# RESTRUCTURING REGULATORY REVIEW OF ENDOCRINE-DISRUPTING CHEMICALS UNDER CALIFORNIA'S PROPOSITION 65: LESSONS FROM THE REVIEW OF BPA

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ABSTRACT

This article proposes a redesign of the regulatory process, especially as it relates to the review of endocrine-disrupting chemicals, under California's Proposition 65—a "public right to know law" of national significance. Drawing lessons from the Proposition 65 review of bisphenol A (BPA), this article proposes a redesign of the chemical listing process that would require the regulatory agency to adopt rules and require findings of fact to increase transparency and accountability. In the face of significant advocacy science fueling well-represented industry opposition, and without full disclosure of conflicts of interest, the current regulatory framework in California assigns a mountain of review work to an inadequately specialized, part-time committee. With no clear standards and little time, the committee is assigned mixed questions of law and science where significant policy decisions are quietly hidden behind purportedly scientific conclusions. Rules are needed to increase transparency by creating an honest demarcation between policy and science so that the public may take action as necessary to further public policy objectives. Rules are also needed to set standards by which to critically evaluate conflicts of interest and advocacy science, and to require that warning labels identify the specific chemical and potential exposure. This article proposes to open a public rulemaking process that would include highly trained and specialized scientists and ultimately create a more specialized review board.



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## INTRODUCTION

One in eight women will be diagnosed with breast cancer, twelve percent under the age of forty-four.[1] Breast cancer now strikes teens and tweens.[2] In 2009 a ten-year-old in California underwent a mastectomy,[3] and in 2010 so did a four-year-old from Toronto.[4] One third of adults[5] and seventeen percent of all U.S.

1. *See SEER Stat Fact Sheets: Breast, Surveillance Epidemiology and End Results*, NAT'L CANCER INST., http://seer.cancer.gov/statfacts/html/breast.html (last visited Dec. 27, 2012) (based on rates from 2005–2009).

2. Madison Park, *Tweens Challenged by Grown-Up Malady: Breast Cancer*, CNN HEALTH (Oct. 26, 2009, 9:38 AM), http://www.cnn.com/2009/HEALTH/10/26/tweens.breast.cancer/index.html (These cases are "extreme examples of a troubling trend emerging with breast cancer, medical experts say. Younger women are getting a disease that usually strikes around menopause—and no one knows why.").

3. *Ten-Year-Old Bravely Battles Breast Cancer*, CBS NEWS (May 19, 2009, 10:32 AM), http://www.cbsnews.com/stories/2009/05/19/earlyshow/health/main5024777.shtml.

4. Greg McArthur, *Four Year Old Battles Breast Cancer*, THE GLOBE & MAIL, http://www.theglobeandmail.com/life/health/four-year-old-battles-breast-cancer/article1704895/ (last updated Mar. 16, 2011, 11:43 AM).

5. *Overweight and Obesity: Adult Obesity Facts*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/obesity/data/adult.html (last updated Aug. 13, 2012).

children between the ages of two and nineteen are obese.[6] One in six men will be diagnosed with prostate cancer in their lifetime.[7] More than 30 million people in the United States have some type of thyroid dysfunction.[8] Endocrine-disrupting chemicals may be contributing to these stunning statistics. Chemicals that interfere with endocrine function have been found to affect male and female reproduction, neuroendocrinology, thyroid function, metabolism and obesity, breast development, breast cancer, prostate cancer, and cardiovascular endocrinology.[9]

The Endocrine Society, the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology, recently issued a statement expressing concern that the public may be at risk because critical information about potential health effects of endocrine-disrupting chemicals is being overlooked in the development of federal health and safety guidelines and regulations.[10] The current federal and state regulatory regimes are struggling in their attempts to deal appropriately with these chemicals. One such chemical, the herbicide Atrazine, effectively banned in Europe, is exported to the United States in massive quantities.[11] Tyrone Hayes, a professor at UC Berkeley, lecturing on the chemically castrating effects of the Atrazine on frogs, including female eggs growing in male testes, described EPA's stunning response—it was "unclear" as to whether this reproductive mutation qualified as an "adverse effect!"[12]

6. *Overweight and Obesity: Childhood Obesity Facts Data and Statistics*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/obesity/data/childhood.html (last updated Dec. 21, 2012).

7. *What Are the Key Statistics About Prostate Cancer?*, AM. CANCER SOC'Y, http://www.cancer.org/Cancer/ProstateCancer/DetailedGuide/prostate-cancer-key-statistics (last updated Dec. 14, 2012).

8. Marilyn Fuller Delong, *Thyroid Dysfunction (Course # 8431)*, CME RES., 3 (July 11, 2012), http://www.netce.com/582/Course_8431.pdf.

9. Evanthia Diamanti-Kandarakis et al., *Endocrine–Disrupting Chemicals: An Endocrine Society Scientific Statement*, 30 ENDOCRINE REVS. 293, 293 (2009), *available at* http://www.endo-society.org/journals/scientificstatements/upload/edc_scientific_statement.pdf.

10. *See* THE ENDOCRINE SOC'Y, POSITION STATEMENT: ENDOCRINE-DISRUPTING CHEMICALS (2009), *available at* http://www.endo-society.org/advocacy/policy/upload/Endocrine-disrupting-chemicals-position-statement.pdf.

11. *See* Tyrone Hayes, *What is Atrazine? And Why Do We Love It?*, OUR WORLD . . . OUR FUTURE, http://atrazinelovers.com/m1.html (last visited Dec. 27, 2012).

12. Tyrone Hayes, Professor of Integrative Biology at Univ. of Cal., Berkeley, From Silent Spring to Silent Night, Lecture at The Univ. of Tex. at Austin Envtl. Sci. Inst., PowerPoint Slide 17 (Notes) (Jan. 30, 2009), *available at* http://www.

Another endocrine-disrupting chemical similarly muddled and mired in politics is bisphenol A (BPA), a synthetic estrogen.[13] The alarm bells have been sounding on BPA for quite some time. In 2006, an expert panel sponsored by the National Institutes of Health, the EPA, and Commonweal (a non-profit health and environmental research group) concluded that people are exposed to BPA at levels that cause problems in wildlife and laboratory animals, and that there is "great cause for concern" with regard to the potential for similar adverse effects in humans.[14] The panel explained that recent trends in human diseases relate to adverse effects observed in experimental animals exposed to low doses of BPA.[15] As specific examples, the panel noted the increase in hormonally mediated cancers, such as prostate and breast cancer; urogenital abnormalities in male babies; a decline in semen quality in men; early onset of puberty in girls; an increase in metabolic disorders, including insulin resistant (type 2) diabetes and obesity; and increases in neurobehavioral problems such as attention deficit hyperactivity disorder (ADHD).[16]

Despite the evidence, the Food and Drug Administration (FDA) has fallen into a state of regulatory malaise. In its review of BPA, the FDA's Science Advisory Board, although operating under a standard where "safety" is defined as "reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal,"[17] ultimately deferred instead to a political decision. The Science Board cautiously concluded:

> Coupling together the available qualitative and quantitative information (including application of uncertainty factors) provides a sufficient scientific basis to conclude that the Margins of Safety defined by FDA as "adequate" are, in fact, inadequate.

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esi.utexas.edu/k-12-a-the-community/hot-science-cool-talks/lecture-archives/from-silent-spring-to-silent-night.

13. BPA mimics the activity of estradiol and is similar in structure and efficacy to the estrogenic drug diethylstilbestrol (DES). Frederick vom Saal & Wade Welshons, *Large Effects from Small Exposures. II. The Importance of Positive Controls in Low-Dose Research on Bisphenol A*, 100 ENVTL. RES. 50, 50 (2006).

14. Frederick vom Saal et al., *Chapel Hill Bisphenol A Expert Panel Consensus Statement: Integration of Mechanisms, Effects in Animals and Potential to Impact Human Health at Current Levels of Exposure*, 24 REPROD. TOXICOLOGY 131, 131, 136 (2007) [hereinafter *Chapel Hill*].

15. *Id.* at 131.

16. *Id.*

17. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784; S. REP. NO. 85-2422, at 2–3 (1958), *reprinted in* 1958 U.S.C.C.A.N. 5300, 5301–02 (describing the relevant standard as one of "reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal").

> This does not mean that the potential exposures are not "*acceptable*". The latter is the subject of policy that appropriately rests with the Commissioner of the FDA.[18]

The FDA itself, although admitting "some concern" about the potential low-dose effects of BPA on the brain, behavior, and prostate gland in fetuses, infants and young children, has thus far deferred any significant regulatory response.[19] Declining a petition by the Natural Resources Defense Council (NRDC) to initiate a rulemaking to prohibit the use of BPA in food and food packaging, the FDA determined, "as a matter of science and regulatory policy," that the best course of action is to continue its review and study of emerging data on BPA.[20] In response to a request from the American Chemistry Council, the FDA is amending the food additive regulations to remove authorization for polycarbonate resins[21] in baby bottles and spill-proof cups, but this action is based on abandonment (following movement in the retail market[22]), not any finding concerning safety.[23]

Although acknowledging that "there are still a lot of outstanding questions," Linda S. Birnbaum, Director of the National Institute of Environmental Health Sciences at the National Institutes of Health recently reported: "Our grantees have published nearly 100 papers [on BPA] since January 2010. Nothing has been published

18. FDA Sci. Bd. Subcomm. on Bisphenol A, Scientific Peer-Review of the Draft Assessment of Bisphenol A for Use in Food Contact Applications 4 (2008) (emphasis in original), *available at* http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4386b1-24.pdf (as modified and submitted from the Science Board to the FDA).

19. *Bisphenol A (BPA): Use in Food Contact Application*, FDA, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm (last updated Apr. 2, 2012) ("FDA is continuing to consider the low dose toxicity studies of BPA as well as other recent peer-reviewed studies related to BPA.").

20. Letter from David Dorsey, Acting Assoc. Comm'r for Policy & Planning, FDA, to Sarah Janssen & Aaron Colangelo, Nat'l Res. Def. Council 15 (Mar. 30, 2010), *available at* http://www.regulations.gov/#!documentDetail;D=FDA-2008-P-0577-0007 (finding the data presented in the petition insufficient to initiate rulemaking).

21. Polycarbonate resins are formed by the condensation of 4,4'-isopropyl enediphenol (i.e., Bisphenol A (BPA)), and carbonyl chloride or diphenyl carbonate. Indirect Food Additives: Polymers, 77 Fed. Reg. 41,899, 41,902 (July 17, 2012) (to be codified at 21 C.F.R. pt. 177), *available at* https://www.federalregister.gov/articles/2012/07/17/2012-17366/indirect-food-additives-polymers#p-3.

22. Ylan Q. Mui, *Wal-Mart to Pull Bottles Made with Chemical BPA*, Wash. Post, Apr. 18, 2008, http://www.washingtonpost.com/wp-dyn/content/article/2008/04/17/AR2008041704205.html.

23. Indirect Food Additives: Polymers, 77 Fed. Reg. at 41,900–01.

that says there isn't any problem here."[24] Meanwhile exposure to BPA, already detected in 92.6% of persons in the 2003/2004 U.S. National Health and Nutrition Examination Survey,[25] is on the rise. Chemists first created polycarbonate from BPA in 1952.[26] It is now a high-volume chemical present in a many products including the interior coating of food cans, wine storage vats, water carboys, milk containers, food storage vessels, baby formula bottles, water pipes, dental materials, automotive lenses, optical lenses, protective window glazing, compact discs, thermal paper, paper coatings, and dyes.[27] In the United States, production quantities increased from 521 million kilograms in 1990 to 736 million kilograms in 1995.[28] Estimated production in the United States in 2007 was one billion kilograms.[29]

Several foreign, state, and local governments have taken action on BPA. In October 2008, Canada added BPA to its toxic substance list.[30] Since that time, the European Commission,[31] the French Na-

24. Bettina Boxall & Eryn Brown, *FDA Decides Not to Ban BPA in Food Packaging*, L.A. TIMES, Mar. 30, 2012, http://articles.latimes.com/2012/mar/30/nation/la-na-bpa-fda-20120331.

25. *See* REPROD. & CANCER HAZARD ASSESSMENT BRANCH, OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CAL. ENVTL. PROT. AGENCY, EVIDENCE ON THE DEVTL. AND REPROD. TOXICITY OF BISPHENOL A 21 (2009) [hereinafter CAL. ENVTL. PROT. AGENCY], *available at* http://oehha.ca.gov/prop65/CRNR_notices/state_listing/data_callin/pdf/BPAd050109.pdf (measured as urinary BPA).

26. Vom Saal & Welshons, *supra* note 13, at 51.

27. Ana M. Sota et al., *Does Breast Cancer Start in the Womb?*, 102 BASIC & CLINICAL PHARMACOLOGY & TOXICOLOGY 125, 127 (2008).

28. ENV'T CAN. & HEALTH CAN., CHEMICAL ABSTRACTS SERVICE REGISTRY NUMBER 80-05-7, SCREENING ASSESSMENT FOR THE CHALLENGE, PHENOL, 4,4' -(1-METHYLETHYLIDENE)BIS- (BISPHENOL A) at i (2008), *available at* http://www.ec.gc.ca/substances/ese/eng/challenge/batch2/batch2_80-05-7_en.pdf.

29. *Id.*

30. *Id.* at 76; *see also Chemical Substances: Bisphenol A*, GOV'T OF CAN., http://www.chemicalsubstanceschimiques.gc.ca/challenge-defi/batch-lot-2/bisphenol-a/index-eng.php (last updated Apr. 12, 2012). The *Canadian Environmental Protection Act (CEPA)* defines "toxic" substances as those that enter or may enter the environment at levels or conditions that have or may have a harmful effect on the environment; are or could be dangerous to the environment on which life depends; or are or could be dangerous to human life or health. Before the government can regulate these substances, they have to be added to the List of Toxic Substances. *Chemical Substances: The Canadian Environmental Protection Act,* 1999, GOV'T OF CAN., http://www.chemicalsubstanceschimiques.gc.ca/about-apropos/cepa-lcpe-eng.php (last updated Mar. 20, 2012).

31. Liz Szabo, *Europe Votes to Ban Chemical from Baby Bottles*, USA TODAY, http://www.usatoday.com/news/world/2010-11-29-BPA29_ST_N.htm (last updated Nov. 29, 2010).

tional Assembly,[32] the United Arab Emirates,[33] and China's Ministry of Health[34] have all taken action to place restrictions on the use of BPA. In the United States, some state and local governments have passed laws banning BPA in beverage containers for young children.[35] Connecticut has gone even further and banned the use of BPA in reusable food and beverage containers.[36] Massachusetts issued an advisory against the use of such products for small children, pregnant women, and breast-feeding mothers, and additional legislation has been under consideration in several states.[37]

In an action that may have significant consequences for the nation as a whole, BPA is currently under review pursuant to Proposition 65 by California's Office of Environmental Health Hazard Assessment (OEHHA).[38] Proposition 65, a "pubic right to know law" adopted by California voters in 1986,[39] requires warning labels on consumer products that contain certain chemicals identified as either carcinogens or reproductive toxicants.[40] Proposition 65 has

32. *Les députés votent l'interdiction du bisphénol A dans les emballages alimentaires*, LE MONDE, Oct. 12, 2011, http://www.lemonde.fr/planete/article/2011/10/12/les-deputes-votent-l-interdiction-du-bisphenol-a-dans-les-emballages-alimentaires_1586413_3244.html, *translated in* Abdelfattah60, *MEPs Vote to Ban BPA in Food Packaging*, THE PACKAGING SAFETY BLOG (Oct. 12, 2011), http://safepackaging.eu/france-bans-bisphenol-food-contact-materials.

33. *UAE to Ban BPA Baby Bottles*, EMIRATES 24—7 (Nov. 28, 2010), http://www.emirates247.com/news/emirates/uae-to-ban-bpa-baby-bottles-2010-11-28-1.322183.

34. Lu Feiran, *China to Ban Plastic Bottles to Feed Babies*, SHANGHAIDAILY.COM (Mar. 5, 2011), http://www.shanghaidaily.com/nsp/National/2011/03/05/China%2Bto%2Bban%2Bplastic%2Bbottles%2Bto%2Bfeed%2Bbabies.

35. Mark N. Duvall & Russell N. Fraker, *Bisphenol A: A Hot Topic at FDA, EPA, States, and the Courts*, CLIENT ALERT (Beveridge & Diamond, P.C., Wash. D.C.), Feb. 19, 2010, *available at* http://www.bdlaw.com/assets/attachments/BD%20Client%20Alert%20-%20BPA%20A%20Hot%20Topic%20at%20EPA%20FDA%20States%20and%20Courts.pdf (including Minnesota, Connecticut, the City of Chicago, and Suffolk, Albany and Schenectady Counties in NY).

36. *Id.*

37. *Id.*

38. Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A, 7-Z Cal. Regulatory Notice Reg. 252, 252–53 (Feb. 12, 2010), *available at* http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/callinBPA021210.html.

39. Clifford Rechtschaffen, *CPR Perspective: The Public Right to Know*, CENTER FOR PROGRESSIVE REFORM, http://www.progressivereform.org/perspright.cfm (last visited Dec. 28, 2012); *Frequently Asked Questions About Proposition 65*, CAL. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT (OEHHA), http://oehha.ca.gov/prop65/p65faq.html (last visited Dec. 28, 2012).

40. *See* CAL. HEALTH & SAFETY CODE § 25249.6 (West 2006). Warnings are generally required unless the chemical is present in the product below a level that

been credited with stimulating significant consumer product reformulation, which, in some cases, has been close to industry-wide with a nationwide effect.[41] For those products that remain on the market, current regulatory standards fall short of requiring full disclosure by allowing generic warning statements that fail to identify the chemical.[42] With some regulatory adjustment, however, Proposition 65 has the potential to publicly expose products containing BPA that the federal government has thus far been unwilling or unable to identify.

Although known as the most ambitious attempt by any state to regulate hazardous chemical exposure through information dissemination,[43] as it stands today, Proposition 65 is failing to live up to its full regulatory potential. As previously proposed by Clifford Rechtschaffen, OEHHA should require labels to specifically expose the chemical and the source of exposure.[44] Reform is also needed in other areas. Difficulties have emerged in determining, defining, and communicating appropriate standards against which to access research, in dealing with conflicts of interest, in working across different regulatory regimes, in handling inappropriate and inadequate back-door cost benefits analysis, as well as responding to a proliferation of industry-sponsored studies creating an overwhelming environment of uncertainty. There are questions as to the role of scientists and advisory boards, appropriate standard setting, communication and implementation of those standards, and how to appropriately inform public opinion.

This article takes a close look at Proposition 65 in relation to the regulation of BPA and proposes a redesign of the regulatory process, especially as it relates to endocrine-disrupting chemicals. In the face of significant advocacy science fueling well-represented industry opposition, and without full disclosure of conflicts of inter-

poses "no significant risk," that is, a level that causes no more than one excess lifetime case of cancer per 100,000 exposed individuals and, for reproductive toxicants, 1/1000th of the highest level at which the chemical has been shown to have no observable reproductive effect. CAL. HEALTH & SAFETY CODE § 25249.10(c) (West 2006); 27 CAL.CODE REGS. tit. 27, § 25703(b) (2012); *Proposition 65 in Plain Language!*, CAL. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT (OEHHA), http://oehha.ca.gov/prop65/background/p65plain.html (last updated Mar. 2010). If a chemical is present in a product, the burden is on industry to show that it does not exceed the allowable level. *See* CAL. HEALTH & SAFETY CODE § 25249.10(c) (West 2006).

41. Clifford Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, 23 ECOLOGY L.Q. 303, 341 (1996).

42. *See id.* at 363–64.

43. *See id.* at 305.

44. *Id.* at 363–64.

est, the current regulatory framework assigns a mountain of review work to an inadequately trained part-time committee. With no clear standards and little time, the committee is assigned mixed questions of law and science where significant policy decisions are quietly hidden behind purportedly scientific conclusions. Standards are particularly important in the context of endocrine-disrupting chemicals, where the science is rapidly evolving with increasing levels of complexity. Given the complexity of the science, a public rulemaking process should open discussion and allow for input from specialized scientists, as well as public consideration of the evolving policy issues. OEHHA should adopt standards to increase transparency and accountability, to expose conflicts of interest, and to require critical evaluation of research design.

The first section of this article discusses the nationwide importance of Proposition 65 in the context of our failing federal regulatory system. This section discusses the separate mechanisms for listing endocrine-disrupting chemicals under Proposition 65 and the increasing importance of review by the Developmental and Reproductive Toxicant (DART) Identification Committee. It also discusses the importance of regulatory reform to keep pace with our evolving understanding of endocrine-disrupting chemicals. The second section identifies the need for clear rules and mandatory fact findings to increase scientific transparency and accountability. This section discusses issues related to the "clear evidence" standard of review and the meaning of "reproductive toxicity" in the context of the evolving science. The third section identifies the need for research design and quality standards to weigh and effectively evaluate advocacy science. The fourth section identifies the need for a more specialized science review committee, an extended review period, and clear disclosure of conflicts of interest. Finally, the fifth section discusses the importance of standards to focus decisionmaking on appropriate scientific criteria, especially in the face of unsubstantiated claims of adverse consequences that may otherwise quietly threaten to disrupt the process.

## I.
## THE FAILING REGULATORY SYSTEM AND RESTORING THE PROMISE OF PROPOSITION 65

It is clear that BPA is leaching from many products, including food and beverage packaging and containers, but the full range of

sources is unknown.[45] BPA is used in the production of epoxy resins and polycarbonate plastic, food and drink packaging, and resins used as lacquers to coat metal products such as food cans, bottle tops, and water supply pipes.[46] The European Union has identified wine as a significant source of exposure due to an epoxy resin used to line wine vats.[47] The coating on metal lids for glass jars and bottles has also been identified as a source of exposure.[48] BPA is used in commercial polyvinyl chloride (PVC) cling films and plastic sheeting bags,[49] certain "microwave-safe" containers, and frozen food packaging.[50] Other potentially important sources include sports and office cooler polycarbonate water bottles,[51] credit card receipts (which reportedly have enormously high levels in an unbound form that may be transferred from fingers to food),[52] and even building materials. One study reported significantly higher urinary levels of total BPA, along with significantly higher levels of

45. See *infra* text accompanying notes 49–52, 54–55.

46. CAL. ENVTL. PROT. AGENCY, *supra* note 25, at 10.

47. U.S. DEP'T OF HEALTH AND HUMAN SERVS. NAT'L TOXICOLOGY PROGRAM CTR. FOR THE EVALUATION OF RISKS TO HUMAN REPROD., NIH PUBL'N NO. 08-5994, NTP-CERHR MONOGRAPH ON THE POTENTIAL HUMAN REPRODUCTIVE AND DEVELOPMENTAL EFFECTS OF BISPHENOL A 4 (2008), *available at* http://ntp.niehs.nih.gov/ntp/ohat/bisphenol/bisphenol.pdf.

48. EUROPEAN FOOD SAFETY AUTH., OPINION OF THE SCIENTIFIC PANEL ON FOOD ADDITIVES, FLAVOURINGS, PROCESSING AIDS AND MATERIALS IN CONTACT WITH FOOD ON A REQUEST FROM THE COMMISSION RELATED TO 2,2-BIS(4-HYDROXYPHENYL)PROPANE (BISPHENOL A), QUESTION NO. EFSA-Q-2005-100, 428 E.F.S.A. J. 1, 1 (Nov. 29, 2006), *available at* http://www.efsa.europa.eu/en/scdocs/doc/s428.pdf.

49. *Id.* at 10.

50. Siel Ju, *Plastic in the Microwave: Is BPA in Your Frozen Dinner?*, MOTHER NATURE NETWORK (Feb. 8, 2010, 3:14 PM), http://www.mnn.com/health/fitness-well-being/blogs/plastic-in-the-microwave-is-bpa-in-your-frozen-dinner (citing a test done by the Milwaukee Journal Sentinal finding that BPA leached from "microwave-safe" plastics, ranging from frozen food trays to plastic baby food packaging, *available at* http://media.jsonline.com/documents/BPAstudy.pdf).

51. Hoa Le et al., *Bisphenol A is Released from Polycarbonate Drinking Bottles and Mimics the Neurotoxic Actions of Estrogen in Developing Cerebellar Neurons*, 176 TOXICOLOGY LETTERS 149 (2008); Jennifer Grayson, *How to Avoid the Sneakiest Sources of BPA*, WebMD (Feb. 9, 2010), http://blogs.webmd.com/health-ehome/2010/02/how-to-avoid-the-sneakiest-sources-of-bpa.html.

52. Janet Raloff, *Concerned About BPA: Check Your Receipts*, SCIENCENEWS (Oct. 7, 2009), http://www.sciencenews.org/view/generic/id/48084/description/Concerned_about_BPA_Check_your_receipts (interviewing John Warner, a former professor of Green Chemistry at the University of Massachusetts, who compared the nanogram quantities of BPA leaching out of polycarbonate water bottles to that of the average cash register receipt, which is not bound into a polymer like the BPA in polycarbonates, but is instead "individual molecules loose and ready for uptake").

follicle stimulating hormones and significantly lower levels of testosterone, in workers applying paint consisting of ten to thirty percent epoxy resins.[53]

Although BPA has been approved for multiple uses as a food contact substance,[54] the FDA has not attempted to identify all of the different types of food products that may be contaminated with BPA.[55] The FDA has made some attempt to evaluate BPA for use in food contact applications, but it looked only at a small sample of canned products as a source of adult exposure and only at canned formula and polycarbonate baby bottles as a source of infant exposure.[56] Under the circumstances, perhaps the job was just too difficult. Interpreting its regulatory authority, the FDA explains:

> Current BPA food contact uses were approved under food additive regulations issued more than 40 years ago. . . . Once a food additive is approved, any manufacturer of food or food packaging may use the food additive in accordance with the regulation. There is no requirement to notify FDA of that use. For example, today there exist hundreds of different formulations for BPA-containing epoxy linings, which have varying characteristics. As currently regulated, manufacturers are not required to disclose to FDA the existence or nature of these formulations. Furthermore, if FDA were to decide to revoke one or more approved uses, FDA would need to undertake what could be a lengthy process of rulemaking to accomplish this goal.[57]

53. The painters had "'follicle stimulating hormone levels of 7.68 international units, which was significantly higher than the non-painter mean of 5.53 international units,'" and the painters had a "'testosterone level of 3.5 nanograms per milliliter, which was . . . 'significantly lower' than the non-painter level of 5.818 nanograms per milliliter.'" *Meeting on Proposition 65 Before the Devtl. & Reprod. Toxicant Identification Comm. of the Office of Envtl. Health Hazard Assessment of the State of Cal.*, 150–51 (July 15, 2009) [hereinafter *DART Meeting on Proposition 65* (July 15, 2009)], *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/DARTICTranscript71509.pdf (statement of Julie Silas, Director of Healthcare Projects for the Healthy Building Network, quoting the authors of the study); CAL. ENVTL. PROT. AGENCY, *supra* note 25, at A1-17 to -18.

54. *E.g.*, 21 C.F.R. § 177.1555 (2012); 21 C.F.R. § 177.1595 (2012).

55. FDA, DRAFT ASSESSMENT OF BISPHENOL A FOR USE IN FOOD CONTACT APPLICATIONS 6 (2008), *available at* http://www.fda.gov/ohrms/dockets/AC/08/briefing/2008-0038b1_01_02_FDA%20BPA%20Draft%20Assessment.pdf ("FDA does not maintain a list of all the specific product manufactured from BPA nor does it maintain a list of the various processors for the BPA-containing products . . .").

56. The FDA relied on sixteen samples of canned food for adults and fourteen samples of canned formula for infants. *Id.* at 7–10.

57. *Bisphenol A (BPA): Use in Food Contact Application*, *supra* note 19.

### *A. Proposition 65's Potential to Unveil Dangerous Sources of Exposure*

Proposition 65 has the potential to unveil not only contaminated food products, but also other potentially dangerous sources of BPA nationwide. Given the importance of the California market and the cost of selling different forms of the same product, businesses often choose to include informational warnings mandated by California law on products sold throughout the United States.[58] However, under the current rules, even if the listing of BPA as a reproductive toxin is finalized under Proposition 65, warnings may do little to lift the curtain on BPA. Proposition 65 requires "clear and reasonable" warnings before exposing consumers to listed chemicals.[59] However, Proposition 65 regulations establish the following "safe harbor" warning messages that have been used on virtually all consumer product warnings: "Warning: This product contains a chemical known to the State of California to cause cancer" or "Warning: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm."[60] The warning statement informs individuals only that the product contains a chemical, not whether the product will expose them to the chemical, not the identity of the chemical, nor the source of the exposure.[61] Allowing such a generic warning statement falls short of Proposition 65's goal of allowing for informed consent.[62] The statutory preamble declares the people's right "to be informed about exposures to chemicals that cause cancer, birth defects or other reproductive harm."[63] The intent of voters was to "receive warnings which will enable them to make informed

58. ZYGMUNT J.B. PLATER ET. AL., ENVIRONMENTAL LAW AND POLICY: NATURE, LAW AND SOCIETY 539–40 (3d ed. 2004).

59. CAL. HEALTH & SAFETY CODE § 25249.6 (West 2006) ("No person in the course of doing business shall knowingly and intentionally expose any individual to a chemical known to the state to cause cancer or reproductive toxicity without first giving clear and reasonable warning to such individual . . . .").

60. *See* CAL. CODE REGS. tit. 27, § 25603.2 (2012).

61. *See* Rechtschaffen, *The Warning Game: Evaluating Warnings Under California's Proposition 65*, *supra* note 41, at 326 (identifying these issues and concluding that the rules should be reformed to improve disclosure).

62. *See id.* at 307, 318, 319 n.78, 363.

63. CAL. HEALTH & SAFETY CODE § 25249.5 hist. n. § 1(a) (West 2006); *see also* CAL. HEALTH & WELFARE AGENCY, REVISED FINAL STATEMENT OF REASONS FOR CAL. CODE REGS. tit. 22, § 12601 at 22 (1988) [hereinafter CAL. HEALTH & WELFARE AGENCY], *available at* http://www.oehha.org/prop65/law/pdf_zip/12601FSORNov1988.pdf (official filing accompanying regulatory amendment) (analogizing purpose of warning requirement to purpose of informed consent doctrine).

choices."[64] The ballot argument read: "Proposition 65 also tells businesses: Don't expose us to any [listed] chemicals without first giving us a clear warning. We each have a right to know, and to make our own choices about being exposed to these chemicals."[65] For individuals particularly concerned about BPA, a generic warning statement that fails to disclose the specific chemical or the potential for exposure does not allow for that choice.

This issue is especially important to pregnant mothers, parents of young children, and other population groups who may be particularly vulnerable to BPA. As acknowledged by the FDA, infants are particularly sensitive to exposure to BPA because their neurological and endocrine systems are developing, and because their hepatic system for detoxification and elimination of such substances as BPA is immature.[66] Although not officially announced by the FDA, its Science Board also discussed the possibility that sensitive populations may include patients with hormone sensitive cancers, including breast cancer.[67] According to the Endocrine Society, the significant increase in the incidence of breast cancer in the industrialized world in the last fifty years may be due to exposure to hormonally active chemicals like BPA that have been released into the environment from industrial and commercial sources.[68] Evidence is also emerging that BPA may also pose a serious risk to the now 2.9 million breast cancer survivors in the United States[69] by interfering with tamoxifen and chemotherapy treatment.[70]

64. CAL. HEALTH & WELFARE AGENCY, supra note 63, at 3–4, 43 ("The apparent purpose of any warning under the Act is to permit the persons exposed to make choices about the exposure.").

65. *Id.* at 43 (emphasis omitted).

66. *See Bisphenol A (BPA): Use in Food Contact Application*, *supra* note 19.

67. *See Meeting Before Science Board Advisory Committee to the FDA* 291 (2008) [hereinafter *Meeting Before Science Board Advisory Committee*], *available at* http://www.fda.gov/ohrms/dockets/ac/08/transcripts/2008-4386t1-03.pdf (statement of Dr. David Parkinson, Member, Science Board Advisory Comm., FDA); *see, e.g.*, Shanaz H. Dairkee et al., *Bisphenol A Induces a Profile of Tumor Aggressiveness in High-Risk Cells from Breast Cancer Patients*, 68 CANCER RES. 2076 (2008); *see also* Martin Mittelstaedt, *Bisphenol A Can Alter Genes, Study Finds*, THE GLOBE & MAIL, http://www.theglobeandmail.com/life/bisphenol-a-can-alter-genes-study-finds/article671016/ (last updated Mar. 13, 2009, 11:45 AM).

68. *See* Diamanti-Kandarakis et al., *supra* note 9, at 305.

69. *Breast Cancer Overview*, AM. CANCER SOC'Y, http://www.cancer.org/Cancer/BreastCancer/OverviewGuide/breast-cancer-overview-key-statistics (last updated Dec. 5, 2012) (reflecting 2012 estimates).

70. William H. Goodson III et al., *Activation of the mTOR Pathway by Low Levels of Xenoestrogens in Breast Epithelial Cells from High-Risk Women*, 32 CARCINOGENESIS 1724, 1724 (2011); Elizabeth W. LaPensee et al., *Bisphenol A at Low Nanomolar Doses Confers Chemoresistance in Estrogen Receptor-a–Positive and –Negative Breast Cancer Cells*,

The FDA has acknowledged that it "supports reasonable steps to reduce exposure of infants to BPA in the food supply," has promised that it "will work with industry to support and evaluate manufacturing practices and alternative substances," and has stated that it will support "the industry's actions to stop producing BPA-containing bottles and infant feeding cups for the U.S. market."[71] Instead of just waiting and hoping for industry to change course, if Proposition 65 were reformed to truly allow for informed consent, consumers could choose to take more decisive precautionary action and encourage change through their own purchase decisions. Environmental and public health organizations are already starting to specifically identify products leaching BPA,[72] but the task is overwhelming.

### *B. The Evolving Role of the DART Identification Committee and the Review of Endocrine-Disrupting Chemicals*

There are four different mechanisms for listing chemicals under Proposition 65.[73] One option is through the state's qualified experts: a chemical can be listed if either the Carcinogen Identifica-

117 ENVTL. HEALTH PERSP. 175, 176 (2009) (the chemotherapy drugs studied were doxorubicin, cisplatin, and vinblastine); Victoria Colliver, S*tudy: BPA, Methylparaben Block Breast Cancer Drugs*, S.F. CHRON., Sept. 13, 2011, http://articles.sfgate.com/2011-09-13/news/30147741_1_cancer-cells-breast-cells-bpa; *see also Meeting Before Science Board Advisory Committee*, *supra* note 67, at 291–92.

71. *Bisphenol A (BPA): Use in Food Contact Application*, *supra* note 19.

72. *See, e.g.*, BREAST CANCER FUND, BPA IN KIDS' CANNED FOOD: A PRODUCT TESTING REPORT BY THE BREAST CANCER FUND (2011), *available at* http://www.breastcancerfund.org/assets/pdfs/publications/bpa-in-kids-canned-food.pdf; *BPA-Free Canned Food Options*, THE SOFT LANDING, http://guide.thesoftlanding.com/bpa-free-canned-food-options/ (last updated Oct. 25, 2012) (identifying BPA free options); *Chemicals and Points of Concern*, THE ALLIANCE FOR A HEALTHY TOMORROW (Oct. 31, 2007), http://www.healthytomorrow.org/2007/10/chemicals.html (posting information on studies identifying sources of BPA).

73. *Mechanisms for Listing and Delisting Chemicals Under Proposition 65*, CAL. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT (OEHHA) (May 15, 2007), http://oehha.ca.gov/prop65/policy_procedure/listde051007.html ("The statute defines four mechanisms by which carcinogens and reproductive toxicants are listed. First, a chemical must be listed if one of the State's Qualified Expert committees decides that a chemical has been clearly shown to cause cancer or reproductive toxicity through scientifically valid testing according to generally accepted principles. Second, a chemical must be listed if it is formally identified as a carcinogen or reproductive toxicant by a body considered authoritative under Proposition 65. Third, a chemical must be listed if a State or federal agency formally requires it to be identified or labeled as a carcinogen or reproductive toxicant. Fourth, a chemical must be listed if it is identified by reference in Labor Code section 6382(b)(1) or (d)."); *see also* CAL. HEALTH & SAFETY CODE § 25249.8 (West 2006).

tion Committee (CIC) or the Developmental and Reproductive Toxicant (DART) Identification Committee finds that the chemical has been "clearly shown to cause cancer or reproductive toxicity."[74] On July 15, 2009, pursuant to procedures very much in need of reform as discussed below, the Proposition 65 DART Identification Committee voted not to list BPA as a reproductive toxicant.[75] However, BPA is still under review[76] through another mechanism for listing. A chemical may also be listed when an organization that has been designated as an "authoritative body" by the CIC or DART Identification Committee has already identified a chemical as causing cancer or birth defects or other reproductive harm.[77] Relevant here is the finding of the National Toxicology Program Center for Risks to Human Reproduction (NTP-CERHR)[78] that there is clear evidence of adverse developmental effects in laboratory animals at high levels of exposure to BPA.[79] Through the authoritative bodies mechanism, once the NTP-CERHR concludes that there is clear evidence of reproductive toxicity, the chemical must be listed unless scientifically valid data that were not considered by the authoritative body clearly establish that the sufficiency of evidence criteria were not met.[80] Based on the NTP-CERHR report and the references cited in that report, the OEHHA staff announced in February 2010 that the evidence appears sufficient for listing BPA and initi-

74. CAL. HEALTH & SAFETY CODE § 25249.8 (West 2006); CAL. CODE REGS. tit. 27, §§ 25102(c), 25302(a)–(c) (2009); CAL. CODE REGS. tit. 27, § 25305 (2012); *see also Mechanisms for Listing and Delisting Chemicals Under Proposition 65*, *supra* note 73.

75. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 253–55.

76. The process was initiated following a petition from the Natural Resources Defense Council. *See* Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A, 7-Z Cal. Regulatory Notice Reg. 252, 252 (Feb. 12, 2010), *available at* http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/callinBPA021210.html.

77. *See* CAL. HEALTH & SAFETY CODE § 25249.8(b) (West 2006); CAL. CODE REGS. tit. 27, § 25102(c) (2009); *Mechanisms for Listing and Delisting Chemicals Under Proposition 65*, *supra* note 73.

78. Designated as an authoritative body by the DART Board in 2002. *Meeting on Proposition 65 Before the Devtl. & Reprod. Toxicant Identification Comm. of the Office of Envtl. Health Hazard Assessment of the State of Cal.*188 (July 12, 2010), *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/DARTIC071211trans.pdf (statement of Caroline Cox, Center for Environmental Health).

79. Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A, 7-Z Cal. Regulatory Notice Reg. at 253.

80. CAL. CODE REGS. tit. 27, § 25306(a), (g), (h), (l)(3) (2012).

ated the listing process, which will include a review of public comments.[81]

BPA may ultimately be successfully listed through the authoritative bodies mechanism; however, NTP-CERHR decisions may no longer be available for listing other endocrine-disrupting chemicals in the future. Although the DART Identification Committee declined a 2011 request from the American Chemistry Council (ACC)[82] to rescind the designation of the NTP-CERHR,[83] at least insofar as it concerns the listing of future chemicals, the NTP-CERHR has nevertheless ceased to be an authoritative body. Recognizing the need for a more holistic approach, the National Toxicology Program Center for the Evaluation of Risks to Human Reproduction recently changed its regulatory structure and its name; it is now called the National Toxicology Program's Office of Health Assessment and Translation.[84] NTP representatives explain:

> A strict focus on reproductive and developmental end points evaluated in the context of current human exposures may not result in the most health protective levels of concern, and could be confusing to the public. From a public health perspective, understanding the implications of current human ex-

81. *Request for Relevant Information on a Chemical Being Considered for Listing by the Authoritative Bodies Mechanism: Bisphenol-A*, CAL. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT (Feb. 2, 2010), http://oehha.ca.gov/prop65/CRNR_notices/admin_listing/requests_info/callinBPA021210.html.

82. *See* Letter from Stanley W. Landfair, Counsel for the Polycarbonate/Global Grp. of the Am. Chemistry Council, et al., to Dorothy Burk, Chairperson, Cal. Devtl. & Reprod. Toxicant Identification Comm. (Oct. 14, 2010), *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/101810accletter.pdf; Letter from Caroline Silveira, Dir., State Affairs, Grocery Mfrs. Ass'n, to Dorothy Burk, Chairperson, Cal. Devtl. & Reprod. Toxicant Identification Comm., & Joan Denton, Dir., Cal. Office of Envtl. Health Hazard Assessment (Oct. 20, 2010), *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/GMA_CEHR110110.pdf.

83. *Meeting on Proposition 65 Before the Devtl. & Reprod. Toxicant Identification Comm. of the Office of Envtl. Health Hazard Assessment of the State of Cal.* 200 (July 12, 2011) [hereinafter *DART Meeting on Proposition 65* (July 12, 2011)], *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/DARTIC071211trans.pdf; *Meeting Synopsis and Slide Presentations: Developmental and Reproductive Toxicant Identification Committee Meeting Held on July 12 and 13, 2011*, CAL. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT (OEHHA) (Aug. 8, 2011), http://oehha.ca.gov/prop65/public_meetings/2011DARTsynop.html.

84. *See* John R. Bucher et al., *The Office of Health Assessment and Translation: A Problem-Solving Resource for the National Toxicology Program*, 119 ENVTL. HEALTH PERSP. A 196, A 196 (2011).

posures should include consideration of all relevant health effects.[85]

Concerned that their regulatory interests may no longer be sufficiently aligned, on July 12, 2011, the DART Identification Committee deferred consideration as to whether to identify the new Office of Health Assessment and Translation as an authoritative body.[86]

The regulatory jurisdiction of DART Identification Committee is limited to "reproductive toxicity,"[87] which OEHHA guidelines define to include "developmental toxicity" (including "adverse effects *on the products of conception*"),[88] "female reproductive toxicity," and "male reproductive toxicity."[89] The guidelines broadly define female and male "reproductive toxicity" to include "impaired or altered endocrine function;"[90] however, as discussed in the following section, it is not clear that the guidelines are being understood or interpreted to include consideration of the full breadth of possible detrimental effects on the endocrine system. Historically, relatively few chemicals have been listed under Proposition 65 in the absence of developmental toxicity.[91]

Given new scientific information as to the breadth of action of endocrine-disrupting chemicals, the DART Identification Committee should consider following the approach of the NTP-CERHR and adopt the broadest possible interpretation of "reproductive toxicity." Although the data is still limited, according to the Endo-

85. *Id.*

86. *See DART Meeting on Proposition 65* (July 12, 2011), *supra* note 83, at 203–04.

87. CAL. CODE REGS. tit. 27, § 25305(b) (2012).

88. CAL. OFFICE OF ENVTL. HEALTH HAZARD ASSESSMENT, CRITERIA FOR RECOMMENDING CHEMICALS FOR LISTING AS "KNOWN TO THE STATE TO CAUSE REPRODUCTIVE TOXICITY" 1–2 (1993) [hereinafter OEHHA CRITERIA FOR RECOMMENDING CHEMICALS FOR LISTING] (emphasis added), *available at* http://oehha.ca.gov/prop65/policy_procedure/pdf_zip/dartCriteriaNov1993.pdf.

89. *Id.* at 1.

90. *Id.* at 2–3.

91. Of the 302 chemicals that have been listed as "reproductive toxins" through all the listing processes under Proposition 65, only 32 are associated with reproductive effects alone; the overwhelming majority, 208, have been listed for developmental toxicity alone. Cal. Office of Envtl. Health Hazard Assessment, Proposition 65 Listing Mechanisms (Informational Agenda Item), Staff Presentation at the Meeting on Proposition 65 Before the Devtl. & Reprod. Toxicant Identification Comm. of the Office of Envtl. Health Hazard Assessment of the State of Cal., PowerPoint Slides 3–4 (July 12–13, 2011) [hereinafter OEHHA Staff Presentation], *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/071211DARTIClisting.pdf.

crine Society, the increased incidence of testicular cancer and malformations of the male genital tract and the decrease in quantity and quality of human sperm may be linked to the introduction of endocrine-disrupting chemicals into the environment.[92] The increase in breast cancer also correlates with increased exposure to endocrine-disrupting chemicals,[93] and these chemicals have been linked through laboratory studies to many female reproductive disorders, including polycystic ovarian syndrome, aneuploidy, premature ovarian failure, reproductive tract anomalies, uterine fibroids, endometriosis, and ectopic gestation.[94]

Considering just one of these disorders, endometriosis (an estrogen-dependent gynecological disorder associated with pelvic pain and infertility), the estimated health care costs for diagnosis and treatment totaled approximately $22 billion in 2002, and there has been only limited success in achieving successful treatment of endometriosis-related pain.[95] In addition to reproductive tract disorders, new research suggests that exposure to endocrine-disrupting chemicals may play a role in both the diabetes and the obesity epidemics in the United States.[96] In 2008, the medical care costs of obesity in the United States totaled about $147 billion.[97]

Given these staggering costs, even while recognizing the possibility of other causal and contributing factors, California should consider a broad focus on all health effects related to endocrine disruption. Such reform may also bring harmony between the practice and interests of the DART Identification Committee and the National Toxicology Program's new Office of Health Assessment and Translation and encourage continued designation of the Na-

92. Diamanti-Kandarakis et al., *supra* note 9, at 305.

93. *See id.*

94. *See id.* at 300–01 (discussing laboratory studies with rodents, ungulates, and nonhuman primates and explaining that many of the mechanisms by which the disorders are caused by endocrine-disrupting chemicals are understood and, moreover, are conserved between animals and humans).

95. *See id.* at 304–05 (citing S. Simoens et al., *Endometriosis: Cost Estimates and Methodological Perspective*, 13 HUM. REPROD. UPDATE 395, 401 (2007)).

96. Jennifer Lee, *Child Obesity Is Linked to Chemicals in Plastics*, N.Y. TIMES, (Apr. 17, 2009, 1:31 PM), http://cityroom.blogs.nytimes.com/2009/04/17/child-obesity-is-linked-to-chemicals-in-plastics/; Thaddeus Schug, *NTP Workshop Investigates Links Between Chemicals and Obesity*, ENVTL. FACTOR (Feb. 2011), http://www.niehs.nih.gov/news/newsletter/2011/february/science-ntp-workshop.

97. *Adult Overweight and Obesity: Causes and Consequences*, CTRS. FOR DISEASE CONTROL & PREVENTION, http://www.cdc.gov/obesity/causes/economics.html (last updated Apr. 27, 2012) (citing Eric A. Finkelstein et al., *Annual Medical Spending Attributable to Obesity: Payer- and Service-Specific Estimates*, 28 HEALTH AFF. w822, w822 (2009)).

tional Toxicity Program as an authoritative body, reopening this important mechanism as a vehicle for listing. Historically many more chemicals have been listed as reproductive toxins through the authoritative bodies mechanism than through the state's qualified experts.[98] Failing designation of the new office of the NTP as an authoritative body, more responsibility will fall to the DART Identification Committee to list endocrine-disrupting chemicals.[99] Reform of the DART Identification Committee review process may thus assume increasing importance. There is a need for new rules to increase the availability and reliability of this vehicle for listing. Regulatory reform is needed to increase transparency and accountability as well as allow for consideration of a broader spectrum of health effects.

## II.
## REQUIREMENTS FOR TRANSPARENCY AND ACCOUNTABILITY

As discussed in detail in the following sections, the 2009 Proposition 65 DART Identification Meeting on BPA[100] encountered serious difficulties due to vague definitions and a dearth of interpretive guidance. Proposition 65 regulates chemicals "clearly shown" to cause cancer or "reproductive toxicity."[101] However, there are only very limited guidelines (the "Criteria for Recommending Chemicals for Listing as 'Known to the State to Cause Reproductive Toxicity'" (Guidelines))[102] and no regulations defining these statutory standards. There was considerable debate at the public hearing as to the scope of adverse effects that fall within the realm of "reproductive toxicity."[103] However, the OEHHA staff, although present and participating at the hearing,[104] did not discuss the Guidelines or take a position as to whether there was sufficient evidence of relevant adverse effects. At the conclusion of the hearing, it was unclear whether the DART Identification Committee's decision was influenced by industry's arguments in favor of a nar-

98. *See* OEHHA Staff Presentation, *supra* note 91, at 5, 7.

99. NTP-CERHR is one of four Authoritative Bodies for Reproductive Toxicity. *Id.* at 5, 17.

100. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53.

101. CAL. HEALTH & SAFETY CODE § 25249.8(b) (West 2006).

102. OEHHA CRITERIA FOR RECOMMENDING CHEMICALS FOR LISTING, *supra* note 88.

103. *See, e.g.*, *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 222–24.

104. *Id.* at i.

row focus as to what qualifies as "reproductive toxicity" or if it was based instead entirely on the question of the adequacy of the evidence.

As reflected in the discussion below, the Guidelines were not clearly referenced at the hearing in a way that would suggest that they were consistently guiding the process. Moreover the Guidelines were "not intended to limit the scope of the committee's consideration"[105] and the Guidelines themselves may need revision to conform to the evolving science. In the absence of clear regulatory standards, the Committee members were left to come up with their own varying interpretations of critical terms. The hearing transcript reflects a need for a discussion that involves both the public and the scientific community to consider appropriate and transparent definitions of both "clearly shown" and "reproductive toxicity." OEHHA should open a rulemaking process.

### *A. Defining "Clearly Shown" Consistent with Scientific Standards and Societal Choices*

One DART Identification Committee member interpreted the statutory requirement that reproductive toxicity be "clearly shown" to require conclusive evidence, an especially difficult standard here, where there have been serious reports of advocacy science.[106] Committee Member Roberts reasoned, "At least, in my perspective, there are not clear effects on the low-dose levels, because we have seen situations where some studies are positive and some studies are negative."[107] Committee Member White explained, "I didn't quite feel like there was conclusive and clear evidence . . . ."[108] Chairperson Burk noted, "[W]e all have . . . probably our own definition of clear."[109]

An interpretation of "clearly shown" that would require conclusive evidence is discordant with the precautionary public policy disclosure objectives of Proposition 65. Regardless of any safety determination, Proposition 65 aimed to allow consumers to make

105. OEHHA CRITERIA FOR RECOMMENDING CHEMICALS FOR LISTING, *supra* note 88, at 1.

106. Jane Houlihan et al., *Timeline: BPA from Invention to Phase-Out*, ENVTL. WORKING GRP., http://www.ewg.org/reports/bpatimeline (last updated Mar. 2011).

107. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 238.

108. *Id.* at 229.

109. *Id.* at 230.

their own choices about chemical exposure.[110] Moreover asking a group of scientists to find that a chemical has been conclusively shown to cause reproductive toxicity is inconsistent with modern scientific theory.[111] Science is based on "generating hypotheses and testing them to see if they can be falsified."[112] Certainty is elusive if not impossible to establish. Reducing one type of error, inevitably increases another—"'Type I' errors are created by accepting hypotheses that are ultimately shown to be wrong, whereas 'Type II' errors are created by rejecting hypotheses that are ultimately shown to be true."[113] Regulatory agencies protecting the public interest should logically be most concerned with false negatives (Type II) errors, whereas industry is generally most concerned with false positives (Type I errors).[114] As William R. Freudenburg et al. explain in their article, *Scientific Certainty Argumentation Methods (SCAMs): Science and the Politics of Doubt*:

> In environmental and technological controversies, a Type II error is not merely an abstract possibility, but a risk that innocent people will get sick or die. In light of this reality, it is difficult to believe that anyone who believes in truly balanced or "sound science"—or for that matter, any well-informed person of good will—could seriously contend that the "proper" balance involves a decision to focus exclusively on Type I errors while deciding to ignore Type II errors completely. That, however, is nevertheless the net effect of successful efforts to argue for full "scientific certainty" before a regulation can be said to be "justified"—and that, in short is a SCAM.[115]

In the context of science, the most we could possibly ask for would be clear *evidence* of reproductive toxicity. Even then, we would still have to consider what is meant by "clear" and what is meant by "reproductive toxicity;" that is, how much certainty and

110. CAL. HEALTH & WELFARE AGENCY, *supra* note 63, at 43 ("The apparent purpose of any warning under the Act is to permit the persons exposed to make choices about the exposure.").

111. Vom Saal & Welshons, *supra* note 13, at 69 ("In experimental research scientists test whether the hypothesis that the observed results come from the same distribution (the null hypothesis) can be rejected with a specific level of confidence. . . . The hypothesis that results all come from the same distribution (or the same population) can be disproved or falsified only at some specified level of confidence, it can never be proven to be correct.").

112. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 593 (1993).

113. William R. Freudenburg et al., *Scientific Certainty Argumentation Methods (SCAMs): Science and the Politics of Doubt*, 78 SOC. INQUIRY 2, 7 (2008).

114. Vom Saal & Welshons, *supra* note 13, at 69–70.

115. Freudenburg et al., *supra* note 113, at 31.

what type of evidence is sufficient. These questions are not purely questions of science. OEHHA's staff, however, failed to acknowledge the complexity. Responding to a complaint about OEHHA's failure to provide any clarification to correct confusion about the charge,[116] OEHHA staff explained:

> We agree that the 'clearly shown" [sic] standard in the statute and regulations has become the subject of much debate in public comments in recent years. This standard is not a legal determination; it is instead a scientific judgment in which the state's qualified experts are expected to apply their own knowledge and expertise to determine if a chemical has been "clearly shown by scientifically valid testing according to generally accepted principals to cause reproductive toxicity."[117]

Yet there must be more than only "scientific judgment" at play. Carefully dissecting this issue in *The Myth of Science as a "Neutral Arbiter" for Triggering Precautions,* Vern Walker explains:

> Numerous non-scientific decisions are necessarily involved in both making and warranting findings that a triggering risk exists. Making a finding of risk involves decisions about the meaning of "risk of harm," about the meaning of any qualitative or quantitative modifiers, and about the truth modality of (or degree of confidence in) the finding as a whole. Moreover, every determination that the available scientific evidence warrants a finding of risk involves decisions about the acceptable degree of various types of uncertainty: conceptual uncertainty, measurement uncertainty, sampling uncertainty, modeling uncertainty, and causal uncertainty.[118]

The lack of rules defining a more articulate standard allows the DART Identification Committee members to create a decisionmaking process that lacks transparency, allows policy decisions to hide behind the cloak of "science," and encourages deferred decisionmaking. In her article, *The Science Charade in Toxic Risk Regulation*,

116. Letter from Dr. Sarah Janssen, Staff Scientist, Natural Res. Def. Council, et al., to Joan Denton, Dir., Cal. Office of Envtl. Health Hazard Assessment 2–3 (July 22, 2009) [hereinafter Letter from Dr. Sarah Janssen et al.], *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/DARTIC072209.pdf (letter joined by Breast Cancer Fund, Clean Water Action, Environment California, Healthy Building Network, and Science & Environmental Health Network).

117. Letter from Joan Denton, Dir., Cal. Office of Envtl. Health Hazard Assessment, to Dr. Sarah Janssen, Staff Scientist, Natural Res. Def. Council, et al. 2–3 (Sept. 1, 2010) [hereinafter Letter from Joan Denton], *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/090110OEHHA.pdf.

118. Vern R. Walker, *The Myth of Science as a "Neutral Arbiter" for Triggering Precautions*, 26 B.C. INT'L & COMP. L. REV. 197, 228 (2003).

Wendy Wagner captures this, apparently common, situation when there is a "statutory mandate that appears to require protective standards to be based at least in part on science, coupled with a deficient understanding of the science-policy nature of risk assessment."[119] She explains:

> Once given responsibility for setting a single, quantitative standard, agency scientists generally take one of two approaches: 1) they continue indefinitely to look to science to resolve the trans-scientific questions; or 2) they substitute their own values for the policy choices needed at the trans-scientific junctures and characterize the final science-policy decisions as the result of scientific experimentation and scientific judgment. In either case, the results are disturbing.[120]

Without publicly accessible standards to guide the process, there is also a lack of transparency that interferes with the proper functioning of our political system. The public must be able to discover and understand the policy decisions hidden within the science in order for the political process to work. In *Using Science in a Political World: The Importance of Transparency in Natural Resource Regulation*, Holley Doremus explains:

> [T]he technical complexities of science must not be allowed to obscure the political judgments that are ultimately at the heart of regulatory decisions. . . . Ultimately, where the burden of proof should lie and how strong that burden should be are societal choices that will depend upon societal judgments about the costs of different types of error. In a democracy, the public must be the final arbiters of the relative importance of goals that may be in tension with one another.[121]

To the extent that the basis for the DART Identification Committee decisions, both scientific and policy decisions, can be separated and made accessible to the public, the public would then have the opportunity to respond as necessary to encourage corrective action through the political and legal system.

No findings of fact were issued at the end of the DART Identification Committee hearings on BPA, and the Committee's decision-making process lacked transparency. In a response to a letter

119. Wendy E. Wagner, *The Science Charade in Toxic Risk Regulation*, 95 COLUM. L. REV. 1613, 1632 (1995) (footnotes omitted).

120. *Id.* (footnotes omitted).

121. Holly Doremus, *Using Science in a Political World: The Importance of Transparency in Natural Resource Regulation*, *in* RESCUING SCIENCE FROM POLITICS: REGULATION AND THE DISTORTION OF SCIENTIFIC RESEARCH 143, 153 (Wendy Wagner & Rena Steinzor eds., 2006).

submitted by several advocacy organizations,[122] the OEHHA staff indicated that they would, in the future, provide a copy of the Guidelines to each Committee member prior to meetings, organize written and oral presentations with the goal of focusing Committee members on each endpoint of concern, and identify the studies that OEHHA staff feels are most important to the Committee's evaluation of the chemical.[123] Although undoubtedly helpful, these actions alone are not enough to resolve problems with the review process. A stronger approach would be to use the rulemaking process to open a public discussion with the scientific community concerning the appropriate scope of the Guidelines given contemporary understanding of the breadth of action of endocrine-disrupting chemicals, and the necessary level of detail to guide the decisionmaking process as to the sufficiency of the evidence.

Resolving issues through a rulemaking proceeding would also create an opportunity to add requirements for findings of fact that could help to focus the Committee's attention on relevant parameters of defensible and unbiased science and encourage the staff to propose findings and conclusions for Committee review. This technique forces the regulatory agency to reflect carefully on what should be the appropriate basis for its decision. As described by the California Supreme Court: "Among other functions, a findings requirement serves to conduce the administrative body to draw legally relevant subconclusions supportive of its ultimate decision; the intended effect is to facilitate orderly analysis and minimize the likelihood that the agency will randomly leap from evidence to conclusions."[124]

A more transparent process with findings of fact may also help inform the public in the face of the inevitably misleading spin presented by opponents to a listing. When the DART Identification Committee declined to list BPA as a reproductive toxicant, it was concluding only that it felt that the evidence fell short of the standard, "clearly shown to cause reproductive toxicity;" it was not concluding that BPA is proven "safe." However, that did not stop blogger Kerri Toloczko from declaring that the DART Committee had indeed made such a finding of safety.[125] Nor did it prevent

122. Letter from Dr. Sarah Janssen et al., *supra* note 116.

123. Letter from Joan Denton, *supra* note 117, at 2–3.

124. Topanga Ass'n for a Scenic Cmty. v. Cnty. of L.A., 522 P.2d 12, 18 (Cal. 1974).

125. Kerri Toloczko, *Junk Science Has Consequences: Environmental Lobby Shows No Concern for California's Financial Woes*, BREITBART (Apr. 29, 2010), http://www.

Nick Kump of Elmets Communications from reporting that the "state's top panel of independent experts found no particular risk in BPA" and referring to a "mountain of evidence showing BPA's benign safety profile."[126] More of the same was reported in a blog of the National Association of Manufacturers (NAM):

> "We can now add California to the growing list of agencies that have concluded that BPA does not pose a risk to the general public," said Dr. John M. Rost, NAMPA [North American Metal Packaging Alliance] Chairman. "It's important to note that when politics and media interference are taken out of the process, and safety decisions are made by qualified, independent scientific experts, we see the same conclusion time and time again—that BPA is safe."[127]

### *B. Defining "Reproductive Toxicity" Consistent with Advancing Science*

There was significant discussion and confusion in the hearing as to the scope of adverse effects within the realm of "reproductive toxicity." Industry took the position that many of the adverse effects identified by the opposition at the hearing are not within the realm of "reproductive toxicity" and thus fall outside regulatory jurisdiction.[128] According to an article authored by thirty-six sponsoring scientists, the effects of BPA excluded from consideration in industry-sponsored studies include: altered metabolism related to metabolic syndrome; altered adiponectin secretion (a condition predicting heart disease and type 2 diabetes); altered epigenetic programming leading to precancerous lesions of the prostate; differential growth patterns in the developing prostate; abnormal growth, gene expression, and precancerous lesions of the mammary glands; adverse effects on the female reproductive system, in-

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breitbart.com/Big-Government/2010/04/29/Junk-Science-Has-Consequences—-Environmental-Lobby-Shows-No-Concern-for-California—s-Financial-Woes. Kerri Toloczko is a Senior Fellow at Let Freedom Ring specializing in policy analysis, issue advocacy, and coalition building for the public policy community. *Kerri Toloczko*, THE HUFFINGTON POST, http://www.huffingtonpost.com/kerri-toloczko (last visited Dec. 30, 2012).

126. Nick Kump, *Unsuspecting Californians Footing Bill for NRDC Scare Campaign*, ELMETS COMMC'NS (July 12, 2011, 12:18 PM), http://www.elmets.com/blog/unsuspecting-californians-footing-bill-for-nrdc-scare-campaign.

127. Carter Wood, *Scientific Integrity: Calif. Board Dismisses BPA as Health Threat*, SHOPFLOOR (July 17, 2009), http://shopfloor.org/tag/proposition-65. Shopfloor is a blog of the National Association of Manufacturers. *About*, SHOPFLOOR, http://www.shopfloor.org/about-nam (last visited Dec. 30, 2012).

128. *See DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at ii, 135–38 (statement of Dr. Jay Murray, Murray & Associates).

cluding uterine fibroids, paraovarian cysts, and chromosomal abnormalities in oocytes; and neurochemical and behavioral abnormalities.[129]

One difficulty during the hearing involved the division of responsibility between the Developmental and Reproductive Toxicant (DART) Identification Committee and the Carcinogen Identification Committee (CIC). Although Proposition 65 simply requires the "opinion of the state's qualified experts,"[130] regulations divide the task: review of toxicity as a carcinogen is completed by the CIC, whereas review of toxicity as a reproductive toxin is completed by the DART Identification Committee.[131] It is evident from the hearing that existing procedures and Guidelines are inadequate to prevent critical issues from falling between the DART Identification Committee and the CIC, and others from potentially being excluded entirely from the review process.

In the Guidelines, the DART Identification Committee reserved for itself the question of "transplacental carcinogenesis."[132] However, in the hearing on BPA, the Committee clearly had difficulty parsing out that issue. The Committee specifically asked its chief counsel whether neoplastic lesions that are attributed to exposure neonatally would be under the DART Identification Committee or under the CIC, and whether it was necessary that the lesion impact the reproductive potential of the animals.[133] She responded by simply turning the question back on the Committee: "[I]t's probably not as clear as it could be, but it is somewhat in your area of expertise whether you think that is an effect or not."[134]

Although there was significant discussion concerning carcinogenicity, in the end, this issue was largely ignored by the DART Identification Committee members. Dr. vom Saal, a leading BPA

129. John Peterson Myers et al., *Why Public Health Agencies Cannot Depend on Good Laboratory Practices as a Criterion for Selecting Data: The Case of Bisphenol A*, 117 ENVTL. HEALTH PERSP. 309, 309, 310 (2009).

130. CAL. HEALTH & SAFETY CODE § 25249.8(b) (West 2006).

131. CAL. CODE REGS. tit. 27, § 25102(c) (2009); CAL. CODE REGS. tit. 27, § 25305(a), (b) (2012).

132. OEHHA CRITERIA FOR RECOMMENDING CHEMICALS FOR LISTING, *supra* note 88, at 2.

133. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 222–24; *see also* Letter from Dr. Sarah Janssen et al., *supra* note 116, at 3 (expressing concern that the Committee, in its confusion, inappropriately avoided the question as to whether BPA was a "transplacental" carcinogen).

134. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 224.

university research scientist[135] testifying in favor of the listing, mentioned that Dr. Huff from the National Cancer Institute wrote an article drawing the conclusion that if BPA were evaluated using current standards,[136] it would be deemed a carcinogen.[137] Also addressing the issue of carcinogens, Dr. Wu of the OEHHA staff reported on effects of BPA in mice that are "typically associated with carcinogenesis," including significant increases in "the number of terminal end buds," "maturation of cells comprising the fat pad," "altered localization of collagen," and "cell cycle alteration" in the mammary gland.[138]

During the final DART Identification Committee discussion, OEHHA staff member Dr. Zeise noted that although they "didn't look in detail at the cancer endpoint, there are a number of early-in-life studies and in utero studies that show precursor lesions."[139] Committee Member White also noted "the possibility of mammary gland alterations and lesions," which he considered "very significant" in relation to "breast cancer lesions."[140] However, Dr. Zeise reiterated that the Committee "didn't evaluate the carcinogenicity studies."[141]

"Developmental effects" that result entirely or predominantly from postnatal exposure were also excluded from consideration.[142] According to OEHHA Chief Counsel Monahan-Cummings, this narrow interpretation was based on the Preamble to Proposition 65, which identifies the chemicals of concern as those that "cause cancer, *birth defects*, or other reproductive harm."[143] She explained, "So our interpretation of that has been that we are looking at prenatal exposures that may cause, you know, developmental effects after birth, but we're not looking at exposures after birth that may cause [developmental] effects later."[144] "Transplacental carcinogenesis,"

135. *Id.* at ii, 56 (Dr. vom Saal is from the University of Missouri and has been conducting BPA research funded by the National Institute of Environmental Health Sciences for 13 years).

136. *Id.* at 234 (based on the studies discussed by an industry representative, Dr. Hentges from the American Chemistry Council).

137. *Id.*

138. *Id.* at i, 26.

139. *Id.* at 251.

140. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 233.

141. *Id.* at 234.

142. *DART Meeting on Proposition 65* (July 12, 2011), *supra* note 83, at i, 117 (statement of Dr. Jim Donald, Chief, Reproductive Toxicology & Epidemiology Section, California Office of Environmental Health Hazard Assessment).

143. *Id.* at 126 (emphasis added) (citing to page 53 of the preamble to Proposition 65).

144. *Id.* at 126–27.

for example, is listed only under "developmental toxicity" (one component of "reproductive toxicity"),[145] and not under the other components, "female reproductive toxicity," or "male reproductive toxicity."[146] "Developmental toxicity" concerns "adverse effects *on the products of conception,*"[147] in other words, effects due to prenatal exposure.

This fragmentation of the review process that excludes consideration of postnatal exposure in evaluating "developmental toxicity," complicates the review of rodent studies. In order to evaluate the period of prenatal exposure in humans, the corresponding time period for analysis of exposure in rodents includes a period of postnatal exposures. As Dr. Woodruff explained in her testimony:

> [W]hile most of the studies on BPA are from rodents or mice . . . the period of development of mice is somewhat different than the period of development for humans in terms of the actual timing of birth. So human gestation goes up to about 40 weeks. This is equivalent to both prenatal gestation for the mice and also postnatal growth up to about Day 50. So any experiments done in mice from prenatal or *up to postnatal day 50* is equivalent to prenatal experiments in humans.[148]

Confusion clearly reigned on this issue. Committee Member Roberts noted, "[W]hat I tried to limit myself to are where the exposure in the animal studies occurred in what would be considered equivalent to prenatal exposure in the human, which is pretty much the gestational period in a rodent, plus maybe *a few days* afterwards."[149] According to Dr. vom Saal, this narrowing of the scope of relevant studies is significant. Many studies have been done on the neonatal rodent, where the researcher can directly control ex-

145. OEHHA CRITERIA FOR RECOMMENDING CHEMICALS FOR LISTING, *supra* note 88, at 1 ("For purposes of these criteria, 'reproductive toxicity' includes 'developmental toxicity', 'female reproductive toxicity', and 'male reproductive toxicity'.").

146. *Id.* at 2–3.

147. *Id.* at 1–2 (emphasis added) (including but not limited to: "(1) Embryo/fetal mortality (including resorption, miscarriage/spontaneous abortion, or stillbirth), malformations, structural abnormalities and variations, altered fetal growth, and change in gestational age at delivery. (2) Postnatal parameters including growth and development, physiological deficits and delay, neurological, neurobehavioral and psychological deficits, altered sex ratio, abnormal sexual development or function, and morbidity or mortality. (3) Transplacental carcinogenesis. (4) Somatic or genetic (germ cell) mutations in the conceptus.").

148. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 81–82 (emphasis added) (statement of Dr. Tracey Woodruff, University of California, San Francisco) (partially reiterating earlier statements by Dr. vom Saal).

149. *Id.* at 235 (emphasis added).

posure instead of trying to control exposure to the fetus through exposure to the mother.[150] By evaluating exposures to the neonatal rodent, researchers can use biomonitoring of chemical blood levels to compare exposure to that of the human fetus.[151]

To simplify matters and align Committee deliberations with the intent of the voters, the issue of "transplacental" carcinogenesis should be included not only under the definition of "developmental toxicity," but also under a broad regulatory interpretation of "reproductive toxicity." "Reproductive toxicity" could be defined to include both prenatal and postnatal exposures that seriously and adversely affect the endocrine system and reproductive organs. The voters broadly stated that they were interested not only in cancer and birth defects, but also "other reproductive harm," which may be understood to include cancer and precancerous conditions in the reproductive organs, regardless of whether those effects were due to prenatal or postnatal exposure. Moreover, treatment for cancer in reproductive organs, both breast and prostate cancer, may include chemotherapy and hormone suppression, the effects of which include "chemical castration" and infertility.[152] Broadly defining "reproductive toxicity" to include consideration of carcinogenicity to the extent that it is related to endocrine disruption would allow for more holistic consideration of endocrine disrupting chemicals and avoid the possibility of significant issues falling between the DART Identification Committee and the CIC.

Even aside from the question of carcinogenicity, there was also considerable confusion in the discourse as to the realm of "repro-

150. Telephone Interview with Dr. Frederick S. vom Saal, Curators' Professor, Div. of Biological Sci., Coll. of Arts & Sci., Univ. of Mo.-Columbia (Sept. 22, 2011); *see* e-mail from Dr. Frederick S. vom Saal, Curators' Professor, Div. of Biological Sci., Coll. of Arts & Sci., Univ. of Mo.-Columbia, to author (Sept. 22, 2011, 10:22 AM) [hereinafter e-mail from Dr. Frederick S. vom Saal (Sept. 22, 2011, 10:22 AM)] (on file with author).

151. Telephone Interview with Dr. Frederick S. vom Saal, *supra* note 150; e-mail from Dr. Frederick S. vom Saal (Sept. 22, 2011, 10:22 AM), *supra* note 150.

152. *See, e.g.*, Tiina Saarto et al., *Chemical Castration Induced by Adjuvant Cyclophosphamide, Methotrexate, and Fluorouracil Chemotherapy Causes Rapid Bone Loss that Is Reduced by Clodronate: A Randomized Study in Premenopausal Breast Cancer Patients*, 15 J. CLINICAL ONCOLOGY 1341, 1341 (1997); *Living with Prostate Cancer: Loss of Fertility*, PROSTATE CANCER FOUND., http://www.pcf.org/site/c.leJRIROrEpH/b.5837043/k.B194/Loss_of_Fertility.htm (last visited Jan. 13, 2013); *cf. Hormone Blockade Makes Radiation Therapy More Effective for Medium and High-Risk Localized Prostate Cancer*, PSA RISING MAGAZINE (Sept. 13, 2000), http://psa-rising.com/medicalpike/ebr/plus-hormone-df-0900.shtml (reporting that radiation in combination with androgen suppression therapy helps block the production or action of male hormones that have been shown to fuel prostate cancer).

ductive toxicity" generally. Industry representatives repeatedly attempted to dismiss studies that revealed negative effects of BPA by arguing that those effects were outside regulatory purview. Dr. Murray (a former DART Identification Committee member introduced by the lawyer representing the American Chemistry Council)[153] explained in his testimony: "most of these studies do not take it out to a reproductive endpoint. A lot of them focus on unique endpoints. Some of them look at molecular approaches and there's nothing wrong with that, but they're not tied to an adverse effect."[154] Dr. Tyl, also speaking on the side of industry, focused the Committee's attention on the most obvious of endpoints:

> So we're looking at endpoints that indicate adverse outcome, okay. We're not looking at the early molecular biochemical kinds of markers. Not that they're not interesting and fascinating and not that they shouldn't be pursued, but we're looking at endpoints. What is the—is there an adverse consequence to these early changes?[155]

Remarking on one study, she noted, "[T]he animals bred. They got pregnant. They had babies. They developed the babies. They went through puberty. They grew up. They had babies."[156]

The OEHHA staff presentation, although evading any conclusions as to whether the regulatory standard had been satisfied, discussed more sophisticated studies and appeared to support reliance on more subtle endpoints as the foundation for a conclusion as to reproductive toxicity. Dr. Moran, a staff toxicologist reporting on the endocrine activity of BPA, explained that BPA interferes with reproductive hormones as well as glucose and insulin in a way that can both increase or decrease production, and that BPA interferes with metabolism.[157] As to female reproductive toxicity, another staff toxicologist, Dr. Wu, concluded that there were "limited data on reproductive effects of Bisphenol A in women," that "recurrence of miscarriage in women is possibly consistent with the perturbation of the meiotic cell cycle and the chromosome misalignment in oocytes noted in laboratory animals," that "[n]umerous female animal studies showed effects on the female reproductive system from Bisphe-

153. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at ii, 94 (statement of Stanley Landfair, American Chemistry Council).

154. *Id.* at ii, 135–36 (statement of Dr. Jay Murray, Murray & Associates).

155. *Id.* at ii, 126 (statement of Dr. Rochelle W. Tyl, RTI International).

156. *Id.* at ii, 121–22 (statement of Dr. Rochelle W. Tyl, RTI International).

157. *See id.* at i, 44 (statement of Dr. Francisco Moran-Messen, Staff Toxicologist, Reproductive Toxicology and Epidemiology Section, California Office of Environmental Health Hazard Assessment).

nol A," and that "[a]lterations to the uterus, ovary, follicles and oocytes, estrous cycle, vagina and mammary gland were notable."[158] Assuming the relevance of these endpoints, limited evidence of the negative effects of BPA in humans, supported by sufficient experimental animal data, would fall within the criteria for a finding of "reproductive toxicity" under the Guidelines.[159]

The Guidelines broadly define female and male "reproductive toxicity" to include "genetic damage to the ovum [or spermatozoon] or its precursors" and "impaired or altered endocrine function."[160] However, it is not clear that they were understood or interpreted so as to allow for consistency with modern science. As Dr. vom Saal explains, if understood in the context of modern science, "endocrine function" includes not only effects on hormones transmitted in the blood, but all methods of signaling between and within cells, including neurotransmitters that act as endocrine signals.[161] According to the Endocrine Society, although endocrine-disrupting chemicals were originally thought to exert actions primarily through nuclear hormone receptors,[162] it is now understood that the mechanisms are much broader than originally recognized: endocrine disruptors act via nuclear receptors, nonnuclear steroid hormone receptors,[163] nonsteroid receptors,[164] enzymatic pathways involved in steroid biosynthesis and/or metabolism, and numerous other mechanisms that involve both the endocrine and the reproductive systems.[165]

Given advances in science, OEHHA should follow the National Toxicology Program's new, more holistic approach and pursue the broadest possible regulatory interpretation consistent with the language of Proposition 65. "Reproductive toxicity" should be clearly defined and interpreted so as to include all serious adverse effects

158. *Id.* at i, 27–28 (statement of Dr. Lily Wu, Staff Toxicologist, Reproductive Toxicology and Epidemiology Section, California Office of Environmental Health Hazard Assessment).

159. OEHHA CRITERIA FOR RECOMMENDING CHEMICALS FOR LISTING, *supra* note 88, at 4.

160. *Id.* at 2–3.

161. *See* e-mail from Dr. Frederick S. vom Saal (Sept. 22, 2011, 10:22 AM), *supra* note 150.

162. Diamanti-Kandarakis et al., *supra* note 9, at 294 (including estrogen receptors, androgen receptors, progesterone receptors, thyroid receptors, and retinoid receptors).

163. *Id.* (e.g., membrane ERs).

164. *Id.* (e.g., neurotransmitter receptors, such as the serotonin receptor, dopamine receptor, and norepinephrine receptor, and orphan receptors, such as the aryl hydrocarbon receptor (AhR)).

165. *Id.*

related to the functioning of the endocrine system, including all effects that cause people pain, cost society money, and lead to other serious health conditions, like precancerous conditions and obesity. As explained above, expanding the realm of relevant endpoints would also allow the DART Identification Committee to remain aligned with the new National Toxicology Program Office of Health Assessment and Translation and may encourage the designation of this reincarnation of the NTP-CERHR as an authoritative body. California's OEHHA should open a rulemaking proceeding and encourage the participation of scientists highly specialized in the effects of endocrine chemicals. According to Dr. vom Saal, the concept of "reproductive toxicity" should include all adverse developmental effects where there is permanent adverse change caused by a chemical at the genetic, epigenetic, molecular, cellular, tissue, organ, organism, or population level.[166] Such a definition would necessarily also include endocrine disruption that leads to precancerous conditions and allow for more holistic review of endocrine-disrupting chemicals.[167]

## III.
## RESEARCH DESIGN AND QUALITY STANDARDS TO ASSESS AND EVALUATE ADVOCACY SCIENCE

Another difficulty that arose in the DART hearing on BPA was the question of how to weigh and evaluate conflicting studies. The only mention of any standard came from Stanley Landfair, the lawyer representing industry, who urged the Committee to use the "weight-of-the-evidence approach."[168] He clarified that the Committee knew better than he what that meant, but that it did not mean "simply to count up the studies."[169] The Guidelines state the following as "weight of evidence" considerations:

> (1) Data on a single species from a well conducted developmental or reproduction study may be sufficient to classify an agent as a reproductive toxicant provided there are not *equally well conducted studies* which do not show an effect and which

166. *See* e-mail from Dr. Frederick S. vom Saal, Curators' Professor, Div. of Biological Sci., Coll. of Arts & Sci., Univ. of Mo.-Columbia, to author (Sept. 22, 2011, 9:58 AM) (on file with author) (noting that considerations at the "population level" should include, for example, changes such as those seen in fish, where populations are found to have fifty percent intersex members).

167. *Id.*

168. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at ii, 95 (statement of Stanley Landfair, American Chemistry Council).

169. *Id.* (statement of Stanley Landfair, American Chemistry Council).

> have sufficient power to call into questions [sic] the repeatability of the observation in the positive study.
> (2) Data on more than one species or from more than a single study increase the confidence for classification of an agent as a reproductive toxicant.[170]

Missing are any detailed criteria by which to evaluate conflicting studies or to consider issues of appropriate research design or conflicts of interest. The lack of such criteria was particularly important in the review of BPA, where, as may be expected when significant economic interests are involved,[171] there have been serious allegations of advocacy science.[172] A 2005 analysis of BPA literature revealed that the funding source correlated perfectly with the findings.[173] Of the 115 studies on health effects of BPA, 94 were government-funded studies conducted in domestic and international academic laboratories.[174] All of these government-funded studies found adverse effects at low-dose exposure, yet not a single industry-funded study reported adverse effects.[175]

Industry involvement with the regulatory review of BPA has been persistent and extensive. In 2006, the National Toxicology Program's Center for the Evaluation of Risks to Human Reproduction (NTP-CERHR) published a draft advisory panel report that was allegedly written largely by an outside consultant who was fired the next year after public disclosure of its conflicts of interest with the regulated industry.[176] Still building on this report as its foundation document,[177] the FDA relied on only two studies, both sponsored by the American Plastics Council, as the basis of its initial decision

170. OEHHA CRITERIA FOR RECOMMENDING CHEMICALS FOR LISTING, *supra* note 88, at 5 (emphasis added).

171. *See generally* THOMAS O. MCGARITY & WENDY E. WAGNER, BENDING SCIENCE: HOW SPECIAL INTERESTS CORRUPT PUBLIC HEALTH RESEARCH (2008).

172. *See* Frederick S. vom Saal & Claude Hughes, *An Extensive New Literature Concerning Low-Dose Effects of Bisphenol A Shows the Need for a New Risk Assessment*, 113 ENVTL. HEALTH PERSP. 926, 926 (2005).

173. *See id.*

174. *Id.*

175. *See id.* at 928.

176. Houlihan et al., *supra* note 106 (citing CTR. FOR THE EVALUATION OF RISKS TO HUMAN REPROD., NAT'L TOXICOLOGY PROGRAM, U.S. DEP'T OF HEALTH & HUMAN SERVS., DRAFT NTP-CERHR REPORT ON THE REPRODUCTIVE AND DEVELOPMENTAL TOXICITY OF BISPHENOL A (2006), *available at* http://ntp.niehs.nih.gov/ntp/ohat/bisphenol/Bispehnol_A_Draft_Report.pdf).

177. Susanne Rust et al., *Plastics Industry Behind FDA Research on Bisphenol A, Study Finds*, JOURNAL SENTINEL (Oct. 23, 2008), http://www.jsonline.com/watchdog/watchdogreports/34469194.html.

concerning the safety of BPA in February 2008.[178] In March of 2008, as part of its investigation of BPA, the U.S. House of Representatives Committee on Energy and Commerce and its Subcommittee on Oversight and Investigations sent an inquiry to The Weinberg Group asking questions about case studies reported on its website that "tout its successes in certain scientific and regulatory matters."[179] Many of the case studies reflected involvement in advocacy science, noting such objectives as "delay[ing] cancellation of a new drug," combining "epidemiologial [sic] expertise with across-the-board strategic thinking," development of a "defensible message," and identifying "a national team of expert scientists" who "also prepared reviews for publication."[180] Later, in October of 2008, after the FDA appointed a subcommittee to review its Draft Assessment of BPA, a research institute founded and co-directed by the subcommittee's chairman was reported to have received five million dollars from an outspoken opponent of BPA regulations,[181] who had reportedly expressed his views that BPA was "perfectly safe" to the chairman on several occasions.[182]

Given the advocacy effort, it is not surprising that industry-funded studies managed to find their way to the forefront of regulatory review. According to an article authored by John Peterson Myers and Frederick S. vom Saal and signed onto by thirty-four scientists, most of whom were employed by national or international universities:

> Despite strong evidence of aberrations caused by low doses of BPA in animals exposed during fetal and neonatal life in studies conducted by the world's leading academic and government experts in the fields of endocrine disruption,

178. Letter from Steven R. Mason, Acting Assistant Comm'r for Legislation, FDA, Dep't of Health & Human Servs., to John D. Dingell, Chairman, Comm. on Energy & Commerce, U.S. House of Representatives 2–3 (Feb. 25, 2008), *available at* http://www.bdlaw.com/assets/attachments/FDA_Letter_to_House_Energy_Committee_re_BPA.pdf.

179. Letter from John D. Dingell, Chairman, Comm. on Energy & Commerce, U.S. House of Representatives, & Bart Stupak, Chairman, Subcomm. on Oversight & Investigations, Comm. on Energy & Commerce, U.S. House of Representatives, to Matthew R. Weinberg, Chief Exec. Officer, The Weinberg Grp. at 1 (Mar. 6, 2008), *available at* http://democrats.energycommerce.house.gov/images/stories/Documents/investigations/public_health/Bisphenol.030608.Weinberg.pdf.

180. *Id.* at 1–2.

181. Susanne Rust & Meg Kissinger, *FDA Looks into Bisphenol A Advocate's Donation to Science Center*, JOURNAL SENTINEL (Oct. 15, 2008), http://www.jsonline.com/watchdog/watchdogreports/34469724.html; Rust et al., *supra* note 177.

182. Rust et al., *supra* note 177.

> endocrinology, neurobiology, reproductive biology, genetics, and metabolism, a relatively small number of studies reporting no adverse effects at low doses of BPA have continued to be promoted by the chemical industry and used by regulatory agencies.[183]

Myers and vom Saal reported that the chemical industry managed to secure a position of superiority for their studies by pointing out that other studies did not conform to "good laboratory practices" (GLP).[184] Not only were industry representatives touting compliance with these GLP standards at the DART hearing,[185] but industry studies also rode this coattail through the FDA review process,[186] which created persuasive precedent for the industry-friendly decision by the DART Identification Committee. The protesting scientists explain, however, that "good laboratory practices," are merely the name given to regulatory standards that involve certain record keeping and related requirements that are not generally the standard at small university laboratories.[187] The GLP rules were issued to address potential conflicts of interest and outright fraud by vested interests, and are arguably inappropriate in a university setting, where studies are publicly funded with no apparent conflicts of interest.[188] Moreover these scientists maintain that reliance on GLP confuses and merges the question of reliability (whether the

183. Myers et al., *supra* note 129, at 309–10.

184. *See id.* at 309–10, 314.

185. *See, e.g.*, *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 115, 123, 125–26 (statements of Dr. Rochelle W. Tyl, representing RTI International) ("[T]his was a guideline study. We did it under the U.S. EPA OPPTS testing guidelines, Office of Prevention—OPP, Pesticides and Toxic Substances." "This study exceeded the OECD regulatory guidelines." "So in conclusion based on our study guidelines—and our studies are guideline studies under good laboratory practices.").

186. Myers et al., *supra* note 129, at 309. The FDA and the European Food Safety Authority (EFSA) each took actions that deemed two industry-funded GLP studies to be superior to hundreds of other publicly funded studies. *Id.*

187. *Id.* at 309. The requirements concern the "care and feeding of laboratory animals, standards for facility maintenance, calibration and care of equipment, personnel requirements, inspections, study protocols, and collection and storage of raw data." *Id.*

188. *See id.* at 309–10. The rules were first issued by the U.S. FDA in 1978 in response to a situation of sloppy laboratory practices that were ultimately discovered to involve outright fraud. The discovery of these practices led the EPA to require reexamination of more than 4000 tests conducted by one of the largest private laboratories, and brought into question fifteen percent of the pesticides brought into use in the United States. *Id.*

results are replicable) with the separate question as to whether the methods used result in finding the truth.[189]

Myers and vom Saal identify many flaws in the industry sponsored studies, including reporting an impossibly high prostate weight for control animals[190] (thus creating an inappropriate point of comparison for the BPA treated animals), selecting inappropriate animal models (use of a species of rat insensitive to estrogen), ignoring the failure of the positive control to show an effect (which "indicates the experiment failed"), ignoring an inordinately high dose required for the positive control (estradiol) to cause an effect (indicating that the system is insensitive to exogenous estrogens and thus inappropriate for studying BPA), ignoring test systems likely contaminated with estrogen (where responses of the negative control animals did not differ from the responses of animals given significant doses of the known estrogenic chemical, DES), and using "outdated and insensitive assays" incapable of detecting low dose endocrine-disrupting effects of BPA.[191]

The sheer number of reputable scientists reporting serious research design problems with industry sponsored studies suggests the need for new rules to create standards for research quality and design. Borrowing from another context, it may be instructive to reflect on the criteria that the Supreme Court identified in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, to address the question of whether potentially dubious evidence may be put before a jury.[192] These standards are not generally applicable in the context of administrative law, where the agency is thought to have sufficient expertise to sort out the quality of the science.[193] However, here, in the context of BPA regulation, where there are questions about the

189. *See* Myers et al., *supra* note 129, at 309–10.

190. *Id.* at 311 (exceeding by seventy percent the prostate weights reported by other studies).

191. *Id.* at 310–12; *see also* Vom Saal & Welshons, *supra* note 13, at 63–66. ("When the positive control does not show a positive effect, one has to decide whether the system being studied is completely unresponsive to estrogenic stimulation . . . or whether there was contamination by estrogen that interfered with detection of an estrogenic response . . . . The purpose of including negative and positive controls for estrogenic activity and making comparisons to historic data on negative and positive control values from prior experiments is to be able to make this determination . . . .") (citation omitted).

192. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579 (1993).

193. *See* Bayliss v. Barnhart, 427 F.3d 1211, 1218 n.4 (9th Cir. 2005) (explaining that *Daubert* does not govern the admissibility of evidence in an administrative proceeding where Federal Rule of Evidence 702 is inapplicable). *But see* Niam v. Ashcroft, 354 F.3d 652, 660 (7th Cir. 2004) (applying the "spirit of *Daubert*" to administrative proceedings).

expertise of the Committee (discussed in the next section) and especially given the complexity of endocrine-disrupting chemicals, some guidelines may be particularly useful.

The *Daubert* inquiry is flexible, but there are several questions the judge must consider. The first is whether the "theory or technique has been subjected to peer review and publication," since submission to the scrutiny of the scientific community is considered "a component of 'good science,' in part because it increases the likelihood that substantive flaws in methodology will be detected."[194] However, publication is not always a marker of good science. As Thomas McGarity and Wendy Wagner show in their book, *Bending Science*, the peer review process has proven incapable of consistently identifying and filtering out bent science.[195] In the ongoing battle over BPA, twenty-four scientists signed on as authors of a letter to the editor of Toxicological Sciences requesting that the journal adopt guidelines to screen out flawed research.[196] Identifying flaws in a study on BPA accepted for publication, the authors explained that the study did not establish the sensitivity of the test animal (the "LE rat") to the positive control ethinylestradiol before determining what dose of BPA to test in their study.[197] They explained that the lowest effect dose of ethinylestradiol for the LE rat was "2500-fold higher than the maternal dose required to stimulate effects on offspring in mice," and that the study reported no effect of ethinylestradiol at doses "sufficient to cause temporary sterility in 99.7% of women who properly use oral contraceptives."[198] They further explained that a potential contributor to the low sensitivity to estrogen was the use of polycarbonate cages made from BPA.[199]

Given the prevalence of advocacy science, rules establishing standards for appropriate research design may be more effective than relying on the peer review process alone. Following *Daubert*, additional considerations might also include the known or potential rate of error, the existence and maintenance of standards controlling the technique's operation (which in this case could include the appropriate use of positive and negative controls), and "general acceptance," meaning "'explicit identification of a relevant scien-

194. *Daubert*, 509 U.S. at 593.

195. MCGARITY & WAGNER, *supra* note 171, at 10.

196. Frederick S. vom Saal et al., *Flawed Experimental Design Reveals the Need for Guidelines Requiring Appropriate Positive Controls in Endocrine Disruption Research*, 115 TOXICOLOGICAL SCI. 612, 612–13 (2010).

197. *Id.* at 612.

198. *Id.* at 612–13.

199. *Id.* at 613.

tific community and an express determination of a particular degree of acceptance within that community.'"[200] Widespread acceptance is an important factor: "'a known technique which has been able to attract only minimal support within the community' . . . may properly be viewed with skepticism."[201] Given the fierce debate between industry scientists on the one hand and government and university scientists on the other, a rule requiring consideration of general acceptance in the scientific community might have led to an entirely different outcome and a significant regulation of BPA.

## IV.
## A MORE SPECIALIZED COMMITTEE, AN EXTENDED REVIEW PERIOD, AND CLEAR DISCLOSURE OF CONFLICTS OF INTEREST

Rules are also needed to establish more specialized qualifications for the review committee, to allow for a longer review period, and to require disclosure of conflicts of interest to assist the Committee in evaluating the "weight of the evidence" in this complicated and specialized area of science.

Endocrine disruptors are particularly complicated not only due to their breadth of action, but also the very different consequences they may have depending upon the age of exposure.[202] There is a lag between the time of exposure and the manifestation of a disorder, and different classes of endocrine disruptors may be additive or even synergistic.[203] There may be transgenerational effects, affecting not just the exposed individual, but also children and subsequent generations.[204] Endocrine disruptors can cause adverse effects at infinitesimally low levels of exposure, and may exert more potent effects at low doses than at higher doses; they have been known to have nontraditional dose-response curves, such as inverted-U or U-shaped curves.[205]

200. Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 594 (1993) (quoting United States v. Downing, 753 F.2d 1224, 1238 (3d Cir. 1985)).

201. *Id.* (citation omitted) (quoting *Downing*, 753 F.2d at 1238).

202. *See* POSITION STATEMENT: ENDOCRINE-DISRUPTING CHEMICALS, *supra* note 10, at 1–2.

203. *See id.* at 1, 3.

204. *Id.* at 2.

205. *See* POSITION STATEMENT: ENDOCRINE-DISRUPTING CHEMICALS, *supra* note 10, at 2; Diamanti-Kandarakis et al., *supra* note 9, at 296.

The current standards do not require the DART review board to have any particular expertise in endocrinology. The regulatory standard for the composition of the review board requires only that they be "experts from among the following areas of specialization: epidemiology, developmental toxicology, reproductive toxicology, teratology, medicine, public health, biostatistics, biology, toxicology, and related fields." [206] The DART Identification Committee meets as infrequently as once a year, and it reviews a broader class of chemicals than just endocrine disruptors.[207] The DART Identification Committee members at the time of the BPA hearing included a toxicologist from Chevron, a family practitioner who has since served as a tobacco industry spokesperson, and representatives from the following university departments: anatomy, epidemiology and preventative medicine, obstetrics and gynecology, pediatrics, nutrition, and family and preventative medicine.[208] Responding to concerns about the adequacy of expertise of Committee members, the OEHHA Director has acknowledged that "the appointment of additional members to the committee with backgrounds in areas such as male reproductive hazards would benefit the committee's overall review of certain chemicals for possible listing."[209]

At the DART Identification Committee's hearing, the discussion on BPA reflected confusion about basic principles of endocrinology. Dr. Keen, rephrasing statements by Dr. vom Saal, identified vom Saal's hypothesis as identifying the possibility of a trimodal response where there are "very bad effects potentially at parts per trillion," at "parts per billion it gets a little bit better," and then at "parts per million maybe it gets worse again."[210] At least one of the

206. CAL. CODE REGS. tit. 27, § 25302(b)(2) (2009).

207. CAL. CODE REGS. tit. 27, § 25302(c) (2009); CAL. CODE REGS. tit. 27, § 25305(b) (2012).

208. *See DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at i, 2; e-mail from Monet Vela, Public Records Act Coordinator, Cal. Office of Envtl. Health Hazard Assessment (OEHHA), to author (May 27, 2011, 11:42 AM) [hereinafter e-mail from Monet Vela] (on file with author) (containing resumes of DART Committee members); *see also* Letter from Dr. Sarah Janssen et al., *supra* note 116, at 1 (expressing concern regarding the lack of expertise of the DART Committee); Dan Morain, *Big Tobacco's Unlikeliest Ally*, SACRAMENTO BEE, http://www.sacbee.com/2012/05/06/4467266/big-tobaccos-unlikeliest-allyphysician.html (last updated Sept. 11, 2012).

209. Letter from Joan Denton, *supra* note 117, at 2.

210. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 73–74 (statement of Dr. Carl Keen, Member, Developmental and Reproductive Toxicant Comm., California Office of Environmental Health Hazard Assessment) (rephrasing statements from Dr. Frederick vom Saal's presentation).

Committee members seemed incredulous, noting, "[I]f it's at high-dose levels, anything—particularly with meds, as we know, the higher you go with respect to dose, then you're going to start to see some effects."[211] Another Committee member mentioned the possibility of a trimodal response, reflected on the need for additional studies and concluded: "I do have a fear. My fear is, is that we are—because we're looking at the data the way we're supposed to, and it's as a whole that . . . we could be missing a clear and present danger."[212]

The science in this area is highly sophisticated and the language is difficult for someone outside the field to comprehend. Take for example, the following explanation from Dr. vom Saal at the hearing:

> And the fact that Bisphenol A can alter epigenetic programming was demonstrated by Dolinoy a couple years ago, where they took a mouse with a retrotransposon, a gene spliced into the animal, that if it's demethylated, and therefore active, then this gene causes obesity and a coat color change. What they demonstrated was that Bisphenol A led to a gene where there were no methyl groups available as opposed to the gene being normally silenced by being methylated. So this is a clear example of epigenetic programming and permanent silencing or activation of genes that totally alter the life history of the animal.[213]

Simplifying the matter somewhat, he did show a picture of a rather fat mouse.[214] As confirmed later via e-mail, the above quoted language means that the study provided evidence that BPA alters genetic programming in such a way as to create a predisposition to obesity.[215]

Even the most basic question as to the applicability of animal studies was at issue. Dr. vom Saal explained:

> [T]hese cell culture studies indicate that at the cellular level, there's no difference in response to Bisphenol A between rat,

211. *Id.* at 230 (statement of Dr. La Donna White, Member, Developmental and Reproductive Toxicant Comm., California Office of Environmental Health Hazard Assessment).

212. *Id.* at 252 (statement of Dr. Carl Keen, Member, Developmental and Reproductive Toxicant Comm., California Office of Environmental Health Hazard Assessment).

213. *Id.* at 71.

214. *See* e-mail from Dr. Frederick S. vom Saal, Curators' Professor, Div. of Biological Sci., Coll. of Arts & Sci., Univ. of Mo.-Columbia, to author (May 29, 2011, 6:05 PM) (on file with author).

215. *Id.*

> mouse, and human cells. There are some pharmacokinetic differences, but they're not anywhere near great enough to account for the effects that you're seeing down in the four part per trillion range.[216]

However, Dr. Hentges, testifying for the American Chemistry Council, later provided another perspective, stating that there is "a significantly longer half-life for BPA in rodents and significantly greater systemic bioavailability" and that "[b]ecause of these key differences, extrapolation of any effects in rodent studies to humans would be tenuous. And in particular, effects that are observed in rodent studies are likely to over predict what could happen in humans."[217] In the final discussion, Committee Member White stated, "I can't see the extrapolation of the animals into human data."[218] Yet an international group of over thirty experts at a 2010 joint meeting of the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) recently came to the opposite conclusion, finding that, given similarities in BPA metabolism, animal studies can be appropriately used for extrapolation to humans.[219]

In addition to exposing the need for a more specialized review board, the discussion during the BPA hearing also suggests that a longer review period is warranted. With no proposed findings of fact or conclusions prepared by the full time OEHHA staff scientists, OEHHA asked far too much, especially of a Committee whose members hold full time professional positions and where their work on the Committee is outside their primary areas of expertise. At the end of the hearing, the DART Identification Committee was clearly overwhelmed. Committee Member Roberts noted the "huge num-

216. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 74–75.

217. *Id.* at 98, 103.

218. *Id.* at 230.

219. "Despite some differences between BPA metabolism and disposition in rodents and primates, internal exposures to aglycone BPA are remarkably similar for adult rodents, non-human primates and humans. This apparent lack of requirement for allometric scaling is atypical in the therapeutic drug and general chemical literature and suggests that a specific adjustment for interspecies differences in toxicokinetics is not required." FOOD & AGRIC. ORG. OF THE UNITED NATIONS & WORLD HEALTH ORG., JOINT FAO/WHO EXPERT MEETING TO REVIEW TOXICOLOGICAL AND HEALTH ASPECTS OF BISPHENOL A SUMMARY REPORT 12, 40–42 (2010), *available at* ftp://ftp.fao.org/ag/agn/agns/BPA_Summary_Report.pdf. According to Dr. vom Saal, this statement leaves no room for discussion as to the applicability of animal studies. e-mail from Dr. Frederick S. vom Saal, Curators' Professor, Div. of Biological Sci., Coll. of Arts & Sci., Univ. of Mo.-Columbia, to author (May 28, 2011, 1:14 AM) (on file with author).

ber of studies"[220] and that he had to review "this entire binder of information."[221] Dr. Hentges, testifying on behalf of the American Chemistry Council, made reference to NTP and European Union documents which hit the Committee members' mailboxes "with a very heavy thud about a month ago."[222] Committee Member Keen said, "I think the materials that we got were—I'll use the word 'overwhelming.'"[223] As a point of reference, in preparation for the 2006 meeting on the state of knowledge on BPA, thirty-eight of the world's leading scientific experts on BPA, organized as five panels of experts from different disciplines, prepared extensive working documents over a six month period reviewing different aspects of the BPA literature, covering in all over 700 published studies.[224] There are now approximately 1000 articles relating to BPA.[225]

An inadequate period of study preceding the DART hearing also sets up a situation where the hearing itself may have assumed predominant importance that is particularly troubling in this setting where there is industry-funded opposition. After a neutral presentation by staff, the format set up the illusion of two sides battling in a fair playing field, where the interests of one side should be balanced against the other. There was no discussion of conflicts of interest, and industry representatives failed to clearly identify themselves. The lawyer representing the American Chemistry Council introduced Jay Murray of Murray and Associates without clarifying whether Mr. Murray was representing a client:

> I don't think you need any introduction to Jay Murray. But for the audience, Jay was many years ago a member of this scientific advisory panel. He's an authority in this field. And he will speak to you about, what we call, the non-conventional studies, why they shouldn't be relied upon to support a regulatory conclusion.[226]

220. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 235.

221. *Id.* at 238.

222. *Id.* at 98–99.

223. *Id.* at 238.

224. The meeting was sponsored by the National Institutes of Health, the EPA, and Commonweal (a non-profit health and environmental research group). *Chapel Hill*, *supra* note 14, at 131–32, 138 (these experts concluded that people are exposed to BPA at levels that cause problems in wildlife and laboratory animals and that there is "great cause for concern" with regard to the potential for similar adverse effects in humans); Pete Myers, ENVTL. HEALTH NEWS (Aug. 11, 2007), http://www.environmentalhealthnews.org/newscience/2007/2007-0803chapelhillconsensus.html (synopsis of *Chapel Hill*, *supra* note 14).

225. Myers et al., *supra* note 129, at 310.

226. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at ii, 94.

Dr. Tyl, also speaking on the side of industry, stressed that she was not speaking as an "advocate," identified herself as working for a "nonprofit contract research organization" that was eighty percent federally funded, and declined to mention whether the particular studies she was presenting were funded by industry. [227]

The issue of undisclosed conflicts of interest was discussed in the aftermath of the BPA hearing. According to a report by representatives from environmental and public health organizations who spoke with Committee members after the hearing, two panel members had expressed their belief that industry had not even been present at the hearing, and that the American Chemistry Council (ACC) was just a non-profit organization,[228] presumably not understanding that it is a trade association representing chemical manufacturers whose stated mission is to improve the public image of the chemical industry and "deliver business value through exceptional advocacy."[229] Publicly discussing the issue of undisclosed conflicts of interest at a later hearing, the Committee was advised by its Chief Counsel that "the Open Meeting Act specifically says you cannot require someone to state their name, affiliation, or any other information if they want to speak in front of the group."[230] However, she also added that "[i]t doesn't say you can't ask."[231] The Committee took no additional action to resolve the issue.

Assuming the accuracy of this interpretation of California's Open Meeting Act,[232] another option would be to require OEHHA

227. *Id.* at ii, 112 ("What I thought I would do is go over the five studies that my staff and I have done at RTI with Bisphenol A. I'd like to just indicate that RTI is a nonprofit contract research organization. . . . We're about 80 percent funded federally and about 20 percent funded commercially.").

228. Letter from Dr. Sarah Janssen et al., *supra* note 116, at 2.

229. *About ACC*, AM. CHEMISTRY COUNCIL, http://www.americanchemistry.com/About (last visited Jan. 2, 2013).

230. *Meeting on Proposition 65 Before the Devtl. & Reprod. Toxicant Identification Comm. of the Office of Envtl. Health Hazard Assessment of the State of Cal.* 103–04 (Oct. 21, 2010), *available at* http://oehha.ca.gov/prop65/public_meetings/pdf/DARTIC102110Transcript.pdf (statement of Carol Monahan-Cummings, Chief Counsel, California Office of Environmental Health Hazard Assessment).

231. *Id.* at 104 (statement of Carol Monahan-Cummings, Chief Counsel, California Office of Environmental Health Hazard Assessment).

232. The Act itself only specifically refers to conditions placed on "attendance at a meeting," not speaking. CAL. GOV'T CODE § 11120 (West 2005); CAL. GOV'T CODE § 11124 (West 2005). However, in its interpretation of the Act, the California Attorney General's Office provides an example that refers to both attendance and speaking: "For example, while the Act does not prohibit use of a sign-in sheet, notice must be clearly given that signing-in is voluntary and not a pre-requisite to either attending the meeting or speaking at the meeting." OFFICE OF THE ATTORNEY GEN., CAL. DEP'T OF JUSTICE, A HANDY GUIDE TO THE BAGLEY-KEENE OPEN

staff to research and clearly identify issues concerning conflicts of interest in all studies that are considered and relied upon by the agency prior to any final decision. As has been recommended by Thomas McGarity and Wendy Wagner in the context of all policy-relevant research, there should be rules that require full disclosure of conflicts of interest, including the level of sponsor of any studies; disclosure of all affiliations, funding sources, and financial or management relationships; certification that all authors have agreed to be listed and have approved the manuscript; disclosure of the role that any sponsors played in study design, in the collection, analysis and interpretation of data, or in the writing of the report, or in the decision to submit the report for publication.[233]

## V.
## STANDARDS AND FINDINGS TO AVOID INAPPROPRIATE RELIANCE ON UNVERIFIED CLAIMS OF ADVERSE CONSEQUENCES

Another troubling issue at the DART hearing on BPA was the potential influence of testimony that brought evidence before the Committee that was both unverified and outside its statutory and regulatory purview. Industry representatives brought forward testimony consistent with their reported public relations strategy to highlight the costs of any restrictive regulatory measures by touting the benefits of BPA. [234] As reported by the *Washington Post*, based on internal notes of a private meeting:

> Industry representatives weighed a range of ideas, including "using fear tactics [e.g. "Do you want to have access to baby food anymore?" as well as giving control back to consumers (e.g. you have a choice between the more expensive product that is frozen or fresh or foods packaged in cans) as ways to dissuade people from choosing BPA-free packaging," the notes said. The attendees estimated it would cost $500,000 to craft a message for a public relations campaign, according to the notes. "Their 'holy grail' spokesperson would be a 'pregnant

MEETING ACT 9 (2004), *available at* http://ag.ca.gov/publications/bagleykeene2004_ada.pdf. An analysis of any First Amendment concerns is outside the scope of this paper.

233. MCGARITY & WAGNER, *supra* note 171, at 237–38.

234. *See* Lyndsey Layton, *Strategy Being Devised to Protect Use of BPA*, WASH. POST (May 31, 2009), http://articles.washingtonpost.com/2009-05-31/politics/36808376_1_bpa-canned-goods-notes.

young mother who would be willing to speak around the country about the benefits of BPA,'" the notes said.[235]

This strategy was in full force at the DART hearing on BPA. Although the testimony related to matters outside its charge, the DART Identification Committee nevertheless heard testimony about the benefits of BPA from both Dr. Hoyle from the North American Metal Packaging Alliance and Caroline Silveira from the Grocery Manufacturers Association.[236] Ms. Silveira testified as to BPA's "critical function in protecting the integrity of certain metal-packaging components" and its importance in helping foods to retain nutrition, quality, and consumer acceptability.[237] She stated that listing would compromise the availability of safe, affordable and nutritious foods.[238] Dr. Hoyle testified as to the "*potential health hazards*" that may arise from listing BPA as a Proposition 65 reproductive toxicant and from requiring warning labels.[239] He said that BPA is "critical" to maintaining the sterility of canned food and eliminates the problem of swelled cans.[240] Dr. Hoyle further stated that there would be public health consequences to deselecting epoxy coatings on metal cans, that they protect against botulism, and that they affect the most needy in our society.[241] He explained that the WIC Program (Special Supplemental Nutrition Program for Women, Infants, and Children)[242] and food pantries both rely on these epoxies, and that if products are required to be labeled, production will cease due to liability concerns.[243] He talked about how metal-packaged products are important when there are disasters and also for the military.[244]

Dr. Hoyle further stated that the alternatives are untested, and that "there is no readily available, suitable, fully tested material that you can drop in as an alternative." [245] Alluding to Dr. vom Saal's previous testimony referencing published research and multiple data sets showing a fifty percent drop in BPA exposure in Japan after changing the can lining away from BPA to polyethylene ter-

235. *Id.*
236. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 87, 139.
237. *Id.* at 88, 89.
238. *Id.* at 90.
239. *Id.* at 139–40 (emphasis added).
240. *Id.* at 141.
241. *Id.* at 142.
242. *About* WIC, USDA Food & Nutrition Serv., http://www.fns.usda.gov/wic/ (last visited Dec. 29, 2012).
243. *DART Meeting on Proposition 65* (July 15, 2009), *supra* note 53, at 142–44.
244. *Id.* at 144.
245. *Id.* at 146.

ephthalate,[246] Dr. Hoyle stated that even the "PET" that was used in Japan relies on epoxies and that PET is not a barrier to the epoxy migrating, so "the same amount of BPA go[es] through whether the PET is there or not."[247]

Particularly troubling about this part of the hearing on BPA was the lack of any supporting evidence or evaluations of these statements. There was no indication that any of these statements as to the necessity of can linings, the extent of any public health hazard, or the feasibility and effectiveness of switching to PET were based on any study, scientific review, or analysis. Presumably because this testimony was irrelevant to the question of whether BPA has been clearly shown to be a reproductive toxicant and thus outside the purview of the Committee, no studies appear to have been submitted on this issue. There was no staff review or analysis of these issues in the staff report or presentation. The information is suspiciously incomplete and seemingly inaccurate given that some companies have now made public statements that they are selling BPA-free cans.[248] Kathleen Roberts, a lobbyist for the North American Metal Packaging Alliance, which represents the makers of metal cans and their customers, acknowledged that "alternatives are available but not for all uses currently in the marketplace."[249]

One practical option would be to explicitly require OEHHA staff to evaluate and discuss all information presented to the Board, including any unverified claims of adverse consequences. However, staff review and discussion of the availability of alternatives may effectively elevate the importance of this discussion and suggest that it is legally relevant to the decision to list a chemical under Proposition 65. As discussed by Daniel Farber in his article *Rethinking the Role of Cost-Benefit Analysis*, "Importing legally irrelevant factors into a decision violates the basic precepts of modern administrative law,"[250] and it's unlikely that OEHHA could successfully interpret the Proposition 65 standard, "clearly shown to cause reproductive

246. *Id.* at 75.

247. *Id.* at 146.

248. *See, e.g.*, *Eden Foods Bisphenol-A (BPA) Free Pioneer*, EDEN ORGANIC, http://www.edenfoods.com/articles/view.php?articles_id=178 (last visited Jan. 3, 2013); Alice Wessendorf, *Desperately Seeking BPA-Free Canned Foods*, HEALTHIER TALK (Dec. 7, 2010, 8:00 AM), http://www.healthiertalk.com/desperately-seeking-bpa-free-canned-foods-2948 (listing seven companies which offer BPA-free canned foods).

249. Layton, *supra* note 234.

250. Daniel A. Farber, *Rethinking the Role of Cost-Benefit Analysis*, 76 U. CHI. L. REV. 1355, 1378 (2009) (book review); *see also* Citizens to Preserve Overton Park, Inc. v. Volpe, 401 U.S. 402, 416 (1971) (requiring the reviewing court to consider "whether the decision was based on a consideration of the relevant factors").

toxicity," to legally require considerations extraneous to the question of toxicity. In the context of the Clean Air Act, for example, in *Whitman v. American Trucking Associations*, the Supreme Court interpreted a standard similarly focused on toxicity to exclude cost considerations. The statutory standard in *Whitman* required that the National Ambient Air Quality Standards (NAAQS) be standards "'which in the judgment of the Administrator, based on [the] criteria . . . and allowing an adequate margin of safety, are requisite to protect the public health.'"[251] The Supreme Court found implausible industry's argument that the "terms 'adequate margin' and 'requisite' leave room to pad health effects with cost concerns."[252] The Court reasoned that the cost of implementation is "both so indirectly related to public health and so full of potential for canceling the conclusions drawn from direct health effects" that it would have to have been mentioned in the statute if Congress had wanted it to be taken into consideration.[253]

Responding to a delegation challenge, the Supreme Court in *Whitman* explained that it has upheld agency implementation of other equally indeterminate standards[254] and that it has never demanded a "determinate criterion" for saying "how much [of the regulated harm] is too much."[255] The practical reality, however, is that if there are no determinate criteria, the decision will still be made with reference to some sort of context, and the cost to industry is unlikely to be ignored. According to credible observers, in actually setting the standards at issue in *Whitman*, "the EPA had in fact considered costs, although tacitly and without public supervision."[256] In his concurring opinion, Justice Breyer acknowledged and condoned at least some consideration of context. It was his opinion that the words "'requisite to protect the public health' with 'an adequate margin of safety' . . . do not describe a world that is

251. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 466 (2001) (alteration in original) (quoting 42 U.S.C. § 7409(b)(1) (2006)).

252. *Id.* at 468.

253. *Id.* at 469 (emphasis omitted).

254. *Id.* at 473–74 (including "necessary to avoid an imminent hazard to public safety" and "set the standard which most adequately assures, to the extent feasible, on the basis of the best available evidence, that no employee will suffer any impairment of health" (internal quotation marks omitted)).

255. *Id.* at 475 (alteration in original) (internal quotation marks omitted). "The constitutional question is whether the statute has delegated legislative power to the agency." *Id.* at 472. The Court of Appeals had reasoned that the EPA "'lack[ed] any determinate criteria for drawing lines. It had failed to state intelligibly how much is too much.'" *Whitman*, 531 U.S. at 472 (alteration in original) (quoting Am. Trucking Ass'ns v. EPA, 175 F.3d 1027, 1034 (D.C. Cir. 1999)).

256. Cass R. Sunstein, *Regulating Risks After* ATA, 2001 SUP. CT. REV. 1, 11.

free of all risk—an impossible and undesirable objective."[257] He explained that the EPA can consider background circumstances when deciding "'what risks are acceptable in the world in which we live.'"[258] He felt that the statute permitted consideration of "comparative health risks," such as health risks that may stem from reducing "tropospheric ozone (which, it is claimed, helps prevent cataracts and skin cancer)."[259] Perhaps quietly acknowledging the reality that cost considerations must have some place in the process, the majority opinion recognized that cost could be taken into consideration at a later point in the administrative process, that is, when regulators determine how to implement ambient air quality standards.[260]

In the case of Proposition 65, however, there is no point later in the process for consideration of consequences. Granted the statute requires only a warning, not a restriction or a ban, still Proposition 65 has been known to have a significant effect on the market and related costs are unlikely to be entirely ignored by decision makers. In this context, it is particularly important that rules create reasonably clear standards. Although it may be impossible to keep extraneous considerations completely outside consideration (especially when faced with an ongoing public relations campaign), clear guidelines and mandatory written findings of fact would create a more transparent process and help focus the Committee's attention on factors relevant to the scientific questions concerning the sufficiency of the evidence on toxicity.

Another option to keep inflated claims of adverse consequences outside consideration would be to adopt an amendment to Proposition 65 that would explicitly allow for staff evaluation of all information before the Board, including information extraneous to the question of toxicity. However, any such law would have to be carefully written so as not to override Proposition 65's ultimate ob-

257. Whitman v. Am. Trucking Ass'ns, 531 U.S. 457, 494 (2001).

258. *Id.* at 495 (Breyer, J., concurring) (quoting Natural Res. Def. Council, Inc. v. EPA, 824 F.2d 1146, 1165 (D.C. Cir. 1987).

259. *Id.* at 495 (Breyer, J., concurring).

260. *See id.* at 466–67 (discussing CAA statutory provisions specifically allowing for waiver of compliance deadlines and consideration of economic costs in setting standards of performance for new sources, setting compliance deadlines for emissions standards for automobiles, fuel additives, and aircraft emission standards, and in performing various other duties); *see also id.* at 493 (Breyer, J., concurring) (explaining that "[s]tates may consider economic costs when they select the particular control devices used to meet the standards" and that "industries experiencing difficulty in reducing their emissions can seek an exemption or variance from the state implementation plan").

jective to enable the purchaser to make an informed decision as to whether there are better alternatives and allow the market to respond accordingly. The focus should remain on the question of toxicity.

## CONCLUSION

In the DART hearing on BPA, the outcome might well be expected given the lack of any special expertise on the part of the board, very complex material, a very short review period, no clear understanding of "reproductive toxicity," inadequately disclosed conflicts of interest, and a dearth of regulatory guidance that left the door open to an interpretation that would require conclusive evidence. Given the prevalence of advocacy science, there was, of course, a body of conflicting evidence.

For Proposition 65 to fully meet its regulatory objectives and truly allow for public disclosure of endocrine-disrupting chemicals, OEHHA needs to adopt clear regulatory standards with requirements for findings of fact that increase transparency and accountability. Standards must be adopted that will separate as clearly as possible the science from the policy decisions. Without better standards, an appointed Committee is left to quietly substitute its policy judgments for those of the public. What is needed is an honest and public admission of what is science, and what is policy, so that the public may take corrective action as may be necessary to further public policy objectives.

In contrast to the decision from the FDA's Science Board on BPA, there was no attempt by the DART Identification Committee to separate the scientific decisions from the policy decisions. Despite a standard that calls for "reasonable certainty in the minds of competent scientists,"[261] the FDA's Science Board on BPA recognized that the decision was really one of mixed science and policy and that they alone were not the arbitrators of the regulatory decision.[262] Standards as to acceptable margins of safety were clearly guiding the process. [263] However, given the regulatory malaise that

261. Food Additives Amendment of 1958, Pub. L. No. 85-929, 72 Stat. 1784; S. REP. NO. 85-2422, at 2–3 (1958), *reprinted in* 1958 U.S.C.C.A.N. 5300, 5301–02 (describing the relevant standard as one of "reasonable certainty in the minds of competent scientists that the additive is not harmful to man or animal").

262. *See* FDA SCIENCE BOARD SUBCOMMITTEE ON BISPHENOL A, *supra* note 18, at 4.

263. *Id.* ("[T]he Margins of Safety defined by [the] FDA as 'adequate' are, in fact, inadequate. This does not mean that the potential exposures are not '*acceptable*'.")

followed, standards are still needed to guide the policy decisions themselves.

OEHHA has publicly taken the position that the ultimate question under Proposition 65 is purely a question of "science,"[264] yet in its refusal to assist the Committee by proposing any conclusions as to the sufficiency of the evidence, the OEHHA staff appear to quietly recognize themselves that there is considerable room for judgment that may fall outside the realm of science: "OEHHA staff avoid making specific arguments for or against the listing of any given chemical since this decision is entirely within the purview of the expert committees."[265] Yet a full time staff with over a year of study on the issue[266] would seem to be in a better position than a part-time committee with no particularly specialized expertise and a very short review period to make at least draft recommendations on the science.

The problems with clarity and transparency identified in this article are not unique to Proposition 65 but reflect a larger problem in regulatory decisionmaking involving scientific assessments. In its ongoing review of the EPA's *Draft IRIS Assessment of Formaldehyde,* a committee of the National Research Council identified problems "similar to those which have been reported over the last decade by other NRC committees," including "problems with clarity and transparency of the methods," the role of guidelines in the "preparation of the assessment," lack of consistency with no clear "underlying conceptual framework," and inadequate "documentation of methods and criteria for identifying evidence . . . [and] critically evaluating . . . studies."[267]

With minor regulatory reform, ideally through a publicly accessible and transparent rulemaking process involving the scientific

264. *See* Letter from Joan Denton, *supra* note 117, at 2–3 ("This standard is not a legal determination; it is instead a scientific judgment in which the state's qualified experts are expected to apply their own knowledge and expertise to determine if a chemical has been 'clearly shown by scientifically valid testing according to generally accepted principals to cause reproductive toxicity.'").

265. *Id.* at 2.

266. CAL. ENVTL. PROT. AGENCY, *supra* note 25, at 8 ("OEHHA had selected BPA through its prioritization process as a candidate for consideration by the DART IC, and substantial staff work on preparation of hazard identification materials had already occurred, before the NTP-CERHR Monograph was published [in September 2008].").

267. REVIEW OF THE ENVIRONMENTAL PROTECTION AGENCY'S DRAFT IRIS ASSESSMENT OF FORMALDEHYDE, Comm. to Review EPA's Draft IRIS Assessment of Formaldehyde, Bd. on Envtl. Studies and Toxicology, Div. on Earth & Life Studies, Nat'l Research Council 4 (2011), *available at* http://www.nap.edu/catalog.php?record_id=13142.

community, Proposition 65 could effectively provide for public disclosure and allow for a precautionary approach to endocrine-disrupting chemicals. OEHHA should adopt rules to define "reproductive toxicity" broadly and consistently with the evolving science recognizing the breadth of action of endocrine-disrupting chemicals. The rules should be broad enough to include all serious adverse health effects relating to the functioning of the endocrine system, including all effects that cause people pain, cost society money, and lead to serious health problems, like precancerous conditions and obesity. The proposed reform is particularly important today following the dissolution of the NTP-CERHR and the increased importance of the DART Identification Committee review as a listing mechanism. OEHHA recognition of a broad definition of "reproductive toxicity" may also align the practice and goals of the DART Identification Committee with the National Toxicology Program's new Office of Health Assessment and Translation, and encourage future designation of the latter as an authoritative body.

OEHHA should also adopt rules to define "clearly shown" that include standards to assess and weigh advocacy science. Such standards should consider the basics of appropriate research design and general acceptance of the work within the scientific community. There should also be clear and detailed standards to require disclosure of all conflicts of interest, related both to the studies relied upon, and to the testimony at hearings to consider the listing of chemicals under Proposition 65.

Clear standards coupled with required findings of fact would help focus the Committee on appropriate issues in the face of any exaggerated claims of adverse consequences due to the alleged unavailability of alternatives. Rules recognizing and sorting the policy questions from the science questions and requiring the DART Identification Committee to issue findings of fact may encourage the staff to provide more comprehensive assistance, ideally including proposed findings of fact, without fear of overstepping into the role of policy-making.

Ideally there should be a transparent discussion of existing alternatives including a serious evaluation of any exaggerated claims of adverse consequences. However, it would be difficult to institutionalize this discussion, especially under the current legal and regulatory regime. The question of alternatives may ultimately be best addressed pursuant to California's Green Chemistry Initiative. In 2008, California Senate Bill 509 established a Toxics Information

Clearinghouse,[268] and California Assembly Bill 1879 required California's Department of Toxic Substances to adopt regulations that would establish a process to identify and prioritize chemicals of concern, identify alternatives, and consider requirements for labeling restrictions or prohibitions.[269] However, this effort too has fallen subject to criticism for failing to identify sufficient legal standards. Commenting on the informal draft rule, Joseph Guth of the University of California, Berkeley Center for Green Chemistry requested that the agency articulate a transparent standard as to how the conflict between the "interests in environmental health and economic factors are 'best' balanced": "Without an articulated standard, there is no hope of . . . decisions being transparent, consistent or accountable to the public."[270] The final regulatory structure of California's Green Chemistry initiative remains to be seen.[271]

Meanwhile Americans may receive some protection from the transnational reach of the European Union's toxic substance law: Registration, Evaluation, and Authorization of Chemicals (REACH).[272] For authorization to use chemicals of "very high concern," REACH requires applications to include an "analysis of alternatives, considering their risks and the technical and economic feasibility of substitution."[273]

268. S.B. No. 509, 2007–2008 Sess. (Cal. 2008) (codified at CAL HEALTH & SAFETY CODE §§ 25251, 25256–25257.1 (West Supp. 2012)).

269. *See* Assemb. B. No. 1879, 2007–2008 Sess. (Cal. 2008) (codified at CAL. HEALTH & SAFETY CODE §§ 25252–25255, 25257 (West Supp. 2012)).

270. Letter from Joseph H. Guth, Ph.D., J.D., Member, Green Ribbon Sci. Panel, Sci. & Envtl. Health Network, Univ. of Cal., Berkeley Ctr. for Green Chemistry, to Debbie Raphael, Dir., Cal. Dep't of Toxic Substances Control 2 (Dec. 31, 2011), *available at* http://www.dtsc.ca.gov/LawsRegsPolicies/Regs/upload/SCPInformalComments201201Web1.pdf (no. (IC)19 of Cal. Dep't of Toxic Substances Control compilation of comments on the informal draft rule).

271. Assembly Bill 1879 required that regulations be adopted by January 1, 2011; however, the Safer Consumer Products regulations are yet to be finalized. Assemb. B. No. 1879; *see Safer Consumer Products Regulations*, CAL. DEP'T OF TOXIC SUBSTANCES CONTROL, http://www.dtsc.ca.gov/SCPRegulations.cfm (last visited Jan. 3, 2013) (indicating several different notice and comment periods for the regulations, including one ending January 22, 2013); Safer Consumer Products Proposed Regulations, R-2011-02 (proposed July 2012) (to be codified at CAL. CODE REGS. tit. 22, §§ 69501–69599), *available at* http://www.dtsc.ca.gov/upload/SCPProposedRegulationsNoUnderlineJuly2012.pdf.

272. *See* Noah M. Sachs, *Jumping the Pond: Transnational Law and the Future of Chemical Regulation*, 62 VAND. L. REV. 1815, 1819, 1822 (2009).

273. Regulation (EC) 1907/2006 of the European Parliament and of the Council of 18 December 2006 Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency, Amending Directive 1999/45/EC and Repealing Council Regulation

Finally, at least in so far as its work involves the review of endocrine-disrupting chemicals, OEHHA should adopt rules that require the DART Identification Committee, or a subcommittee, to have a high level of expertise in the area of endocrinology and that allow for a longer review period as necessary to consider the complexity of the science, the number of studies under review, and any time demands that may be involved in identifying and dealing appropriately with advocacy science.

The issue of adequate expertise of boards and scientific peer review panels to address endocrine-disrupting chemicals has been recognized at the national level. In 2011, a bill was introduced in the House of Representatives that would establish an Endocrine Disruption Expert Panel to guide federal regulatory decisions regarding endocrine-disrupting chemicals in the context of several existing federal health and environmental statutory programs.[274] Members of the panel would have "established expertise in the field of endocrine disruption research by publishing research in peer-reviewed literature and have received Federal endocrine-research-related funding within the 2 years preceding appointment."[275] California should consider a similar standard for the DART Identification Committee. The federal bill also recognizes the "need to educate the public on the results of research on endocrine-disrupting chemicals so that manufacturers, processors, retailers, and individual consumers can make informed decisions about potential exposures to harmful chemicals."[276] The bill declares that "[p]eople should be protected from chemicals that are found to have endocrine-disrupting effects."[277]

With a little reform to the regulatory framework, Proposition 65 could live up to the expectations of the California voters and create an opportunity for people to protect themselves from endocrine-disrupting chemicals. To fully inform the public, require-

(EEC) 793/93 and Commission Regulation (EC) 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, 2006 O.J. (L396) 1, 25 (EC), *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uriOJ:L:2006:396:0001:0849:EN:PDF.

274. *See* Endocrine-Disrupting Chemicals Exposure Elimination Act of 2011, H.R. 2521, 112th Cong. §§ 4(2), 101(a)(2) (2011).

275. *Id.* § 101(b)(1)(A).

276. *Id.* § 3(6). The bill would also establish a research program and a hazard classification system for endocrine-disrupting chemicals. *See id.* § 101(a)(1), (2). It would require federal agencies to develop strategies for reducing exposure, and require exposure pathways to be mitigated where the expert panel has identified a chemical as being of a high level of concern. *See id.* §§ 101(a)(4), 201(a), (c)(1).

277. *Id.* § 3(7).

ments for warning labels must also be reformed to specifically identify the chemical and the source of potential exposure.