, *Defectiveness Restated: Exploding the "Strict" Products Liability Myth* (1996) 1996 U. Ill. L.Rev. 743, 766.) This "warnings pollution" creates a problem of information overload that

promotes maximum, rather than effective, warning information. (*Ibid.*; see also Barsa, *California's Proposition 65 and the Limits of Information Economics* (1997) 49 Stan. L.Rev. 1223, 1237 [discussing the dangers of over-warning in the Proposition 65 context and noting that "[p]olicymakers have long recognized the dilemma of overwarning in other contexts, such as over-the-counter drugs"].)

In the context of prescription drugs, for example, the California Supreme Court has noted that if warnings must be given of every "' … possible risk, no matter how speculative, conjectural, or tentative, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given." (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1115-1116 [quoting *Finn v. G.D. Searle & Co.* (1984) 35 Cal.3d 691, 201]; see also *id.* at p. 1126 (conc. & dis. opn. of Kennard, J.) ["The problems of overwarning are exacerbated if warnings must be given even as to very remote risks …."]; Barsa, *supra*, 49 Stan. L. Rev. at p. 1231 ["exaggerated warnings may lead to a 'boy who cried wolf' problem as consumers simply ignore future warnings because past warnings have been misleading"].) In the broader products liability context, the 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 [quoting *Finn*, *supra*, 35 Cal.3d at p. 701]; see also Restatement (Third) of Torts: Prod Liab., § 2, com. i(3) [counseling courts against imposing a duty to warn against "trivial or far-fetched risks," because "[s]uch warnings would tend to debase warnings and detract user's attention from warnings about risks of greater significance"] .) Requiring manufacturers to warn consumers about exposure to chemicals such as DINP that do not pose a cancer hazard to humans will inevitably dilute the impact of Proposition 65 warnings.

Finally, OEHHA's erroneous listing will unleash a barrage of harmful and costly litigation against manufacturers that use DINP in their products. Indeed, bounty hunters have already filed more than 200 60-day notices with the California Attorney General's office alleging that hundreds of products—including vinyl gloves, coaxial cable, and vinyl tool grips—have violated Proposition 65.[14] (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, last visited Feb. 3, 2016.) These notices often lead to costly litigation, and dozens of lawsuits

[14] Pursuant to Proposition 65's implementing statutes, parties must file a 60-day notice of an alleged violation before commencing a private action. (§ 25249.7, subd (d).)

bringing claims based on DINP exposure have already been filed in courts throughout California. (*Ibid.*; see *Consumer Defense Group v. Rental Housing Industry Members* (2006) 137 Cal.App.4th 1185, 1215 ["instigation of Proposition 65 litigation [is] … almost absurdly easy at the pleading and pretrial stages"].) Defendants are under substantial pressure to settle these suits 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 the penalties assessed. (§ 25249.7, subds. (b)(1), (f); see also *Consumer Defense Group, supra*, 137 Cal.App.4th at p. 1215 [explaining "just how simple it is for a hypothetical unemployed lawyer, eager to cash in on Proposition 65, to extract money from businesses using the initiative"]; Caso, *Bounty Hunters and the Public Interest—A Study of California Proposition 65* (Mar. 2012) 13 Engage 30, 32 [reporting that defendants paid more than $142 million in settlements to bounty hunters between 2000 and 2010, and that over $90 million of that total constituted attorneys' fees].) OEHHA's erroneous listing of DINP will thus have (and has already had) severe financial ramifications for California businesses and consumers.

The harms generated by the listing of DINP are just the tip of the iceberg. If the Court sanctions the erroneous listing of DINP, it will free OEHHA from any obligation to adhere to its own guidelines and render

future chemical listings even more likely to be untethered from the relevant science. The people of California did not intend to give the unelected members of the CIC (or OEHHA's staff) *carte blanche* authority to list chemicals based on whatever criteria the Chairman feels like applying on a given day. The potential dangers of an unaccountable administrative state have been well chronicled, and this Court should remind OEHHA of "one of our nation's most basic precepts: that we are a 'government of laws and not men.'" (*People v. Williams* (2001) 25 Cal.4th 441, 459 [quoting *Reynolds v. Sims* (1964) 377 U.S. 533, 568].)

VI. CONCLUSION

OEHHA's decision to list DINP under Proposition 65 was based on an incorrect statement of the law, a deeply flawed administrative record, and the CIC's failure to follow its own guidelines. Accordingly, this Court should reverse the trial court's denial of ACC's petition for writ of mandate, and direct OEHHA to remove DINP from the list of chemicals known to the State of California to cause cancer.

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The undersigned certifies that pursuant to the word count feature of the word processing program used to prepare this brief, it contains 13,971 words, exclusive of the matters that may be omitted under Rule 8.204(c)(3).

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