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The Broken Science Behind Proposition 65

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California's Safe Drinking Water and Toxic Enforcement Act of 1986, known by its more popular name as Proposition 65, is in need of a critical overhaul after 30 years of capricious enforcement. The law, according to the Office of Environmental Health Hazard Assessment (OEHHA), has a singular goal — to "protect[] the state's drinking water sources from being contaminated with chemicals known to cause cancer, birth defects or other reproductive harm, and requires businesses to inform Californians about exposures to such chemicals."[1] And while this mission may seem noble, the application of this poorly drafted initiative is nothing less than a categorical failure.

The law has done virtually nothing to advance protection of California's water supplies — which are closely guarded by the Federal Safe Drinking Water Act, and the state's enforcement of that act under its primacy agreement with the U.S. Environmental Protection Agency. We simply do not need Proposition 65 to ensure our drinking water is clean — the U.S. Congress enacted laws over a decade before the initiative was presented to the voters to address our water supply.

Further, enforcement of the warning provisions of Proposition 65 has created a cottage industry for indolent plaintiffs attorneys, and has provided virtually no benefit to consumers who have been so over-cautioned they simply ignore the warnings. When was the last time you refused to visit your local market or pump gas at a filling station — all of which carry Proposition 65 warnings?

When explaining the purpose of Proposition 65, the OEHHA notes its dual purpose: "(1) Proposition 65 requires business to provide warnings to Californians about significant exposures to chemicals that cause cancer, birth defects or other reproductive harm ... (2) Proposition 65 also prohibits California businesses from knowingly discharging significant amounts of listed chemicals into sources of drinking water."[2]

The efficacy of Proposition 65, then, rises and falls with the legitimacy of the listing process of those chemicals to which the law applies. The bloated nature of that list — which stands at over 900 chemicals now[3] — suggests a broken system that refuses to discriminate those chemicals that will actually cause harm from those that are inert.

Proposition 65 allows the state bureaucracy to exercise its own scientific discretion to list substances, but the methodology applied is inadequate and leads to inaccurate results, creating a legacy of flouting federal agencies' advice and making findings contrary to solid scientific research. It's time for California

to take a hard look at the scientific method (colloquially speaking) that it applies to implementing this law before the list further balloons with chemicals which have no place on the list.

There are four ways in which a chemical can find itself on the Proposition 65 list,[4] the one at issue here is the so-called "State's Qualified Experts," constituting two committees — the Carcinogen Identification Committee (CIC) and the Developmental and Reproductive Toxicant Identification Committee (DARTIC).[5] These committees have the power to "find that a chemical has been clearly shown to cause cancer or birth defects or other reproductive harm."[6]

Sadly, their discretion to do so is utterly unchecked, as they need not defer to findings that a chemical is, in fact, safe, frequently ignoring good studies, and the conclusions of other scientific bodies that have exhaustively reviewed the chemical's safety profile.[7] This unbounded discretion makes the committees' failure to commit to a thorough, legitimate scientific analysis of these substances indefensible. The current system requires change.

As noted previously, the state committees may disregard the research and conclusions of other entities that led to determinations that a given chemical was safe. One recent controversy that arose as a direct result of this wide latitude involved the state's decision to list Bisphenol A (BPA) under Proposition 65. BPA is used to make a certain kind of plastic, one often found in consumer productions, including food packaging.[8]

BPA use in food packaging dates back to the 1960s.[9] The U.S. Food and Drug Administration, in contrast to the state's BPA listing decision, affirms that "based on its most recent safety assessment ... BPA is safe at the current levels occurring in foods. Based on the FDA's ongoing safety review of scientific evidence, the available information continues to support the safety of BPA for the currently approved uses in food containers and packaging."[10] The European Union's food safety agency has found similarly.[11]

Similarly, a member of the Polycarbonate/BPA Global Group of the American Chemistry Council "strongly disagree[d]" with the BPA listing and argued that it was in direct contradiction to the science "presented to the committee" and the FDA's input.[12] In fact, the FDA's acting chief scientist also provided the committee with information contrary to its ultimate decision to list BPA.[13]

If the committees are so willing to make findings that fly in the face of contrary information, there is either something wrong, or the latitude of discretion must be significantly cut back. Either way, a discerning look at their processes for evaluating the science must be had. It's disturbing from any angle. The OEHHA website summarizes the committee diligence as follows: "The committees base their decisions on the most current scientific information available. OEHHA staff scientists compile all relevant scientific evidence on various chemicals for the committees to review. The committees also consider comments from the public before making their decisions."[14]

But when this succinctly stated process is examined, this description is inaccurate and the methods inadequate. For example, one of the state committees determined that five chemicals were to be considered for the Proposition 65 list, including benzo(a)pyrene and uranium.[15] The committee's decision was supported by a literature review that had been limited to only the titles and/or abstracts of certain studies.[16] The same critique of the process found that OEHHA relied on "dated" information.[17] In the case of Hexafluroacetone, the OEHHA's review consisted of studies that had been put out over an astonishing time frame from 1979 through 1991.[18]

Proposition 65's science can be just as surface-level as the committees' diligence, leading to questionable conclusions about risk. According to the OEHHA, "[b]y law, a warning must be given for listed chemicals unless exposure is low enough to pose no significant risk of cancer or is significantly below levels observed to cause birth defects or other reproductive harm."[19] The agency goes on to define "no significant risk level" relevant to listings related to cancer as "the level of exposure that would result in not more than one excess case of cancer in 100,000 individuals exposed to the chemical over a 70-year lifetime."[20]

Yet, it has been pointed out that the law does not adequately distinguish between containing a chemical and the actual exposure to that chemical.[21] In fact, the law has been likened to "the epitome of the precautionary principle"[22] and disregards a bedrock principle of toxicology — the dose makes the poison. In fact, the latter failing can lead to results that would be comical, if they weren't so unnecessarily costly to businesses and California taxpayers.

In an oft-cited example, Proposition 65 requires labeling for French fries due to the acrylamide listing. But to reach dangerous levels, one would have to eat 182 pounds of French fries each day for life — a laughable impossibility. While such examples can be humorous, they are serious enough to have caused the FDA to write to the California attorney general criticizing Proposition 65's disregard for the amount of the substance required to reach danger levels.[23] That letter was sent in 2005,[24] however, and quite clearly had no effect.

And with all these ways of getting it wrong —— both procedurally and substantively — at least the chemicals can be delisted. But how? It's certainly not easy — procedurally or substantively. In fact, a review of the OEHHA website provides a quick indication that listing is the priority here, not cleaning up mistakes in those listings. The very first "Quick Link" offered on the page is to "Adding Chemicals to the Prop. 65 List."[25] It's not until one reaches the very bottom of that page that there is some information about delisting.[26] Delisting is apparently so difficult that, not surprisingly, toxicological and epidemiological experts must be hired to even get consideration for delisting.

Proposition 65 simply cannot fulfill its stated mission if the science behind it is broken. And it certainly cannot be fixed by the arduous delisting procedure, targeting those chemicals that should never have been placed on the list in the first place. The law must be fundamentally reformed so that only proper substances make it onto the list in the future. The concept is simple — decisions to list chemicals must be based on sound science. But how does California get there?

Potential changes would not be difficult. In fact, perhaps the most effective change would scale back on the bureaucracy behind the law. Aside from the state's committees, there are three other ways in which chemicals become listed:

- Those "identified by reference in Labor Code Section 6382(b)(1) or (d)" are incorporated (Section 6382(b)(1) "incorporates chemicals identified by the World Health Organization's International Agency for Research on Cancer (IARC) as causing cancer in humans or laboratory animals");

- Those identified by "authoritative bodies" as qualifying (the authoritative bodies include the U.S. EPA, IARC, U.S. FDA, the National Toxicology Program of the U.S. Department of Health and Human Services, and the National Institute for Occupational Safety and Health); and

- Those required by the state or federal government (the majority of these are prescription drugs required to be listed by the FDA).[27]

The state committees' work stands in stark contrast to these other three means for chemicals being listed. The state committees must not be allowed to ignore contrary scientific evidence and conclusions from other authoritative entities, particularly when the state committees' diligence in making their own decisions is so cursory. The easiest solution is to rely on the entities (or laws) that are committed to these scientific determinations, many of them listed above as "authoritative bodies" and use their conclusions to make listing decisions.

Should the committee system stay in place, they must commit to real risk assessment for chemical carcinogenicity, conducted by independent groups of qualified scientists, or learn and adopt the methods used by the entities listed above. It makes little sense for the state to trust the assessments of these other entities for three of the four avenues for listing, but to allow the state committees to ignore those same entities' findings that a substance is safe.

California should leave the science to those who conduct the proper diligence to make sound conclusions or mandate that its own committees adopt the methodologies of those authoritative bodies. And all of the good science and findings of other scientific bodies such as the Academy of Science must be incorporated into such decision making. Proposition 65 will continue to be ineffective and its conclusions inaccurate until its procedures are fixed, allowing for credible scientific conclusions to support it as it heads into another decade of enforcement.

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This article is part of a monthly column by Gibson Dunn & Crutcher discussing issues related to environmental law. To read previous articles, click here.

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[2] Office of Environmental Health Hazard Assessment, About Proposition 65, OEHHA, http://oehha.ca.gov/proposition-65/about-proposition-65 (last visited Aug. 5, 2016).

[3] Id.

[4] Office of Environmental Health Hazard Assessment, How Chemicals Are Added to the Proposition 65 List, OEHHA, http://oehha.ca.gov/proposition-65/how-chemicals-are-added-proposition-65-list (last

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[5] Office of Environmental Health Hazard Assessment, State's Qualified Experts – Proposition 65 Committees, OEHHA, http://oehha.ca.gov/proposition-65/states-qualified-experts-proposition-65-committees (last visited Aug. 5, 2016).

[6] Office of Environmental Health Hazard Assessment, supra note 4.

[7] See Joseph Perrone, Sc.D, Removing Uncertainty: Proposed Standards-Based Reforms to California's Proposition 65 (Ctr. for Accountability in Sci., February 2015) 6, https://www.accountablescience.com/wp-content/uploads/2015/02/Prop65_Report.pdf.

[8] U.S. Food and Drug Administration, Bisphenol A (BPA): Use in Food Contact Application, U.S. Food and Drug Administration, http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm064437.htm (last visited Aug. 5, 2016).

[9] Id.

[10] Id.

[11] Steven G. Hentges, Ph.D., Decision to List BPA On Proposition 65 Contradicts Extensive Scientific Record, American Chemistry Council (May 7, 2015), http://www.prnewswire.com/news-releases/decision-to-list-bpa-on-proposition-65-contradicts-extensive-scientific-record-300080083.html.

[12] Id. (internal quotation omitted).

[13] Id.

[14] Office of Environmental Health Hazard Assessment, supra note 5.

[15] Perrone, supra note 7, at 3.

[16] Id.

[17] Id.

[18] Id.

[19] Office of Environmental Health Hazard Assessment, Proposition 65 in Plain Language, OEHHA, http://oehha.ca.gov/proposition-65/general-info/proposition-65-plain-language (last visited Aug. 5, 2016).

[20] Id.

[21] See Rebecca Trager, California's Prop 65 Controversy, chemistryworld (June 16, 2016), http://www.rsc.org/chemistryworld/2016/06/california-prop-65-controversy-harmful-chemicals.

[22] Gil Ross, California's Prop 65: Bad for Public Acceptance of Science, About to Get Worse, American Council on Science and Health (Feb. 5, 2016), http://acsh.org/news/2016/02/05/calis-prop-65-bad-

enough-already-now-to-get-worse/.

[23] The Ctr. for Consumer Freedom, The Dose Makes the Poison, The Center for Consumer Freedom (May 15, 2006), https://www.consumerfreedom.com/articles/176-the-dose-makes-the-poison/.

[24] Id.

[25] See Office of Environmental Health Hazard Assessment, supra note 2.

[26] See Office of Environmental Health Hazard Assessment, supra note 4.

[27] Id.
