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 AND DR. LAUREN ZEISE, ACTING DIRECTOR,** Respondents and Appellees	Case No. C079260

Sacramento County Superior Court, Case No. 34-2014-800001868
Honorable Christopher Krueger, Judge

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

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(Cal. Rules of Court, Rule 8.208)

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[ ] Interested entities or persons are listed below:

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May 6, 2016

(Date)

TABLE OF CONTENTS

Page

TABLE OF CONTENTS
(continued)

Page

TABLE OF AUTHORITIES

Page

CASES

TABLE OF AUTHORITIES
(continued)

Page

STATUTES

REGULATIONS

TABLE OF AUTHORITIES
(continued)

Page

OTHER AUTHORITIES

INTRODUCTION

On December 5, 2013, the Carcinogen Identification Committee ("CIC"), the "State's qualified experts" for listing carcinogens under "Proposition 65" (Health & Saf. Code, § 25249.5 *et seq.*), voted six to one, with one abstention, to list the chemical, diisononyl phthalate ("DINP"), as a chemical known to the State to cause cancer. The "State's Qualified Expert listing mechanism," applied by the CIC, requires review and consideration of highly technical scientific evidence by preeminent independent scientists with demonstrated expertise in areas relevant to the identification of carcinogenic chemicals. In making its determination, the CIC concluded – and Petitioner American Chemistry Council ("ACC") does not dispute – that DINP causes various types of invasive cancer in animals. Consistent with the CIC's *Guidance Criteria For Identifying Chemicals For Listing as "Known to the State to Cause Cancer* ("Guidance Criteria"), the CIC further considered whether the evidence also showed that the mechanisms by which DINP causes cancer in animals are not relevant to humans. The CIC exercised its scientific judgment and concluded that the evidence before it failed to show that the mechanisms by which DINP causes cancer in animals are not relevant to humans. The CIC therefore determined that DINP met the CIC's Criteria for listing under Proposition 65.

The CIC's decision was not surprising. Virtually all of the government organizations that have evaluated DINP agree that it causes invasive and malignant tumors in animals; no organizations have concluded that DINP absolutely does not cause cancer in humans; the Consumer Product Safety Commission staff report stated that it considered DINP to be "possibly carcinogenic" to humans [Administrative Record ("AR")1631; AR2411]; the Environmental Protection Agency ("EPA") stated that the relevance to humans of certain animal tumors caused by DINP "cannot be

discounted" [AR1632; AR7616]; and multiple papers have concluded that the data are not sufficient to identify all the possible mechanisms by which DINP causes cancer in rodents, and to rule out the possibility that DINP will cause cancer in humans. [See AR60; AR2251 AR9011] Even the single member of the CIC who voted *not to list* DINP noted that this was very much a "judgment call," that his decision not to list went against his "usual nature," and that, with so many tumor types, "it really is very difficult not to list it."

ACC does not dispute that the members of the CIC are the "state's qualified experts" with demonstrated scientific expertise in evaluating carcinogenic chemicals. Nor does ACC deny that all of the materials submitted by ACC and its allies were provided to the CIC for its consideration prior to the CIC's listing decision, and are included in the Administrative Record in this case.[1] Instead, ACC argues that the listing process was invalidated because the Office of Environmental Health Hazard Assessment ("OEHHA") did not summarize the data in the way ACC urged, because the CIC did not have sufficient time to review the material, and because Dr. Mack, the CIC Chair, made a handful of remarks that ACC claims "directed" five other independent CIC scientists (including one member who has served on the CIC as long as Dr. Mack and helped to draft the Guidance Criteria) to relinquish their scientific judgment, ignore the mechanistic data, and utterly disregard their own Criteria.

[1] The Administrative Record contains more than 10,000 pages of relevant documents -- scientific papers, research studies, data, and summaries of studies conducted over several decades, including all comments and documents submitted for the CIC's consideration to OEHHA by ACC and other members of the public -- that were provided to each member of the CIC before the Committee's public meeting to deliberate on the carcinogenicity of DINP.

These arguments are without merit. The record demonstrates that OEHHA summarized for the CIC the most relevant and recent scientific data; ACC and its members exercised multiple opportunities to present scientific data and arguments directly to the CIC, including submitting hundreds of pages of written comment and studies, all of which OEHHA provided to the CIC; four representatives of ACC presented arguments directly to the CIC at the public meeting; and counsel for OEHHA informed the CIC that they did not have to vote on the day of the meeting but could ask for more time and/or information. [AR9461-9486; AR9431:22-9432:3]

The record also demonstrates that the statements by Dr. Mack, which ACC claims "directed" the other CIC members to ignore the mechanistic data, were legally correct, consistent with the Guidance Criteria, and simply expressed Dr. Mack's view of how he exercised his judgment and discretion to weigh the evidence. The record demonstrates that the CIC members considered and understood the mechanistic arguments; at least five members questioned the industry presenters about the mechanistic data; of those five members, four indicated that they understood the arguments, but did not believe that industry had proven that the mechanisms causing cancer in rodents were not relevant to humans; and the fifth indicated that, although he intended to vote against listing, that decision was very much a "judgment call" that went against his "usual nature."

In the end, ACC is simply unhappy with the CIC's conclusion, and would have come to a different conclusion had *it* been tasked with evaluating the data. The fact that a party disagrees with an agency decision, however, is not a basis on which the Court can overrule the decision, particularly where the agency has significant scientific expertise and is evaluating highly technical and complex scientific data. As in *Exxon Mobil Corporation v. Office of Environmental Health Hazard Assessment* (2009)

169 Cal.App.4th 1264, a case upholding OEHHA's decision to list a chemical under Proposition 65: "In 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." The scope of judicial review therefore "is limited, out of deference to the agency's authority and presumed expertise," and the court "may not reweigh the evidence or substitute its judgment for that of the agency." (Rather, the court's inquiry is limited to whether the agency's decision is "arbitrary, capricious, or entirely lacking in evidentiary support." (*Id*. at p. 1277 [citations omitted].)

ACC has failed to show that the CIC's decision is arbitrary and capricious, entirely lacking in evidentiary support, unreasonable, unlawful, or unsupported by the evidence. Ultimately, this Court may not second-guess the CIC's conclusion that DINP causes cancer, and its determination that the current state of the research does not show that the mechanisms by which DINP causes cancer are irrelevant to humans. ACC's petition should be denied.

STATUTORY AND REGULATORY BACKGROUND

Proposition 65 is implemented in a two-step process. In the first step, chemicals are placed on the list of substances "known to the state to cause cancer or reproductive toxicity." (Health & Saf. Code, § 25249.8, subd. (a)[2]; *Exxon*, *supra*, 169 Cal.App.4th at pp. 1291-92.) In the second step, the statute prohibits businesses from exposing individuals to listed chemicals without providing a warning, and from discharging listed chemicals into sources of drinking water (§§ 25649.5, 25649.6), unless the

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

business can establish that the exposure or the discharge to drinking water it causes is below the level that will pose "no significant risk." (§§ 25249.9, 25249.10, subd. (c).)

A. Chemicals are listed based on the "hazard" they pose.

Consistent with the two-step process under Proposition 65, the only consideration for listing is whether the chemical poses a particular "hazard," in this case carcinogenicity, regardless of the level of "risk" the chemical poses to humans based on the exposure that is currently occurring. Risk becomes a factor *after* the chemical is listed, when a business seeks to prove that it is exempt from the warning requirement because the exposure it causes is below the "no significant risk" level. As the court held in *Exxon Mobil*, the issue of the level of exposure and the risk to humans is not "relevant to determining whether [the chemical] should be listed. . . ." (*Exxon Mobil, supra,* 169 Cal.App.4th at pp. 1291-92.). Thus, a chemical that poses a cancer hazard must be listed, regardless of the currently anticipated level of exposure of humans to the chemical and the risk it poses.

B. Chemicals must be listed based on evidence of carcinogenicity in animals

It is no longer open to dispute that chemicals must be listed under Proposition 65 even if they are identified as causing cancer or reproductive toxicity solely on the basis of animal studies. In 1989, this Court rejected the State's argument that "chemicals known to the state to cause cancer or reproductive toxicity" refers only to those "known to the state to cause cancer or reproductive toxicity *in humans*." The Court stated that "[n]o such limitation is expressed in the Act" (*AFL-CIO v. Deukmejian* (1989) 212 Cal.App.3d 425, 435), and held that the "Act applies to those chemicals which respected scientific agencies have already determined cause cancer

or reproductive toxicity in humans *or animals*." (*Id*., at p. 441 (emphasis added).) As the Court explained, it is unethical to test humans, and, because of the long latency period of human cancers, waiting for epidemiological (human) studies will not adequately protect humans from the risk of cancer. Thus, the principle of extrapolating from evidence 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, n.7 [citation omitted]; see also *Western Crop Protection Association v. Davis* (2004) 80 Cal.App.4th 741, 749 ["'chemicals known to the state to cause cancer' includes chemicals . . . known to be carcinogenic as to animals only . . .]; *Baxter Healthcare Corp. v. Denton* (2004) 120 Cal.App.4th 333, 345 ["The [Proposition 65] list must include not only those chemicals that are known to cause cancer in humans, but also those that are known to cause cancer in experimental animals"].)

C. Mechanisms For Listing Chemicals Under Proposition 65

There are four independent mechanisms for listing chemicals under Proposition 65. Three of the mechanisms are what might be called "streamlined"; they rely on work performed by other entities. Thus, OEHHA must list a chemical as causing cancer: (1) if the chemical is identified by reference in California Labor Code sections 6382(b)(1) or 6382(d) (§ 25249.8, subd. (a)); (2) if a body considered to be authoritative by the state's qualified experts "has formally identified [the chemical] as causing cancer" (*id.,* subd. (b)); *or* (3) if a state or federal agency has formally required the chemical to be "labeled or identified as causing cancer." (*Ibid.*)

The fourth mechanism requires review by a group of independent scientists known as the "state's qualified experts" ("State's Qualified Expert listing mechanism"). OEHHA must 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 . . . ." (§ 25249.8, subd. (b).)

D. Listing Carcinogens by the State's Qualified Expert Listing Mechanism

At issue in this case is a decision made pursuant to the State's Qualified Expert listing mechanism. The state's qualified experts for purposes of identifying carcinogens are the members of the Carcinogen Identification Committee ("CIC"). (Cal. Code Regs., tit. 27 ("27 CCR"), § 25302, subd. (a).) The CIC is made up of independent experts with doctoral degrees and research experience in epidemiology, oncology, pathology, medicine, public health, statistics, biology, toxicology, and related fields, and with demonstrated expertise "in the conduct of advanced scientific work of relevance to the identification of carcinogenic chemicals using generally accepted and scientifically valid principles and methodologies." (*Id.*, subds. (b)(1)(i), (ii)); see also Clerk's Transcript ("CT")75-76 [summarizing qualifications of CIC members].) Members of the CIC bring their own scientific background, experience and expertise to the task of assessing the scientific materials. The Governor appoints a Chair of the CIC, who calls and presides over meetings, designates an Executive Secretary, and designates subcommittees as appropriate. (27CCR, § 25302, subd. (c).) Other than these administrative tasks, the Chair has no special authority that differs from that of the other CIC members.

E. The CIC Guidance Criteria

The CIC conducts its review according to Guidance Criteria that it revised in 2001.[3] [AR8889-8893] The Criteria state that the CIC shall use a "weight-of-evidence" approach to evaluate the body of information available for a given chemical, including "all evidence bearing on the issue of carcinogenicity shown through scientifically valid testing according to generally accepted principles" of scientific inquiry. [AR8889 (1C)]

Unlike the mandatory rules and regulations in the case law cited by ACC (ACC Opening Brief ("ACC Brief") at 44-46), the Guidance Criteria are similar to general statements of policy issued by an agency to advise the public prospectively as to how the agency intends to exercise its discretion,[4] and are not intended to be binding regulations.[5] Thus, the Guidance Criteria make clear they are not intended to provide a rigid roadmap that must be followed slavishly. Rather, the document states that "[t]hese criteria are intended to give the CIC maximal flexibility in

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[3] The Court denied ACC's request for judicial notice of the transcript of the hearing at which the CIC adopted the Criteria, and related documents. (March 3, 2016.) The discussion at pages 37 to 41 of ACC's Opening Brief ("ACC Brief") is therefore beyond the scope of the evidence in this case and should not be considered by the Court.

[4] Since listings under Proposition 65 are not subject to the Administrative Procedure Act ("APA") (§ 25249.8, subd. (e)), the Guidance Criteria are similarly not subject to the APA.

[5] See *Brock v. Cathedral Bluffs Shale Oil Co*. (1986) 796 F.2d 533, 537, 538 [document is a general policy where it characterizes itself to be used "as guidance" in making individual decisions, and when criteria are introduced by terms such as "as a general rule" or "ordinarily"]; *Mada-Luna v. Fitzpatrick* (1987) 813 F.2d 1006, 1013 [document that provides guidance, while preserving flexibility and discretion to make individualized determination is general statement of policy]; *Modesto City Schools v. Education Audits Appeal Panel* (2004) 123 Cal.App.4th 1365, 1382 [audit guide was not a binding regulation because auditor has discretion to follow alternative procedures].

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 judgement available at the time." [AR8889 (1B)] The Criteria emphasize that they require "scientific judgements 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." [*Id*. (1E)] The CIC members must therefore weigh the evidence as a whole and exercise their scientific judgment and expertise in making a listing decision.

At issue here is Criterion 1D, which incorporates the generally-accepted scientific assumption that a chemical that causes cancer in animals will cause cancer in humans. (See *AFL-CIO, supra,* 212 Cal.App.3d at p. 438, n.7.) Criterion 1D states that the CIC will "*normally* identify that chemical for listing" under Proposition 65 "if the weight of scientific evidence clearly shows that a certain chemical. . . causes invasive cancer in animals (*unless the mechanism of action has been shown not to be relevant to humans*)." [AR008889 (emphasis added).] As discussed in more detail below, a "mechanism of action" that operates in animals is not relevant to humans when the biological processes by which the chemical causes cancer in animals (the chemical's mechanisms of cancer causation) have been shown not to occur in humans. Thus, in order to defeat the generally accepted toxicological assumption that animal data are relevant to humans, the party opposing the listing must prove two things: First, it must prove the mechanism by which the chemical causes cancer in animals. A hypothesized mechanism is just that – a hypothesis – and does not rule out the possibility that other mechanisms may be causing the cancer. Second, it must prove that the mechanism is not relevant to humans.

There are well-recognized limitations to relying on mechanism of action hypotheses in assessing chemicals. "Carcinogens . . . can act

through multiple mechanisms to induce cancer and other adverse health outcomes," and the "possible contribution of alternative mechanisms must be considered before concluding that tumors observed in experimental animals are not relevant to humans." (Smith, MT et al., *Key Characteristics of Carcinogens as a Basis for Organizing Data on Mechanisms of Carcinogenesis*, Environmental Health Perspectives, (Advance Publication Nov. 24, 2015) at pp. 20, 22-23, http://ehp.niehs.nih.gov/wp-content/uploads/advpub/2015/11/ehp.1509912.acco.pdf (as of May 3, 2016).) Further, some mechanistic assessments are based on "untested or incomplete mechanistic hypotheses," and problems arise when researchers give insufficient consideration to "the possibility that more than one mechanism might be operating." (Cogliano, et al., *The Science and Practice of Carcinogen Identification and Evaluation* (Sept. 2004) 112 Envtl. Health Persp. No. 13, 1269, 1271, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1247515/ (as of May 3, 2016).)

Consistent with these limitations, 1D does not state, as ACC represents, that a chemical that causes cancer in animals "*will not be listed*," if the mechanism of action has been shown not to be relevant to humans. (ACC Brief at 10 [emphasis added].) Rather, if it is shown that a particular mechanism operating in animals is not relevant to humans, the Criteria state that the "normal" presumption in favor of listing the chemical does not apply. The CIC must, however, consider the evidence as a whole, and decide whether or not it is still appropriate to extrapolate from animals to humans and to list the chemical based on the weight of the evidence.

STATEMENT OF FACTS

A. Data collection and public comment

The CIC's review of DINP began in 2009, when OEHHA asked it to rank a set of chemicals for review. ACC and industry members submitted over 200 pages of comments, arguing that the CIC should rank DINP as "no" or "low" priority because of evidence that the mechanism of carcinogenesis does not operate in humans. [See AR229-476] The CIC was not convinced by these arguments. On May 29, 2009, it voted to rank DINP as a "high priority" chemical for its review. [AR661-662]

On October 16, 2009, OEHHA issued a Notice to Interested Parties seeking relevant information on the carcinogenicity of DINP. The public comment period lasted for sixty days. [AR661-62.] OEHHA "reviewed and considered those submissions" [AR1567] and prepared a 77 page Hazard Identification Document ("HID"), entitled "*Evidence on the Carcinogenicity of Diisononyl Phthalate (DINP)*." [AR1565-1646] The HID included what OEHHA considered to be the most current and relevant research on the carcinogenicity of DINP, including the most recent evidence on the *hypotheses* about the mechanisms of action by which DINP operates. The HID "was not intended to be a "comprehensive document citing every single study . . ." but rather, tried to "look at new more recent literature and thinking on those hypotheses. . . ." [AR9460:8-13]

At the time that the HID was prepared, there were no epidemiological (human) studies of the carcinogenicity of DINP, which is true for most chemicals. (See *AFL-CIO, supra*, 212 Cal.App.3d at p. 438, n.7) DINP, however, had been tested in twelve dietary carcinogenicity studies on laboratory animals. [AR001580] The HID described and discussed all

twelve studies [AR1580-1594; AR1632-1634], and OEHHA provided the actual studies to the CIC. [See, e.g., AR001821-2000; AR3217-3228; AR3311-6601; AR6603-6666] No known animal carcinogenicity studies were omitted. The HID also discussed or referenced a total of 114 documents, which were included in the supporting documents provided to the CIC, together with the HID. [AR001647-8894] Among the materials referenced in the HID are at least 32 documents provided and/or referenced by ACC and others in response to OEHHA's 2009 Notice to Interested Parties. [CT123-24; 145]

Summarizing the twelve animal carcinogenicity studies, the HID noted that three different types of cancers were seen at statistically significant levels – liver tumors (hepatocellular), mononuclear cell leukemia ("MNCL"), and kidney tumors (renal tubular cell) – and that a number of additional rare or uncommon tumors were seen, but not at statistically significant levels.[6] [AR1580-94; AR1632-34]

The HID pointed out that the "mechanisms by which DINP induces tumors *are not known*; however several studies provide information on a number of possible mechanisms of action" [AR1617 (emphasis added)], including activation of peroxisome proliferator activated receptors ("PPAR") [AR1618-1626]; activation of CAR and PXR[7] [AR1626]; effects on steroidogenesis and androgen-responsive tissues [AR1627-28]; tumor

[6] The rare or uncommon tumors were renal transitional cell carcinoma, pancreatic acinar cell carcinoma, testicular interstitial (Leydig) cell carcinoma, and uterine adenocarcinoma. [AR1571-72]

[7] Constitutive androstane receptor and pregnane X receptor

necrosis factor-alpha induction [AR1628-29]; and alpha2u-globulin nephropathy. [AR1629-31]

The HID devoted thirteen pages to discussing these hypothetical mechanisms of action, including eight pages on the PPAR mechanism [AR1618-26] and the publication relied on by ACC (Klaunig et al. (2003)), which hypothesized that PPAR activation was the mechanism of action that led to liver tumors in rodents, and that PPAR activation is not relevant to humans. [AR1620] The HID then discussed the later studies by Ito et al. (2007) and Yang et al. (2007), which determined that a closely related chemical, di(2ethylhexyl)phthalate ("DEHP"), induced liver tumors in rodents *even when the PPAR mechanism was known not to be operating*. [AR1621] The new evidence disproved Klaunig's hypothesis that PPAR activation is the only mechanism of action inducing liver tumors in rodents. These newer studies caused the World Health Organization's International Agency for Research on Cancer ("IARC") in 2013 to change the designation of DEHP from Group 3 ("not classifiable as to its carcinogenicity in humans") to Group 2B ("possibly carcinogenic to humans"). IARC stated that the relevance to humans of mechanisms of carcinogenesis in rodents "cannot be ruled out." [AR 1621]

The HID also addressed ACC's mechanistic hypothesis that renal (kidney) tubular cell cancers are caused by the mechanism of alpha2u-globulin nephropathy, which is not relevant to humans, and explained that the mechanistic evidence for DINP did not meet three of the IARC criteria for determining whether alpha2u-globulin nephropathy is the mechanism of action by which a chemical causes kidney tumors. [AR 1629-30] Finally, the HID compared DINP to two similar chemicals, DEHP and butyl benzyl

phthalate ("BBP") [AR1612-14], noting that all three share common biological activities [AR1616] and cause similar tumors.[8] [AR1614]

OEHHA provided the 77-page HID to the CIC on October 7, 2013, along with supporting documents, including the papers discussed in the HID. [AR1541-64] At the same time, OEHHA released the HID to the public for a 45-day comment period. [AR001539-40] At the conclusion of the comment period, OEHHA provided all public comments and accompanying documents, to the CIC on November 20, 2013. [AR8895-8902] By providing the CIC with *all* of the public comments and documents received, OEHHA ensured that the CIC was able to consider all arguments for and against listing the chemical, including those submitted by ACC.

B. The CIC meeting and vote to list DINP

1. OEHHA summarizes the data; Industry representatives present their arguments to the CIC.

The CIC met on December 5, 2013. At the start of the meeting, counsel for OEHHA reminded the CIC 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." [AR9430:21-25]. Counsel also informed the CIC that it was *not* obligated to "make a decision today," and could ask the

[8] DINP, DEHP, and BBP belong to a family of chemicals known as phthalates. All three cause pancreatic tumors and MNCL in rats, and DINP and DEHP cause liver tumors in rats and mice, and testicular tumors in rats. [AR1614]

agency "to get you more information." [AR9431:22-9432:3] The CIC then heard presentations from OEHHA scientists concerning the carcinogenicity of DINP. [AR9436-9458] Dr. Rajpal Tomar, a toxicologist, pointed out some of the strengths of the data: that the three significant cancers were strongly "dose dependent" [AR9457:14-21; AR9436:17; AR9437:13-14], i.e., the number of cancers increased with increasing doses of the chemical, a factor considered in the Guidance Criteria [AR8891 (2(A)(ii)(e)(2))]; that a number of the cancers observed in the studies were rare or uncommon [AR9436:20-25; AR9440:19-20; AR9457:22-9458:2]; that the pharmacokinetics of DINP – metabolism, absorption, distribution, and excretion – are similar in humans and animals [AR9444:14-21]; and that there is a similarity between DINP and two other phthalates, DEHP and BBP, and that all three induce pancreatic tumors and MNCL in rats, and DINP and DEHP cause liver tumors in rats and mice, and testicular tumors in rats. [AR9449:1-17]

Dr. Tomar devoted a significant portion of his time to discussing various possible mechanisms of action of DINP [AR9450:15-9455:5], including induction of tumor necrosis factor-alpha [AR9451:13-9452:1]; decreased gap junction intercellular communication [AR9542:2-8]; activation of CAR and PXR [AR9452:9-15]; activation of PPAR [AR9452:17-9453:19]; and alpha2u-globulin nephropathy. [AR9453:21-9455:4] In addition, Dr. Tomar noted that, although the tests conducted to date did not show that DINP was genotoxic, DINP had not been tested for "oxidated DNA damage" in more sensitive tests, which could detect genotoxicity. [AR9450:18-22]

Dr. Tomar discussed in particular detail the two hypothetical mechanisms of action that were at the center of ACC's arguments. As

noted above, industry argued that activation of PPAR causes liver tumors in rodents, that alpha2u-globulin nephropathy causes renal tubular cell tumors in rodents, and that neither mechanism operates in humans. Dr. Tomar noted that recent evidence proved that the closely-related chemical, DEHP, induces liver tumors in mice *without activation of PPAR*, thus demonstrating that there are other possible mechanisms causing the liver tumors. [AR9452:23-9453:13]

Dr. Tomar also stated that alpha2u-globulin could not be assumed to be the mechanism by which DINP caused renal tubular cell cancers in rodents, because DINP did not meet the IARC criteria for causing cancer according to the alpha2u-globulin mechanism. [AR9453:25-9455:4][9]

At the conclusion of OEHHA's scientific presentation, the CIC heard from four representatives of industry, who reiterated the highly technical scientific arguments they had raised in written comments. They argued that the MNCL cancers are of "questionable significance" because the studies were done in Fisher 344 rats, which are highly susceptible to these leukemias [AR9481:3-9482:12]; that the kidney tumors were not relevant because alpha2u-globulin nephropathy met the IARC criteria of being the assumed mechanism of action for renal tubular cell tumors, and does not operate in humans [AR9475:4-9478:19]; and that the liver tumors were not relevant because PPAR activation was the assumed mechanism that caused liver tumors in rodents and does not operate in humans. [AR9468:1-9474:16] Industry did not argue that the mechanisms that cause the four

[9] According to IARC, a chemical is only assumed to cause renal tubular cell cancer by the alpha2u-globulin mechanism if it meets certain criteria (causing hyaline droplets, kidney changes, etc.). DINP does not meet criteria 2, 4, and 5. [AR1630]

rare and uncommon tumors were not relevant to humans. Rather they argued that three of these tumors were not rare or uncommon, but rather were within the normal levels for historical controls. [AR9479:23-9481:1]

2. The CIC deliberates and votes to list DINP.

At the conclusion of all presentations, the CIC members questioned the presenters extensively and began their discussion of the data. A number of the CIC members agreed that the animal evidence was unusually strong. Dr. Landolph, one of the two lead CIC reviewers for DINP [AR9429:1-3], who had studied the material extensively [AR9499:7-8], and who was familiar with many of the scientific issues [AR9509:6-17], summed up the evidence as he saw it: First, he noted the strong positive data – four tumor sites – and stated that it would be "intellectually dishonest" to "throw that positive data out the window." Second, he noted that a lot of the data "is very dose responsive," and for much of it, "the trends are statistically significant. . . So I respect that data." [AR9509:19-9510:4] Dr. Landolph concluded that it was easy for him to state that "this stuff causes cancer in rodents and rats and mice." [AR9510:12-14]

Dr. Mack noted that he was struck by the number of different cancers occurring in unusual circumstances. [AR9520:18-21]; Dr. Dairkee stated that "tumors in animals of such a vary [sic] diverse kind also concern me." [AR9519:5-6] Dr. Bush stated that it was "clear" that DINP causes tumors in animals. [AR9520:5-6]

Dr. Zhang rejected industry's argument that the CIC should ignore the MNCL tumors. She commented that there were similar results from two different studies in two different laboratories, and the studies showed a dose

response. The MNCL studies were therefore a good model for determining carcinogenicity, despite high variability in the historical control data, and she "totally agreed[d] with Dr. Landolph" that DINP is an animal carcinogen. [AR9513:23-9514:8]

The Members discussed ACC's mechanistic arguments in great detail and, with one exception, expressed reservations about those arguments. Dr. Landolph asked a series of questions about other possible mechanisms of action in addition to the PPAR activation and alpha2u-globulin mechanisms. (See Landolph [AR 9488:5-8, 16-21 (asking if there were any studies showing oxidative stress and certain mutations associated with the liver tumors); AR9487:16-19; AR9499:20-24 (suggesting that tumors might be caused by 8-hydroxydeoxyguanosine from increased cellular peroxide production); AR9510:4-9 (noting that it was still an open question whether DINP is generating oxygen radicals through hydrogen peroxide leakage)].) In conclusion, Dr. Landolph noted that he was simply not convinced by ACC's arguments. He stated that, while he "struggle[s] with the issue of the relevance to human tumors," and respects the industry comments that DINP is acting by the mechanisms of PPAR activation and alpha2u-globulin nephropathy, which are not relevant to humans, he also respects the comments made by OEHHA scientists, "that maybe this issue is not quite so settled is [sic] that these are acting by PPAR mechanisms or by the hyaline droplet [alpha2u-globulin] mechanism. There's still a little bit of wiggle-room there." [AR9512:21-9513:5]

Dr. Thomas summarized his view. He repeated the standard in the guidelines: "As I read the guidelines that says that [a chemical will normally be listed] if it causes invasive cancer in animals parenthesis, unless the mechanism of action has been shown not to be relevant in

humans." He then referred to the industry argument that the "PPAR alpha mechanism is not relevant in humans. . . ," and noted the counterargument that PPAR alpha is "not the only possible mechanism, that there are others about which we are simply unsure. And so the possibility that it's relevant still stands. . ." [AR9522:13-23.][10]

Dr. Dairkee stated that, as a cell biologist, she was very concerned that nuclear receptors are activated by DINP, indicating it was possible that the mechanism of carcinogenesis was through endocrine disruption and would not necessarily show up in the animal studies because the tumors may be too slow growing to be observed in animals, but "they may have human relevance, that is my major concern. The nuclear receptor activation is something that really concerns me." [AR9518:22-9519:5]

Dr. Mack stated that he "understand[s] completely" the mechanistic arguments made by the industry, and would not be surprised if, *in the future*, they were able to prove the argument that the tumors were caused by mechanisms not relevant to humans, but that, based on the state of the present evidence, assuming that the mechanisms are not relevant to humans "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

[10] ACC characterizes Dr. Thomas's statement as "pointing out the discrepancy" between the Guidance Criteria and Dr. Mack's statement that "in the absence of epidemiological information, we're stuck making decisions about animal data." (ACC Brief at 26-27) In fact, Dr. Thomas was not pointing out any discrepancy or error in a statement by Dr. Mack. He was merely reciting his understanding of the Guidance Criteria and indicating that he did not believe that that ACC had proven that the mechanism that causes cancer in rodents is not relevant to humans.

are invasive and truly malignant . . . . I know that that's the case." [AR9520:21-9521:7]

The only CIC member who was convinced by the industry's arguments was Dr. Eastmond, and he was conflicted. He admitted that his normal inclination would be to list DINP, that with this many positive tumor types "it really is very difficult not to list it"; not listing "goes against my usual nature"; but that, in the end, it was really a "judgment call," and he saw enough weaknesses that he was not convinced to list. [AR9517:20, AR9518:10-19]

When reviewed as a whole, the transcript of the CIC meeting demonstrates the following: The animal evidence is particularly strong; studies showed that DINP caused three different statistically significantly increased cancers with a strong dose response, and several rare or uncommon cancers in animals. ACC offered mechanistic arguments about only two of the significant cancers (liver and renal tubular cell), but did not argue that the mechanisms of action for the third significant cancer (MNCL) or the rare or uncommon cancers were not relevant to humans. During the discussion, five of the CIC members[11] indicated that they did not agree with industry's arguments that the animal data were flawed and that the mechanisms of action were shown not to be relevant to humans; instead, they believed that the animal evidence was unusually strong, and they believed that there could be other mechanisms of action in operation that

[11] Landolph [AR9509:18-9510:14; 9512:22-9513:5]; Dairkee [AR9518:22-9519:6]; Mack [AR9520:16-9521:7]; Zhang [AR9513:15-9514:8]; Thomas [AR9522:13-23]

were relevant to humans.[12] Only Dr. Eastmond indicated that he would vote not to list and even he admitted that, because the animal evidence was so strong, it was "really difficult not to list it," and a decision not to list was a "judgment call."

Although they had been told that they could ask for more information and/or more time, the CIC requested neither. At the conclusion of the presentations and discussion on DINP, Dr. Mack called for a vote of the members. Six members voted to identify DINP as known to the state to cause cancer, one voted against, and one abstained. [AR9526:14-9527:4]

Following the CIC's vote, OEHHA added DINP to the Proposition 65 list on December 20, 2013. (27CCR, § 27001.)

C. The trial court's decision denying ACC's Petition

On June 9, 2014, ACC filed suit against OEHHA, challenging the listing of DINP. [CT1-26] After full briefing and a hearing, the trial court issued its ruling, denying ACC's petition for writ of mandate. The court noted that ACC would be entitled to a writ if it "could prove the CIC's decision was based on an incorrect interpretation of the law. Petitioner fails to make this showing."[13] [CT180] The decision is summarized below.

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[12] Contrary to ACC's representation that the transcript demonstrates that several CIC members "initially pushed back against Chairman Mack's erroneous interpretation of the guidance criteria" (ACC Brief at 49), the transcript makes clear that at least four members indicated that they did not believe that ACC had met the standard set out in Criterion 1D.

[13] In its brief, ACC misquotes the Court as stating that ACC was "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." (ACC Brief at 43.) This "quote" conflates two entirely different statements by the trial court. First, the court was repeating ACC's argument that Dr. Mack incorrectly instructed the CIC on

(continued…)

Rejecting ACC's argument that the HID was incomplete, the court pointed out that the HID discussed a number of the studies relied on by ACC to argue that the rodent cancers were not relevant to humans [CT179, n. 12]; that, in addition to the HID, OEHHA submitted to the CIC "voluminous additional materials regarding DINP's carcinogenicity," including comments by ACC's members reviewing studies that it claimed showed that the rodent studies were not relevant to humans; and that ACC and several of its members spoke at length at the public meeting, arguing against the listing. [CT174] In response to ACC's claim that the CIC did not have time to review this voluminous information, the court stated that "[a]bsent evidence to the contrary, the court will assume the CIC reviewed sufficient evidence to come to an informed decision. (Evid. Code, § 664.)" [CT180, n.13]

Next, the court rejected ACC's assertion that the studies categorically demonstrated that the mechanisms that cause cancer in rodents, such as PPAR, do not operate in humans, noting that, "some of the studies Petitioner cites are less categorical than it suggests. For example, the ILSA [sic] Health and Environmental Sciences Institute concluded" that the carcinogenic potential of PPARs "cannot be ruled out under extreme conditions of exposure." [CT174, n.6]

Further, the court stated that "it is clear the CIC considered the evidence Petitioner accuses it of disregarding" [CT179], noting that the CIC members discussed the issue of mechanistic data and human relevance,

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(…continued)
the law concerning mechanistic evidence. Second, the court was describing the basis for a writ – if ACC proved that the CIC had ignored the law. The court never suggested that a misstatement of the standard by Dr. Mack would be sufficient to invalidate the entire proceeding. [CT180]

and stated that they understood the points that were made, and "considered and wrestled with" the evidence. [CT180]

Finally, the court rejected ACC's argument that Dr. Mack incorrectly stated the Guidance Criteria and thereby invalidated the entire CIC review process. The court carefully parsed through, not just isolated statements taken out of context, but the entire passages from Dr. Mack's discussion, in the context in which they were stated. The court held that, viewed in context, Dr. Mack's statements demonstrated that he understood the mechanistic arguments, acknowledged that, in the future, there might be evidence to prove the arguments, but exercised his judgment in declining to make that assumption "right now" in light of the number of "invasive and truly malignant" cancers "which pop up in unusual circumstances" [CT182], and that Dr. Mack's statements could be interpreted for the correct and unremarkable proposition that, in the absence of human studies, the CIC must rely on animal studies. [CT183-84]

After careful analysis, the court concluded that ACC did not "meet its burden of establishing the CIC failed to follow its own criteria in deciding to list DINP or that its decision was otherwise arbitrary and capricious." The court denied the petition. [CT184]

STANDARD OF REVIEW

In seeking to overturn OEHHA's listing of DINP, it is ACC's burden to show that OEHHA's action is "inconsistent with the governing statute, section 25249.8." (See *Western Crop*, *supra*, 80 Cal.App. 4th at p. 757.) In particular, where the courts are reviewing OEHHA's scientific analysis that a chemical meets the standard for listing under Proposition 65, the standard is particularly deferential: "In 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, supra,* 169 Cal.App.4th at p. 1277 [citations omitted].) The scope of judicial review "is limited, out of deference to the agency's authority and presumed expertise," and the court "may not reweigh the evidence or substitute its judgment for that of the agency." Rather, the court's inquiry is limited to whether the agency's decision is "arbitrary, capricious, or entirely lacking in evidentiary support." As long as the agency has "adequately considered all relevant factors, and has demonstrated a rational connection between those factors, the choice made, and the purposes of the enabling statute," its decision will be upheld. (*Ibid.* [internal quotations and citations omitted].)

Consistent with all of the above, a court may not substitute its judgment for that of the agency. "[I]f reasonable minds may disagree as to the wisdom of the [agency's] action, its determination must be upheld." (*Alejo v. Torlakson* (2013) 212 Cal.App.4th 768, 780 [citations omitted].

Further, in reviewing petitions for writ of mandate, courts are bound by Evidence Code section 664, which establishes the presumption that an agency has regularly performed its official duty. In the absence of contrary evidence, the court must presume that an official duty has been regularly performed (*City of Sacramento v. State Water Resources Control Bd.* (1992) 2 Cal.App.4th 960, 976), including assuming that the agency has found the "necessary facts, based on the standards as prescribed" by their applicable guidelines. (*City and County of San Francisco v. Superior Court of San Francisco* (1959) 53 Cal.2d 236, 251; see also *McAllister v. California Coastal Comm'n* (2008) 169 Cal.App.4th 912, 931 [assuming that Coastal Commission understood and applied policies and standards of the Coastal Act].) This presumption is particularly strong where the findings were made by "experienced administrative bodies . . . after a full and formal hearing, especially in cases involving technical and scientific evidence." (*Fukuda v. City of Angels* (1999) 20 Cal.4th 805, 812.)

ARGUMENT

This case involves review of a detailed, complex, and technical scientific record, and the exercise of scientific judgment in the application of a provision of the CIC's Guidance Criteria, designed to guide members of the CIC in making the scientific and highly technical evaluation of chemical carcinogenicity delegated to the Committee pursuant to the statute. Neither OEHHA nor the CIC acted arbitrarily and capriciously or abused their discretion in this matter. OEHHA included a fair representation of ACC's arguments and supporting documents in the initial HID it prepared for the CIC's consideration of DINP. OEHHA then provided the CIC with all additional documents, studies and detailed comments submitted by ACC and other members of the public in response to the HID. After considering all of the evidence, listening to public presentations and comments, asking informed and pointed questions, and publicly deliberating the implications of the evidence before them, six of the CIC's eight independent scientists concluded that: (1) DINP causes several types of invasive cancers in laboratory animals, and (2) the evidence was not sufficient to show that all of the possible mechanisms underlying these various types of cancer are not relevant to humans. Consistent with the requirements of Proposition 65, OEHHA added DINP to the list of chemicals known to the state to cause cancer.

As discussed below, the CIC's decision was not arbitrary and capricious. There is ample evidence in the record that the CIC applied its Guidance Criteria; there is evidentiary support for the CIC's decision; and there undoubtedly exists a rational connection between the relevant factors, the choice made, and the purpose of the statute. (See *Exxon Mobil*, *supra*, 169 Cal.App.4th at p. 1277.)

I. THE INDEPENDENT CIC SCIENTISTS DID NOT ABUSE THEIR DISCRETION IN VOTING TO LIST DINP

In asking this Court to overturn the listing of DINP, ACC focuses on a few statements made by the Committee Chair, Dr. Mack, taken out of context, and argues that these isolated sentences invalidate the entire listing process because Dr. Mack "directed" the CIC to disregard the Criteria. The statements, however, when read in context, are absolutely consistent with the CIC Guidance Criteria. Further, nothing in the record demonstrates that the five other independent CIC members who made, what Dr. Eastmond called, the "judgment call" to list DINP, relinquished their independent judgment and ignored their own Guidance Criteria, based on Dr. Mack's comments. Such a supposition is not only unsupported speculation; it is directly contrary to the record.

1. The CIC members agreed that the animal data were strong

There appears to be absolutely no dispute that DINP causes cancer in animals. The CIC members commented, in particular, on the strength of the animal evidence. (See, e.g., Landolph [AR9509:18-9510:14]; Mack [AR9520:17-21].) While industry's representatives questioned the scientific evidence about certain of the cancers, arguing, for example, that the MNCL cancers should be disregarded because of the high variability in the historical controls, CIC members specifically rejected these arguments. (Zhang [AR9513:23-9514:8].)

2. The CIC members considered the mechanistic arguments.

There is also no dispute that the CIC members received extensive written information about the mechanistic arguments. As noted above, the HID devoted thirteen pages to a discussion of the various hypotheses regarding the mechanisms by which DINP may cause cancer in animals

[AR1617-31], including eight pages on a discussion of the PPAR hypothesis and the publication by Klaunig et al. (2003) [AR1618-26], and three pages on the alpha2u-globulin hypothesis. [AR1629-31] In addition the CIC received hundreds of pages of studies and written argument from industry concerning their mechanistic arguments. [See AR9612-10463]

At the meeting, the CIC also heard from four representatives of industry who argued that the data showed that the PPAR and alpha2u-globulin mechanisms, which are hypothesized to cause liver cancer and renal tubular cell cancer, respectively, in rodents, do not operate in humans. [AR9466-9486] The CIC members questioned the representatives in detail about these arguments, and stated repeatedly that they understood the arguments and were wrestling with them, and that (with one exception), they simply were not convinced that the industry had shown that the mechanisms that caused cancer in animals were not relevant to humans.

In particular, Dr. Landolph, stated that the issue of whether cancer in animals is caused by the PPAR mechanism or some other mechanism, is not settled, and this gives the committee "a little bit of wiggle room." [AR9513:1-5] Dr. Dairkee, stated that, as a cell biologist, she was particularly concerned with the activation of nuclear receptors, which indicated that DINP might cause endocrine disruption as the mechanism for carcinogenesis. [AR9518:21-9519:5] Dr. Thomas stated that, while he understood the argument made by industry, the PPAR mechanism was "not the only possible mechanism," and "there are others about which we are simply unsure. And so the possibility that it's relevant still stands. . . ." [AR9522:13-23] Dr. Mack stated that he understood "completely the points . . . about the mechanism issue," but that he could not assume that

the mechanisms that cause cancer in animals are not pertinent in humans. [AR9520:18-9521:7]

Among all the Committee members, only Dr. Eastmond indicated that he was convinced not to list by the ACC's arguments, and even he stated that he was conflicted about his decision, that it was very much a "judgment call"; "usually I would list this because there are just so many tumor types that are positive"; "it really is difficult not to list it"; and a vote not to list "goes against my usual nature." [AR9517:20; AR9518:10-19]

After reviewing the record and listening to multiple presentations urging particular interpretations of that record, a majority of the scientists on the Committee were not convinced that it had been shown that the known mechanisms of action for each of the cancers caused in animals by exposure to DINP are not relevant to humans. Thus, the majority voted to identify DINP for listing. (AR9526:14-9527:4.) While ACC's experts may disagree with the majority vote, that vote was not arbitrary and capricious, was supported by the scientific evidence in the record, and was consistent with the limitations of the mechanistic arguments expressed by prominent scientists, who have recognized that cancers act through multiple mechanisms and scientists must consider that more than one mechanism may be operating before they determine that the mechanisms are not relevant to humans. (*See, e.g.*, Smith, M.T., et al., *supra*, at pp. 22-23; Cogliano, et al., *supra*, at p. 1271.)

3. Dr. Mack's statements were consistent with the Guidance Criteria and did not invalidate the listing process.

The only "evidence" that ACC points to in its effort to undermine the listing and the required presumption of regularity of agency action (Evid.

Code, § 664), are a handful of statements made by Dr. Mack, taken out of context. As discussed below, each of the statements, viewed in context, is correct as a matter of law and consistent with the Guidance Criteria.

> Dr. Mack: "So the question to me is does this stuff cause cancer? And I have to rely upon the dose response relationships." [AR9520:16-17] (ACC Brief at 26)

ACC argues that, in making this statement, Dr. Mack was dismissing the question of human relevance. This is incorrect. Dr. Mack was responding to a question by CIC member Dr. Bush about whether the high doses that induced cancer in animals were relevant to humans, who are exposed at much lower levels. [AR9519:16-9520:7] Dr. Mack correctly explained that, for purposes of listing a chemical under Proposition 65, the anticipated level of the exposure to humans is not a relevant question. Dr. Mack's statement is a correct statement of the law under Proposition 65. (See *Exxon Mobil*, *supra,* 169 Cal.App.4th at pp. 1291-92 [level of exposure to humans is not "relevant to determining whether [the chemical] should be listed. . . ."].)

> Dr. Mack: "The 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 epidemiological information, we're stuck making decisions about animal data." [AR9521:17-24] (ACC Brief at 26, 50)

Dr. Mack's statement came after a question from Dr. Zhang about whether the CIC required human data or could list a chemical based on

animal data alone. [AR9521:10-14] Both Dr. Mack and OEHHA counsel responded, "[t]hat's correct" [AR9521:15-16], and Dr. Mack explained that the law requires OEHHA to list chemicals based on evidence in animals, even if there is no epidemiological (human) data. This is, of course, a correct statement of the law. (See *AFL-CIO, supra,* 212 Cal.App.3d at p. 441 ["Act applies to those chemicals which respected scientific agencies have already determined cause cancer or reproductive toxicity in humans *or animals*."]; *Western Crop , supra,* 80 Cal.App.4th at p. 749 [same].) Thus, contrary to ACC's argument, Dr. Mack's statement was consistent with the Guidance Criteria and was absolutely correct.

> Dr. Mack: "Can I make a comment first. 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 [sic] 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 epidemiological data. We have to go solely on the animal data." [AR9522:24-9523:12] (ACC Brief at 27, 47)

> Dr. Mack: "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 epidemiological 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."
[AR9524:13-20] (ACC Brief at 28)

Dr. Mack's statements above are an expression of how he would weigh the evidence and assess the question of relevance to humans, based on his judgment and his expertise. In Dr. Mack's view, where there is strong animal evidence and no epidemiological evidence, data on unproven hypotheses about the mechanisms that cause cancer in animals, such as those presented by the ACC on PPAR activation and alpha2u-globulin nephropathy, are not sufficient to overcome the generally accepted scientific assumption that chemicals that cause cancer in animals will also cause cancer in humans. The fact that another member of the CIC, Dr. Eastmond, weighed the evidence differently and made a "judgment call" against his "usual nature" not to list, does not make Dr. Mack's statement wrong, nor does it invalidate his "judgment call" in deciding to list.

Dr. Mack statement: "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] (ACC Brief at 10, 28, 48)

Dr. Mack was reacting to an incorrect statement of the law and the Guidance Criteria, made by counsel for the ACC. ACC counsel stated, "And the question before the Committee is whether those data are relevant to humans?" [AR9523:22-24]. Dr. Mack responded, "That's not the question."

In fact, Dr. Mack was correct: *It is not the question*. Counsel's statement turned the listing standard on its head, suggesting that, in order to list a chemical, the CIC had to determine that the mechanisms *were relevant* to humans. The exact opposite is true. Pursuant to its Guidance Criteria, and consistent with the law under Proposition 65, the CIC must assume that animal data are relevant to humans and list the chemical based solely on such animal data, unless it is clearly shown that all the mechanisms by which the chemical acts to induce cancers in animals *are not relevant* to humans. In that event, the normal assumption of relevance to humans does not apply, and the CIC must consider the weight of the evidence to determine whether it still believes that the chemical should be listed.[14]

The record therefore demonstrates that Dr. Mack did not "direct[] the CIC to ignore the text of paragraph 1.D of the Guidance Criteria and apply a different standard of his own creation," and did not insist "insist[] that the committee ignore the mechanistic evidence," as ACC asserts. (ACC Brief at 43, 47.) Nor did he deliberately turn the focus away from

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[14] In a footnote, ACC points to a quote by Dr. Mack made later in the meeting on the listing of a different chemical, BBP. "Remember that the authoritative bodies - - other authoritative bodies don't have quite the same mandate we have. . . In other words, they can consider human pertinence, whereas our law doesn't permit us to do that." [AR9600:11-16] ACC argues that the statement confirms that Dr. Mack did not want the CIC to consider human relevance. (ACC Brief at 48, n.9) ACC's citation is highly misleading. Dr. Mack was not talking about Guidance Criteria 1D and the question of whether mechanisms are relevant to humans. He was pointing out that other entities consider *risk* to humans in evaluating chemicals, whereas Proposition 65 requires that a chemical be listed based on its *hazard*, regardless of the risk to humans from current levels of exposure.

mechanistic data, or tell the committee that "the question of human relevance was irrelevant to the listing decision." (*Id*., at 48) Quite to the contrary, he repeatedly indicated that he understood the mechanistic argument [AR9520:21-23], and, in fact, agreed with Dr. Landolph that the Committee had several times made the decision to delist a chemical based on evidence that the mechanism that caused cancer in animals did not exist in humans [AR9522:1-11], but he was simply not convinced, at this point, that the industry had met its burden of proving that all possible mechanisms of carcinogenesis for DINP were not relevant to humans. [AR9520:16-9521:7]

While reasonable minds might disagree over the correctness of Dr. Mack's view and how he weighed the scientific evidence overall, disagreements are not sufficient to render his statement erroneous. He was merely doing exactly what he was expected to do as a scientific expert and member of the CIC – weighing the evidence, considering the criteria, and exercising his scientific judgment.

Finally, even if ACC were correct that Dr. Mack had misstated the Guidance Criteria, which he did not, his statements did not overrule the written Guidance Criteria, which the CIC had before it, and which was referenced and quoted by OEHHA counsel and by members of the CIC. [AR9430:21-25; AR9510:21-9511:1; AR9522:15-17] Dr. Mack had no more authority to "direct[] the committee to apply his criteria, not the published criteria," as ACC asserts (ACC Brief at 48-49), than the Presiding Justice on this Court has the authority to tell the other Justices how to apply the law, and there is no reason to believe that five independent scientists – one of whom had been on the CIC as long as Dr. Mack and had also helped to draft the Guidance Criteria [CT75-76;

AR9511:3-5] – who demonstrated close attention to the mechanistic arguments and, in large part, indicated they were not convinced by them, would relinquish their expertise, their judgment, and their own reading of the standard, simply based on a remark by a sixth member.

The lengthy and highly technical exchanges at the public meeting amply demonstrate that, far from ignoring the human relevance and mechanistic data as ACC accuses, CIC members were intimately familiar with the evidence and fully understood the issues. In the end, a majority of CIC members were not convinced that all of the various cancers caused by DINP in experimental animals have no relevance to humans. Six members voted in favor of identifying DINP as a chemical known to the state to cause cancer, one voted against, and one abstained. (AR9526:14-9527:4.)

Nothing in the record demonstrates that the CIC acted arbitrarily and capriciously in reaching its decision.

II. OEHHA DID NOT ABUSE ITS DISCRETION IN PREPARING THE HAZARD IDENTIFICATION DOCUMENT.

Although the listing of a chemical is not considered a regulation under Proposition 65, and OEHHA need not comply with the APA (§ 25249.8, subd. (e)), the lead agency handles its listings in a manner that incorporates full public access and opportunity to be heard. Here, OEHHA began with a sixty-day "data call-in" period in which it permitted the public to submit information on the proposed listing of DINP. [AR661-63] OEHHA then reviewed that information, along with independent research, and created a 77-page HID which summarized what the OEHHA scientists believed to be the most up to date and relevant information on DINP. OEHHA provided the CIC with the HID, and with the studies referenced in the HID [AR1565-8884], including more than thirty-two documents provided by

industry during the data-call-in period. [CT123-124, 145] OEHHA simultaneously provided the HID to the public for a 45-day comment period. [AR1539-40] At the conclusion of the comment period, OEHHA submitted all public comments to the CIC, including *all* of the evidence and commentary provided by ACC and other interested parties. [AR8895-9339; AR9612-10650] Finally, four of the industry's representatives spoke at length against the listing at the public meeting. [AR9461-86] Thus, it is absolutely undisputed that the CIC received the evidence submitted by ACC, and clearly heard the arguments it made against listing.

Despite the openness of the process, and the multiple opportunities for ACC to provide its input directly to the CIC, ACC now argues that OEHHA did not present a fair view of the science concerning DINP because it did not mention all of the studies submitted by ACC and characterized the evidence differently than ACC would have. At best, ACC's arguments amount to a disagreement among experts over highly technical scientific issues. While ACC is entitled to disagree with OEHHA on the science, it is not entitled to substitute its opinion or that of its scientists for the expert regulatory agency. Nothing in the record demonstrates that OEHHA was arbitrary and capricious in preparing the HID, and ACC had every opportunity to, and did present its opposing views of the science to the CIC.

A. The HID Did Not Omit Key Data

As noted above, the HID is prepared by OEHHA scientists, who have significant expertise and experience in preparing HIDs for review by the CIC. Rather than being a "comprehensive document citing every single study . . ." it is intended to be a summary document, and to include the most current and relevant literature on the chemical. [AR9460:4-13] To the extent interested parties disagree with the HID, or wish to present

additional information to the CIC, they are free to do so, through the public comment process.

1. Primate studies

The HID discussed over 114 studies on DINP, including all twelve of the carcinogenicity studies performed on animals. ACC now complains that the HID did not mention two primate studies, both of which involved a small number of animals, short term exposures to DINP (14 days and 13 weeks), and *which were not designed to elicit cancer*. ACC argues that these studies provide evidence that the hypothesized PPAR activation mechanism assumed to cause liver tumors in rodents does not operate in primates (including humans). Because more recent evidence indicates that PPAR activation is not the only mechanism of liver cancer in rodents (see discussion *supra* at pp. 13, 16), OEHHA determined that the primate studies were not sufficiently relevant to include in the HID. In any event, OEHHA did provide the primate studies to the CIC, along with all of ACC's arguments concerning the studies, thus allowing the CIC members to make their own decision about the relevance of the studies. [AR1409-10; AR1247-54; AR1059-1066]

2. Toxicity reviews by other agencies

In its discussion of reviews by other agencies, the HID noted that DINP has not been classified as to its carcinogenicity by the EPA, the Food and Drug Administration ("FDA"), the National Toxicology Program ("NTP"), the National Institute for Occupational Safety and Health ("NIOSH"), or IARC.[15] [AR1631-32] The HID also discusses toxicity

[15] All of these entities are designated "Authoritative Bodies" under Proposition 65. (27CCR, § 25306, subd. (m).) Had DINP been classified as a carcinogen by any of these Authoritative Bodies, OEHHA would likely have proceeded to consider the chemical for listing pursuant to the

(continued…)

reviews by the Consumer Product Safety Commission ("CPSC"), the Cancer Hazard Assessment Panel ("CHAP") of the CPSC, and the EPA. [AR1631-32]

ACC complains that OEHHA omitted "several" toxicity reviews submitted by ACC, without identifying which reviews were omitted. All reviews submitted by ACC, however, were provided directly to the CIC members for their consideration. [AR8905-9339; AR9612-10650]

ACC also quarrels with the manner in which OEHHA cited to the toxicity reviews, claiming that it "cherry- picked" language. The only example that ACC provides is that the HID omits what ACC claims is a conclusion by the EPA that the alpha-2u-globulin mechanism meets all of the EPA and IARC criteria for being the assumed mechanism of action for the kidney tumors. (ACC Brief at 55)

Contrary to ACC's assertion, the EPA stated that DINP *did not meet* all of the IARC criteria for the alpha2u-globulin mechanism. [AR7587] While the EPA did state that DINP met the three EPA criteria for the alpha2u-globulin mechanism, the HID relied on the IARC criteria, because they are newer and more detailed than the 1991 EPA criteria. [AR 9504:13-14]

The record demonstrates that the HID presented a fair representation of the current state of the science concerning DINP.

(…continued)
Authoritative Body listing mechanism, rather than bringing the chemical to the CIC for review. (See § 25249.8, subd. (b).) Thus, virtually all the chemicals brought to the CIC for *de novo* listing consideration have not been formally identified as carcinogens (as defined in 27CCR, § 25306) by an Authoritative Body at the time they are considered by the CIC.

B. The HID did not mischaracterize data.

1. Liver tumors

The HID devoted eight pages to the discussion of ACC's hypothesis that the PPAR activation mechanism causes liver tumors in rats and is not relevant to humans. [AR1618-26] ACC now argues that the HID ignored the data on this hypothesis and "suggested a much greater degree of uncertainty about the role of [PPAR] in rodent liver tumors than is warranted by the scientific evidence." (ACC Brief at 58.) This argument is contrary to the record. First, the HID details the findings of each known animal study regarding liver carcinogenesis [AR1580-1594], presents the hypothesis promoted by ACC that PPAR activation explains the liver tumors in rodents and is not relevant in humans [AR1618-1625], and includes the key paper supporting this hypothesis (Klaunig, et al.) [AR1620, AR734, AR1083].

Second, the HID explained that more recent studies have demonstrated that chemicals known to activate PPAR can cause liver tumors in rodents that *lack* PPAR. These more recent studies show that these chemicals cause liver tumors in rodents *even without PPAR activation* [AR1621], and that "PPAR-alpha activation may not be causally related to DINP-induced liver tumors in rats and mice." [AR1625] Thus, the HID presented all relevant data and contained a scientifically reasonable interpretation of that data. While ACC has a different interpretation, the disagreement does not rise to the level that makes OEHHA's analysis arbitrary and capricious.

Third, there is a much greater degree of uncertainty about the role of PPAR activation in rodent liver tumors than ACC acknowledges. Even the seminal paper relied on by ACC, Klaunig et al. (2003), which hypothesizes that PPAR is the mechanism that causes liver tumors in rodents, notes that

"there remain some unanswered questions that would benefit from further investigation," and the additional "data collection would serve to improve substantially our understanding of whether or not the responses observed in rats and mice could occur in the human." [AR3049]

Further, while a publication by the CPSC staff in 2004 stated that DINP is not likely to present a risk to humans "*under foreseeable conditions of exposure*"[16] [AR53], it also noted that the data are limited and "some authors have concluded that the available data are not sufficient to rule out the possible cancer hazard of peroxisome proliferators [PPAR]" chemicals like DINP. [AR60] The European Chemicals Agency ("ECHA") *Evaluation of New Scientific Evidence Concerning DINP and DIDP* noted that, "the literature indicates that the mechanisms of carcinogenicity in rodents with peroxisome proliferators [PPAR] have not entirely been elucidated and that multiple pathways might exist. Some of those pathways might be PPARα-independent. It could be noted in this context that IARC has reviewed the classification of DEHP to 'possibly carcinogenic to humans (Group 2B)'. This conclusion was reached considering new evidence that activation of PPARα might not be the only pathway for cancer with DEHP in rats and mice." [AR10108, see also AR10109 ("literature indicates that mechanisms of liver carcinogenicity in rodents with [PPARs] have not been entirely elucidated and that multiple pathways might exist")]

2. Kidney tumors

With respect to the kidney tumors that develop in laboratory animals exposed to DINP, the HID discusses the theory, urged by ACC, that the

[16]This analysis was conducted prior to the new studies indicating that DEHP can cause liver cancer in rodents through non-PPAR mechanisms.

observed renal tubular cell tumors are not relevant to humans because the hypothesized mechanism of action – alpha2u-globulin nephropathy – does not operate in humans [AR1629-1631], and reports the conclusion of the key paper relied upon by proponents of this theory. [AR1629] The HID, however, identifies specific aspects of the data reported in this paper that call into question the authors' conclusion. [AR1630] The HID also discusses application of the well-known IARC criteria for establishing whether or not a chemical causes kidney tumors through the alpha2u-globulin mechanism, noting that "the . . . data for DINP does not meet IARC criteria items 2, 4 and 5." [AR1630-31]

Further, and as noted above, ACC had full opportunity to present its alternative view to the CIC – that DINP meets the IARC criteria for causing kidney tumors through the alpha2u-globulin mechanism – and did so in its written materials [See AR8975-76, 8917-18], and verbally during the meeting. [AR9475-78]

3. MNCL

In its written comments and its presentation to the CIC, ACC argued that the strong evidence that DINP causes MNCL cancers in animals is of "questionable significance" because the studies were done in Fisher 344 rats, which are highly susceptible to these leukemias [AR9034-36; AR9467, AR9481-82], and that the CIC should ignore the evidence. The CIC did not accept these arguments. (See Zhang [AR9513:23-9514:4].)

ACC now complains that the HID mischaracterized the scientific evidence because it did not report that an Australian entity stated that MNCL is not relevant to humans, and failed to inform the CIC that the NTP has stopped using Fisher 344 rats because of high spontaneous incidence of MNCL. (ACC Brief at 59-60)

While the HID did not mention the particular Australian statement, it did report the 1999 Caldwell paper stating that there is no human

counterpart to rat MNCL. [AR1603] The HID also pointed out that a more recent EPA report (2012) notes that several authors have concluded that rat MNCL is similar to a type of human leukemia, "human natural killer cell (NK) LGL leukemia" [*ibid*.], thus indicating that MNCL is relevant to humans.

Further, the rodent studies reported in the HID had been reviewed by the CPSC CHAP (2001) [AR2149], which stated that the MNCL lesions were likely related to DINP exposure. "[W]hile the lesion [MNCL] rarely occurs in untreated rats less than 20 months of age [citation], DINP treated animals were first observed with this tumor at considerably younger ages. . . . It is therefore highly unlikely that these findings were unrelated to treatment." [AR2236] EPA reached a similar conclusion that "the data for MNCL are indicative of a carcinogenic response to DINP." [AR7587]

Finally, ACC is wrong in asserting that the NTP has stopped using Fisher 344 rats. OEHHA scientist, Dr. Budroe, explained that the NTP has only discontinued the use of one sub-strain of the Fisher 344 rats, and is still using other sub-strains of the Fisher 344 rats. [AR9501:18-9502:1] Thus, the HID did not in any way mischaracterize the data on MNCL.

4. The rare and uncommon cancers

The HID explained that the animal studies showed an increase, although not statistically significant, in a number of tumors that were rare or uncommon in untreated animals, and included citations from the scientific literature identifying these particular tumor types as either rare or uncommon. These included pancreatic islet cell tumors, Leydig (interstitial) tumors of the testes, uterine tumors, and renal (kidney) transitional cell tumors. [AR1571, 1572]

ACC disagreed with this analysis. In its written and oral submissions to the CIC, it argued that *three* of the above cancers – pancreatic, testicular,

and uterine – were not rare or uncommon. (See ACC Brief at 60 [citations to record]; [AR9480:4-19].) ACC conceded however, that the fourth type of tumor – renal transitional cell tumors – *were rare*. [AR9489:15-16]

Thus, at most, ACC points out that its experts disagreed with the OEHHA scientists and the scientific literature cited by OEHHA concerning three of the four rare or uncommon cancers. That disagreement does not make OEHHA's analysis arbitrary and capricious.

ACC further complains that the HID described only the positive test results that showed significant increases in cancers and did not describe the results that did not show a significant increase in cancers. (ACC Brief at 60.) It is the generally accepted scientific practice in reporting animal cancer studies, to describe the tumor findings for those tumor sites/types that are observed to increase in treated animals, as compared to untreated controls. This practice is reflected in Guidance Criteria 2(B)(ii), which focuses on the *increase* in tumor occurrence, when discussing how to weigh the evidence. [AR8892-93] OEHHA merely followed this practice.

In sum, the HID previewed for the CIC the various theories that could be drawn from the available animal data and cited the key arguments and papers ACC and others submitted. There is nothing in the record that supports ACC's argument that the HID presented a biased view of the relevant data because it did not present the data in precisely the manner urged by ACC. Further, OEHHA provided the CIC with all of the studies and papers discussed and reported in the HID, as well as all additional materials submitted by commenters following release of the HID for public comment in 2013. Thus the CIC had available for its independent review all of the data, summary papers and reports that OEHHA believed relevant, as

well as all of the additional reports, papers and other evidence that other interested persons believed relevant.

III. THE TIMING OF THE CIC REVIEW DID NOT INVALIDATE THE LISTING PROCESS.

OEHHA provided the HID to the CIC on October 7, 2013, along with references cited in the document, including thirty-two documents submitted by industry. [CT123-24, 145]. The CIC had two full months to review those documents prior to the December 5 meeting. On November 20, 2013, OEHHA provided the CIC with additional documents submitted by industry in commenting on the HID. [AR8895-9339] The CIC had two weeks to review the additional documents. At the start of the CIC meeting, counsel for OEHHA informed the CIC Members that they did not have to vote that day, but could ask for additional time. [AR9431:22-9432:3]

Four members of industry spoke against the listing of DINP and were given 30 minutes total for their presentation. At the conclusion of the presentation, CIC members asked questions of the industry presenters. Dr. Mack did not cut off the questioning. Instead, he stated, "if there are no questions – if there are no more questions, then Joe [Landolph], would you like to provide your summaries, views." [AR9499:3-5] Even after the conclusion of all questions, Dr. Mack permitted industry spokespersons to offer further comment. [See AR9525:24-9526:11] Finally, Dr. Mack asked, "can we go now with the vote." There was no objection, and the CIC took its vote. [AR9526:12-13]

ACC was given full opportunity to present its views to the CIC and the CIC had ample opportunity to review the comments of ACC and other members of the public. The CIC could have, but did not, request additional time for review. There is absolutely nothing in the record that demonstrates that the CIC review was so rushed as to render it arbitrary and capricious.

IV. THE STATEMENTS OF OTHER AGENCIES DO NOT RENDER THE CIC DECISION ARBITRARY AND CAPRICIOUS.

A number of scientific agencies have reviewed DINP without concluding either that DINP is or is not carcinogenic to humans. This is, of course, precisely the situation which the CIC often faces, since, if a chemical had been designated as carcinogenic by one of the major scientific bodies such as FDA, EPA, NTP, IARC, or NIOSH, all of which are Authoritative Bodies under Proposition 65 (27CCR, § 25306, subd. (m)), OEHHA would normally rely on the Authoritative Body listing mechanism to list the chemical (§ 25249.8, subd. (b) [OEHHA must list chemical "if a body considered to be authoritative by [the state's qualified] experts has formally identified it as causing cancer. . . ."]), and would not present the chemical to the CIC for its review.

ACC nonetheless points to statements made by other agencies that it claims demonstrate that those agencies concluded that the rodent studies were not relevant to humans, and that the CIC is an outlier in failing to reach the same conclusion. In the first place, the views of other agencies are not dispositive for purposes of Proposition 65. The only relevant opinion is that of the expert members of the CIC. Further, the cited studies (ACC Brief at 19) rely on the PPAR activation hypothesis and do not consider the newer evidence cited in the HID, which tends to disprove the hypothesis that PPAR activation is the only mechanism through which liver cancer is induced in rodents by DINP. Finally, ACC's presentation of the views of other agencies is itself biased. Many of the documents leave open the possibility that DINP can cause cancer in humans, either by the PPAR activation mechanism or by some other mechanism. Thus, the reports note that, due to inter-individual variation, there may be certain individuals who are at increased cancer risk from chemicals that activate PPAR [AR2248], and that "further research is necessary to conclusively identify mechanisms

underlying [species differences in response to DINP] and their potential relevance to human risk assessment" [AR2251]; that PPAR activation may be relevant to humans at extremely high exposures [AR9011]; and that more research is necessary before any definitive conclusion can be drawn about the mechanism of action and "some authors have concluded that the available data are not sufficient to rule out the possible cancer hazard of peroxisome proliferators [PPAR]." [AR60]

Finally, ACC confuses statements about "risk" to humans, with statements of the "hazard" posed by DINP. As noted above, Proposition 65 is implemented in a two step process. The first step, listing of chemicals, is based on the cancer *hazard* posed by the chemical, regardless of the level of *risk* to humans based on current levels of exposure. Risk to humans is not considered until the second step, after the chemical is listed. (*Exxon, supra*, 169 Cal.App.4th at pp. 1291-92.) While other agencies have concluded that there is little *risk* to humans *based on current levels of exposure* to DINP, these statements are not relevant to the listing decision under Proposition 65.[17]

The CIC's decision, that ACC did not clearly show that the mechanisms by which DINP causes cancer in rodents are not relevant to humans, is consistent with the agencies that have reviewed the PPAR hypothesis and have acknowledged that it is just that – a hypothesis – that has not yet been conclusively proven.

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[17] The CPSC CHAP concluded that the *current levels of human exposure* to DINP are not high enough to be associated with a "significant increase" in cancer risk [AR2279], and that the PPAR mechanism is "believed not readily induced in humans under *current exposure conditions involving consumer products*. The human risk is therefore negligible." [AR2150 (emphasis added).] These conclusions about the current level of risk to humans are not relevant to the listing decision under Proposition 65.

V. ACC WAS NOT PREJUDICED BY THE REVIEW PROCESS.

Even assuming that ACC's arguments are correct, there is no evidence that it has been prejudiced by the listing process.

To the extent that the HID did not present a fair and balanced view of the science concerning DINP, which OEHHA disputes, every comment, every study, every analysis, and every document submitted by ACC during the public comment period was provided directly to the CIC for its review, and four representatives of industry presented their arguments directly to the CIC at the meeting. Thus, the CIC had before it all of the evidence that ACC wished it to consider, and there is no evidence that the CIC failed to consider the evidence. To the contrary, the discussion by the CIC members during the meeting demonstrates that they read and understood ACC's arguments. There was no demonstrated prejudice to the ACC from OEHHA's drafting of the HID.

Second, even if Dr. Mack had expressed an incorrect interpretation of Guidance Criteria 1D, which he did not, there is nothing that demonstrates that his statement influenced the other members of the CIC in any manner. The record demonstrates that at least four of the members who voted to list (one of whom had been a member of the CIC as long as Dr. Mack and helped to draft the Guidance Criteria [CT75-76; AR9511:3-5]) expressed disagreement with the ACC's arguments about the mechanistic data, stating that they were not convinced that the possible mechanisms of action were not relevant to humans. The sole CIC member who voted not to list DINP noted how difficult it was "not to list," and it really came down to a "judgment call."

Third, and finally, even if the CIC members had been so misled by Dr. Mack's statements that they ignored Criteria 1D, which OEHHA denies, the evidence in the record still supports the listing. ACC offered no evidence to show that the mechanism of action by which MNCL causes

cancer in rodents does not operate in humans. Nor did the ACC offer any evidence to show that the mechanisms by which the rare and uncommon cancers operate in rodents are not relevant to humans. Thus, even if the CIC had agreed that the liver and renal tubular cell cancers were not relevant to humans, there is sufficient evidence in the record to support the listing based on the other cancers. ACC has not demonstrated prejudice from Dr. Mack's statements.

VI. ARGUMENTS CONCERNING WARNINGS ARE IRRELEVANT TO THE LISTING DECISION

In its final argument, ACC asserts that an erroneous decision to list DINP will have severe consequences in terms of over-warning to consumers and litigation against manufacturers using DINP. Neither of these unsupported assertions has any bearing on the question of whether OEHHA abused its discretion in listing DINP and whether this Court should substitute its judgment for that of the highly qualified and independent scientific experts who make up the CIC.

Further, the decision to list a chemical does not determine whether or not a warning is required. Rather, Proposition 65 deals with any concerns about over-warnings by enabling a business to avoid providing a warning if it can prove that the exposure it causes is below the level that will have "no significant risk." (§ 25249.10, subd. (c).) This appeal involves only the first step in the Proposition 65 process, namely, whether DINP should be listed. During the second step, ACC and its members will have the opportunity to prove that they are "exempt from the Proposition 65 requirements because a specific exposure that [they cause]is below the level" that will have no significant risk. (Exxon, *supra*, 169 Cal.App.4th at p. 1291.)

Finally, to the extent the Court wishes to consider the potential harm that can arise from a wrong decision, it should consider, as well, the impact

of an erroneous decision to overturn the CIC's careful and well-considered scientific determination that DINP is known to cause cancer. Consumers who buy products containing DINP will spend large portions of their lives, as will their children, exposed to DINP. They will be deprived of the opportunity to make choices that would enable them easily to avoid exposure to a carcinogenic chemical. The consequences to innocent consumers in being deprived of a warning about a carcinogen that poses a significant risk of cancer, will be much more dire than the speculative possibility of over-warning or lawsuits that ACC asserts.

CONCLUSION

After taking public comment, reviewing documents submitted by industry, hearing the presentation of ACC's representatives at the public hearing, and extensively discussing the mechanistic arguments advanced by ACC, six independent expert scientists on the CIC voted to list DINP. ACC may disagree with the CIC decision, but nothing in the CIC's decision, or in the process it used to reach its decision, was arbitrary and capricious. OEHHA therefore requests that this Court affirm the trial court order and deny ACC's petition for writ of mandate.

Dated: May 6 , 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I certify that the attached APPELLEES OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT AND DR. LAUREN ZEISE, ACTING DIRECTOR, RESPONDENTS' BRIEF uses a 13 point Times New Roman font and contains 13,792 words.

Dated: May 6, 2016

KAMALA D. HARRIS
Attorney General of California

/s/ Susan S. Fiering
SUSAN S. FIERING
Supervising Deputy Attorney General
Attorneys for Office of Environmental Health Hazard Assessment and Dr. Lauren Zeise, Acting Director

DECLARATION OF SERVICE BY FIRST CLASS U.S. MAIL AND ELECTRONIC MAIL

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

Case No.: **Court of Appeal of the State of California**
Third Appellate District, Case No. C079260
[Sacramento County Superior Court,
Case No. 34-2014-80001868]

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; my business address is: 1515 Clay Street, 20th Floor, P. O. Box 70550, Oakland, California 94612-0550. I am familiar with the business practice at the Office of the Attorney General for collection and processing of correspondence for mailing with the United States Postal Service. 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 that same day in the ordinary course of business.

On **May 6, 2016**, I served the attached **APPELLEES OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT AND DR. LAUREN ZEISE, ACTING DIRECTOR, RESPONDENTS' BRIEF** by placing a true copy thereof enclosed in a sealed envelope in the internal mail system of the Office of the Attorney General; and also by transmitting a PDF copy via electronic mail to the e-mail address(es) for each of the parties as shown, addressed as follows:

SEE ATTACHED SERVICE LIST

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 **May 6, 2016**, at Oakland, California.

DEBRA BALDWIN	/s/ Debra Baldwin
Declarant	Signature

OK2015950017
Appellees OEHHA and Dr. Lauren Zeise, Acting Dir., Respondents' Brief.doc

SERVICE LIST

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Third Appellate District, Case No. C079260
[Sacramento County Superior Court,
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