

**Robert Reinhard  
68 Yukon Street  
San Francisco, CA 94114  
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**Via email and Hardcopy**

Carol J. Monahan-Cummings, Esq.  
Chief Counsel  
Office of Environmental Health Hazard Assessment (OEHHA)  
1001 I Street  
Sacramento, CA 95812  
e-mail: [cmcumings@oehha.ca.gov](mailto:cmcumings@oehha.ca.gov)

RE: Request for Public Participation, Notice of Public Workshop, Proposition 65  
Regulatory Update Project - Labor Code Mechanism Regulatory Concept ("Labor  
Code Concept")<sup>1</sup>

Dear Ms. Monahan-Cummings:

**I Introduction and Request**

Please accept these comments regarding OEHHA's Labor Code Concept for adding chemicals to the Proposition 65 list of substances known to the state to cause cancer or reproductive toxicity under Health and Safety Code § 25249.8. My interest follows on from previous occasions representing patient advocate organizations in the Agency's requests for information about individual prescription pharmaceuticals and also how those compounds are evaluated under the Agency's Prioritization Procedure.<sup>2</sup>

Important public health principles were articulated in those earlier administrative actions:

- OEHHA and the related Departments of Public Health and Health Care Services (DPH)<sup>3</sup> agencies must fulfill their mission jointly to promote and protect health when significant life saving pharmaceuticals are evaluated.
- The current Proposition 65 listing procedure does not give the public any signal of life saving benefits of drugs that can appear on the list of carcinogens or reproductive toxins. It does not display the different weight of evidence classes applied to pharmaceutical compounds that make the list as do the authoritative organizations – such as IARC or NTP - that OEHHA has consulted. As far as

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<sup>1</sup> <http://www.oehha.ca.gov/prop65/law/workshop051608.html>

<sup>2</sup> OEHHA (2004) PROCESS FOR PRIORITIZING CHEMICALS FOR CONSIDERATION UNDER PROPOSITION 65 BY THE "STATE'S QUALIFIED EXPERTS"  
[http://www.oehha.ca.gov/prop65/CRNR\\_notices/state\\_listing/pdf/finalPriordoc.pdf](http://www.oehha.ca.gov/prop65/CRNR_notices/state_listing/pdf/finalPriordoc.pdf)

<sup>3</sup> <http://www.dhs.ca.gov/>

the Proposition 65 list is concerned, benzene, an industrial chemical known to cause leukemia based on epidemiological data in humans, is just as “bad” as an essential cancer fighter or a drug to treat a fatal infection listed on the basis of less certain animal data or that demonstrate a lower level of evidence in humans. All are deemed equally “known to the state to cause cancer or reproductive toxicity.”

- Patients with serious or life threatening treatable illness must not be deterred or scared off in the first instance by OEHHA’s own public characterizations and its one-risk-only listings from seeking physician directed advice and warnings where true risks and benefits of the life saving drugs indicated for those conditions are explained in a medical setting.
- Treatment success for serious illness depends on timely consultation to avoid late diagnosis or disease progression. Medicines may be ineffective if fearful patients delay seeking care because of lack of balanced description or the public circulation of disreputable myths about drug risks. Don’t add to those fears or cause harm by giving the wrong risk-only signal, the previous record said. OEHHA should err on the side of public health driven caution to direct patients towards early and best professional care warnings consistent with authorized clinical practice.<sup>4</sup>

As discussed further below, the Labor Code Concept of listing for pharmaceuticals would thwart these principles. It would do so without regard to health benefit. The concept would use an automatic procedure that denies the public and the State’s experts other existing mechanisms available to qualify listings, examine the weight/sufficiency of evidence in light of new information or determine that criteria are not met before identifying the drug as hazardous. It would prevent carefully considering the adverse health consequences of such a choice to list or ways to mitigate them. The traditional means that Proposition 65 uses to mitigate consequences – determining safe levels of exposure – is strictly off limits for drugs since their efficacy depends on adherence to scientifically determined dosing regimens at critical levels which cannot be undercut. The listing of drugs treating serious illness, if it occurs at all, ought not take place casually, automatically or without the input of the public, state scientific and Department of Public Health expertise, else it risks derailing sensitive medical decisions.

These comments show the concept would be contrary to the plain language of Proposition 65, directions from the State’s qualified experts, and relevant case law. Drugs are categorically exempt to a large degree from the scope of the Labor Code and are not “identified by reference,” as that term is used in Health and Safety Code §

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<sup>4</sup> Harm occurs not from the presence or absence of warnings on a drug product. Physician directed care and FDA labeling inform those patients about risks who finally do make it to a doctor’s office. A Proposition 65 compliant warning will always accompany an Rx labeled product prior to exposure or the warning requirement is preempted. (Vaccine Cases. *William F. Bothwell v. Abbott Labs.* (2005, Cal App 2nd Dist) 134 Cal App 4th 438, 36 Cal Rptr 3d 80; *Dowhal v. SmithKline Beecham Consumer Healthcare* (2004, Cal) 32 Cal 4th 910, 12 Cal Rptr 3d 262, 88 P 3d 1.) Harm occurs when OEHHA itself places life saving chemicals on its list of all equally bad chemicals “known to the state to cause cancer or reproductive toxicity” without the careful professional explanation of risks and life saving benefits. That administrative act adds to the risks of scaring the public away from learning about their proper medical use.

25249.8(a). An automatic listing would not be sufficiently sensitive to the requirement the State's experts and OEHHA have taken to heart that, before they can be added, any IARC or NTP listed chemical must be clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity as further explained in 27 C.C.R. § 25306. All relevant data should be accommodated. Previous decisions also demonstrate that chemicals considered by the American Conference of Industrial Hygienists (ACGIH) are not "identified by reference."

OEHHA's hands are not tied with regard to the application of Health and Safety Code §25249.8(a) to drugs. Drugs may continue to be addressed as they have been under *other* Proposition 65 rules and priorities.<sup>5</sup> Adoption of the recommendations in these comments would not interfere with continued and responsible application of Proposition 65 to drugs or to list them by other means if justified.

For these reasons, I request that OEHHA withdraw the Labor Code Concept, retain the status quo whereby OEHHA implements the statute without the need for regulations, and exercise authority to address drugs *only* as directed by the State's experts, 27 C.C.R. § 25306 and the Prioritization Procedure, not by automatic Labor Code listings. This request is designed to avert potential unintended, automatic additions of chemicals – especially pharmaceuticals – to the Proposition 65 chemical list. If OEHHA nevertheless proceeds with the Labor Code Concept generally, please provide an opportunity to meet and craft responsible ways to exclude pharmaceuticals from listing by this means while acting in ways that are consistent with public health to address drugs.

If drugs are listed by any mechanism under Health and Safety Code §25249.8, I also repeat my earlier requests in other OEHHA actions, that the list be annotated. Please consider revising the list format so that drugs are cordoned off in a separate portion of the list to provide responsible risk/benefit information consistent with sound principles of care.

I believe I have the same goal as OEHHA's by its activation of the listing process – to effectuate prompt responsible warnings. I also want patients to receive clear and reasonable warnings swiftly – i.e. those which are supported by good medical science and to appreciate benefits of treatment - to make medical decisions. The best way to make that happen is to implement the statute so that patients go *towards* the qualified professional setting where they will receive them, not be scared *away from* taking drugs that could save a life.

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<sup>5</sup> OEHHA has compiled a summary of the pharmaceuticals listed as "known to cause cancer" and the mechanisms under which they were considered. <http://www.oehha.ca.gov/prop65/pdf/drugs1.pdf> Pharmaceuticals make up >10% of the Proposition 65 list. That is an inordinate and unbalanced number considering that the voters were never informed that these life saving compounds were to be regulated as "extremely toxic" pollution causing chemicals (chemicals that cause cancer not cure it) or that pharmaceuticals already had a highly developed system in place to warn prior to exposure.

## **II Drugs Are Not Like Other Chemicals Subject to Proposition 65. Why OEHHA Should Refrain From Any Approach That Might Adversely Affect Public Health.**

### **A. Unlike Other Chemicals, Risks and Benefits of Drugs Are Deliberately Known From Direct Testing in Humans.**

A critical element in the extension of Proposition 65's list to chemicals tested only in animals was the default caution that extrapolation of results to humans was a public health imperative to know and regulate those chemicals which cause cancer or reproductive toxicity. Such tests are conducted for the purpose of evaluating the safety of chemicals in commercial distribution for which there may be multiple uses and alternatives. This principle was cited by the court in *AFL-CIO v. Deukmejian*.<sup>6</sup> Reviewing the critical guidelines, the court noted that Proposition 65 applies to chemicals tested in animals because:

It is unethical to test humans...epidemiological studies do not adequately warn humans and protect them from the risk of exposure to new carcinogens. For recognized human carcinogens, the first evidence of carcinogenicity frequently is found in test animals...

But this basis for the court's decision does not apply to life saving pharmaceuticals. Drugs are deliberately tested directly in humans and with their full informed consent under good clinical practices by means of injection, oral dosing, or other routes to determine the careful balance of safety risks and benefits before they can be legally marketed to the public and sold only through prescription.<sup>7</sup> The end result of that process is to allow marketing of drugs only with a data driven, clinical trial derived, label or package insert that displays a detailed summary of warnings, benefits, and test results. These warnings are also conveyed by the physician prescribing them.

Unlike household consumer products, there are most often no alternative efficacious choices to drugs for serious life threatening illness. That is why risks even of potential cancers or other adverse effects are deemed tolerable in the circumstances if benefits are sufficiently potent to outweigh them and when patients make it to the professional health care setting where they can be alerted to risks. All drugs carry some risk.

### **B. With Drugs, The Agency Itself Must Take Care to Do No Harm**

The ballot argument to accompany the Proposition 65 initiative declared that its overall scheme and purpose was to correct a gap perceived by the proponents in existing toxics laws as they affected obligations of businesses identified as "polluters." It stated:

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<sup>6</sup> 212 Cal.App 3d 425, at 438 ("Duke")

<sup>7</sup> 21 C.F.R. Part 312.

Polluters ...expose us to extremely toxic chemicals without our knowing it. The health of innocent people is jeopardized.<sup>8</sup>

Thus, any implementation of the statute either by ministerial, discretionary or other means must take care not to act in any way to jeopardize health.

If the Labor Code Concept were to apply to life saving drugs and list them, it would have virtually no regulatory effect on the businesses towards whom listings are ordinarily directed and their duty to warn “innocent people.” However, it would put OEHHA in the position of acting in manner to jeopardize health, especially if a drug is listed precipitously without additional review. As applied to businesses:

- 27 C.C.R. § 25601(b)(2) would maintain the compliance status of all FDA labeling or physician warnings or the warnings would be preempted;<sup>9</sup> or
- Warnings for occupational exposures to pharmaceuticals would either be preempted or achieved by compliance with OSHA requirements.

Warnings to patients are more than adequately accomplished under federal rules or a Proposition 65 warning is preempted. It remains to be asked what effect the agency’s risk-(and no benefit)-only listing may have in conveying hazard information divorced from the clear, reasonable and more complete discussion found in package inserts or from a qualified physician.

The Proposition 65 list “labeling” of chemicals precedes the warnings that businesses could offer and can be used by jurisdictions outside of California for their own “authoritative bodies” purposes. California’s decisions have an international reputation and have consequences for patients outside its own borders.

Substances touted as “safer” healing products compared to “harsh” FDA approved drugs that “cause cancer” to treat serious illness can be and have been promoted as cure-alls that dissuade patients from seeking qualified medical advice and prescription. Patients don’t see the authorized warnings because they don’t go for the correct treatment. In this case, no exposure to the listed drug jeopardizes health. Reacting to just such a scam, on June 17, 2008, FDA acted against 23 companies purveying false inducements to give up on “painful chemotherapies” and “conventional treatments” for cancer or AIDS. The result was:

FDA officials said the statements made about these products are dangerous because they could prevent a patient from seeking proper treatment for cancer.

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<sup>8</sup> Voter Pamphlet, November 1986, p. 54.

<sup>9</sup> In previous actions to acquire information for Proposition 65 listings such as for statins or for other drugs, OEHHA received official notice from FDA it opposed such listings and that federal law preempted Proposition 65 warning for drugs. Any action to achieve a different result would make the drug misbranded. See also Fn 4.

They could also harm a cancer patient by interacting with other drugs the patient is taking.

“FDA is very concerned that consumers will purchase these products on the Internet and use them instead of products that have been proven safe and effective,” said Michael Levy, director of labeling the agency's new drug division.

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Unless medical information about drugs, is complete and truthfully communicated by government authorities, the medical system and marketers, scammers will add to their arsenals to exploit the difference. At a minimum, patients who consult OEHHA’s list independently, would not be alerted to sufficient information. Of course OEHHA cannot prevent information abuses by others, but – like IARC and NTP in their monographs, public and patient information materials – it is responsible for telling the whole picture so that its words are true, correct and meaningful.<sup>11</sup> That would not be the case if an automatic listing occurred without opportunity for qualification, weighing of all the evidence or other measures.

### **III The Plain Language of Proposition 65, Its Implementation and the Labor Code Do Not Support Addition of Pharmaceuticals Automatically.**

#### **A. Listing Requirements of Proposition 65**

OEHHA bases its Labor Code Concept on a strict but incomplete reading of applicable Health and Safety Code provisions that state:

25249.8. (a) On or before March 1, 1987, the Governor shall cause to be published a list of those chemicals known to the state to cause cancer or reproductive toxicity within the meaning of this chapter, and he shall cause such list to be revised and republished in light of additional knowledge at least once per year thereafter. Such list shall include at a minimum those substances identified by reference in Labor Code Section 6382(b)(1) and those substances identified additionally by reference in Labor Code Section 6382(d).

(b) A chemical is known to the state to cause cancer or reproductive toxicity within the meaning of this chapter if in the opinion of the state's qualified experts it has been clearly shown through scientifically valid testing according to generally accepted principles to cause cancer or reproductive toxicity, or if a body considered to be authoritative by such experts has formally identified it as causing cancer or reproductive toxicity, or if an agency of the state or federal government

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<sup>10</sup> FDA cracks down on 'cancer cures' <http://www.cnn.com/2008/HEALTH/06/17/cancer.fraud.ap> and <http://www.fda.gov/bbs/topics/NEWS/2008/NEW01852.html>. Another potent example of scaring seriously ill patients away from allegedly harmful proven therapies in favor of quack cures is described at <http://fumento.com/duesberg.html>

<sup>11</sup> See, e.g. NTP’s clarifications for tamoxifen - <http://www.niehs.nih.gov/news/releases/news-archive/2000/9thROC.cfm>

has formally required it to be labeled or identified as causing cancer or reproductive toxicity. ...

(d) The Governor shall identify and consult with the state's qualified experts as necessary to carry out his duties under this section.

OEHHA apparently asserts that subsection (a) is an independent free standing requirement, unrelated to subsections (b) and (d). The Agency also believes that the term "shall" – applied to the Governor's listing responsibilities to add chemicals – leaves no room to keep substances "identified by reference" off the list or to prefer other means described in subsection (b): listing by experts, authoritative bodies or labeling. In the past, OEHHA has also stated that it may use any of the four methods at its disposal to list a chemical, even if one of the methods would not result in its listing. I disagree.

OEHHA's application of a mandatory independent ministerial duty under subsection (a) ignores the equally mandatory duty that under subsection (d) it "shall" consult with the state's experts for *all* listing duties. The duties include the experts' views of the ways in which any chemicals identified by reference – i.e. chemicals listed by IARC, NTP or OSHA ( not ACGIH)<sup>12</sup> – should be processed when they come to OEHHA's attention for Proposition 65 purposes. OEHHA's Labor Code Concept would nullify and give no effect to subsection (d).

In fact, the state's experts have weighed in explicitly on the ways *all* IARC and NTP chemicals should be addressed – derived under the Labor Code or otherwise - and also on pharmaceuticals as a category. When IARC and NTP were designated by the state's experts as authoritative bodies, the experts were clear to recognize that the full procedures of 27 C.C.R. §25306 would act as a check on the uncontrolled – automatic – listing of chemicals those two organizations identify. The statement of reasons for the regulation recorded:

**The Panel has serious concerns that the listing of chemicals as the result of such a [authoritative bodies] designation should be controlled....**

**If the Panel has discretion in designating authoritative bodies, it may condition its designation. One of the Panel's primary concerns is that the designation of authoritative bodies will result in the uncontrolled listing of chemicals. Therefore, to satisfy its own concerns, it makes sense for the Panel to condition its designation upon the application of suitable controls. This section simply affirms that this solution is available. ... Thus, chemicals will be listed only in a controlled manner. ...At its meeting on April 14, 1989, the Panel made a provisional decision to designate the EPA as an "authoritative body" for purposes of the Act. One commentor objected that this was inaccurate; that the Panel had identified EPA on a provisional basis on certain terms and conditions. The commentor recommended that the regulation be amended to add the phrase "on the express condition that all the procedures and**

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<sup>12</sup> Section IV. of these comments discusses why ACGIH chemicals are not identified by reference in the cited sections of the Labor Code.

**safeguards set forth in this section 12306 be given full force and effect."** (C-13, p. 10.) ...

On October 20, 1989, **the Panel ... designated IARC and NTP** as authoritative bodies, **subject to the controls in section 12306,.... Accordingly, subsection (j) states that the Panel has identified... IARC and NTP as authoritative bodies "for purposes of this section." This subsection is intended to provide an easy reference to designated authoritative bodies, yet be consistent with the conditions established under the regulation.**<sup>13</sup>

Thus, Health and Safety Code § 25249.8(d) has been given real meaning by the state experts' advice on the organizations "identified by reference." That advice could not be more clear – in order for IARC or NTP substances to be added to the list by *any* subsection of §25249.8, all the controls and procedures laid out in the authoritative bodies regulation must be available. OEHHA agreed completely: this "*makes sense.*" OEHHA would be acting contrary to sense, contrary to the express meaning of Health and Safety Code §25249.8(d), if it automatically listed the IARC and NTP chemicals without the "procedures and safeguards" and controls of the authoritative bodies requirements.

The state's experts – and OEHHA in response to the experts' concerns – have also weighed in on how listing mechanisms should be applied to pharmaceuticals in particular. Taking the example of tamoxifen, Panel members stated:

The question comes up what priority should prescription drugs have compared to environmental chemicals. We clearly faced this dilemma with Tamoxifen. **Our committee spent a lot of energy and time evaluating this drug which is prescribed by physicians, which by definition makes access to the chemical by the California Population under a qualified experts control. This seems overkill and against the spirit of Prop. 65.** I would like to propose that we give chemicals for consideration a lower priority for evaluation if they are prescription drugs. With the large number of environmental chemicals still to be evaluated, I think we could do more public health good to concentrate our efforts on chemicals for which the public needs to be warned of their potential carcinogenicity.<sup>14</sup>

OEHHA agreed with this assessment in its Prioritization Procedure policy, developed at the request of its experts, and also with the effect of preemption on listing by stating:

This prioritization process will not generally be applied to chemicals contained only in prescription or over-the-counter medications with mandatory cancer or reproductive toxicity warnings approved by the federal Food and Drug Administration, based on the California Supreme Court decision in *Paul Dowhal*

<sup>13</sup> Emphasis added; FSOR pp. 26-28 [http://www.oehha.ca.gov/prop65/law/pdf\\_zip/12306FSRFeb1990.pdf](http://www.oehha.ca.gov/prop65/law/pdf_zip/12306FSRFeb1990.pdf)

<sup>14</sup> Letter to Dr. Val Siebel, July 22, 1999. <http://www.oehha.org/prop65/pdf/LJF799.pdf>

*v Smith-Kline Beecham Consumer Healthcare et al.* (2004) 12 Cal. Rptr. 3d 262; 4 Cal. Daily Op. Serv. 3259, 2004 Daily Journal D.A.R. 4601.<sup>15</sup>

Pharmaceuticals would not be excluded from Proposition 65 altogether under these directions justified by Health and Safety Code § 25249.8(d) to gloss the use of subsections (a) and (b). But when drugs are evaluated, the state’s experts and OEHHA both agree that they are a low priority for *all* listing purposes, including for any chemicals “identified by reference” in the Labor Code.

**B. Pharmaceuticals Are Excluded For the Most Part from the Labor Code and Are not “Identified by Reference” for Purposes of Proposition 65.**

Even if OEHHA maintains that Health and Safety Code §25249.8(a) is not affected by other subsections, priorities or common “sense,” pharmaceuticals as a class are not “identified by reference” in the operative sections of Labor Code §6382(b)(1) or (d). Labor Code § 6385 states:

The provisions of this chapter [including §6382] do not apply to hazardous substances contained in... Products intended for personal consumption by employees in the workplace, or consumer products packaged for distribution to, and use by, the general public.

Pharmaceuticals are a unique type of personal “consumption” product. Household products may contain chemicals that are used industrially or in the home. However, the active therapeutic compound, although occasionally mixed with excipients or other inert materials, is most often the chemical OEHHA seeks to list under Proposition 65. Personal consumption is the *only* intended use of these chemicals. There are no industrial or nonprescription uses for the cancer fighting drugs on OEHHA’s list or for pure medical compounds IARC and NTP may evaluate.<sup>16</sup> Such chemicals could not be “identified by reference” in Labor Code § 6382 when patients use them because the reference does not apply in the first instance. If a pharmaceutical compound – such as tamoxifen – can be listed under Proposition 65 by virtue of an IARC or NTP listing it must *and can still* occur solely through mechanisms identified in Health and Safety Code §25248.8(b), not by a provision which excludes it from scope entirely. Excluding these substances from automatic listing still preserves other means for them to be evaluated under Proposition 65.

The state law exclusion under Labor Code §6385 is broader than additional exclusions which pertain under the federal rules. With regard to chemicals identified by Labor Code §62382(d) – the hazard communication standard (HCS) – federal OSHA provides a

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<sup>15</sup> [http://www.oehha.ca.gov/prop65/CRNR\\_notices/state\\_listing/pdf/finalPriordoc.pdf](http://www.oehha.ca.gov/prop65/CRNR_notices/state_listing/pdf/finalPriordoc.pdf)

<sup>16</sup> To the extent few, if any, incidental and accidental occupational exposures to health care providers could theoretically occur when drugs are administered, warnings are preempted under Proposition 65. It would not “make sense” to invoke the elaborate machinery of automatic listings for chemicals for which no new warnings are crafted and where the only common use is personal use that the Labor Code excludes.

regulatory exclusion for solid form Rx and for OTC drug compounds. It states the HCS - including any hazard identification requirements or references - does not apply to:

Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace<sup>17</sup>

The federal exclusion operates as an additional limitation to define or exclude substances capable of being identified by this reference in the Labor Code.

#### **IV Chemicals Evaluated by ACGIH Are Not “Identified by Reference” Under Health and Safety Code §25249.8(a)**

OEHHA announced its current view that not only its reading of the literal language of the statute but also applicable case law requires it to conclude that chemicals ACGIH evaluates are “identified by reference in the Labor Code” under Proposition 65. To the extent pharmaceuticals are affected by any such use of ACGIH (either carcinogens or reproductive toxicants), I disagree with that assessment. ACGIH chemicals are not “identified by reference” in the Labor Code as chemicals known to the state to cause cancer or reproductive toxicity.

##### **A. The HCS Does Not Make ACGIH An Identified Reference**

OEHHA believes that since the Labor Code references the HCS and because the HCS mentions ACGIH - just as it does IARC and NTP and OSHA listed carcinogens - that ACGIH must be meant as “identified” also. This is a misreading of the HCS. ACGIH is not mentioned in the same part of the HCS rule or for the same result as IARC and NTP

ACGIH is certainly not a source to identify carcinogens (even if OEHHA’s possible regulatory concept language refers currently only to reproductive toxicity in connection with ACGIH. ) The HCS language is specific. Lists of the only chemicals that must be considered carcinogens are described in the section of the HCS called appendix A "mandatory" health hazard definitions. It states:

"Carcinogen:" A chemical is considered to be a carcinogen if:

- (a) It has been evaluated by the International Agency for Research on Cancer (IARC), and found to be a carcinogen or potential carcinogen; or
- (b) It is listed as a carcinogen or potential carcinogen in the Annual Report on Carcinogens published by the National Toxicology Program (NTP) (latest edition); or,
- (c) It is regulated by OSHA as a carcinogen"

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<sup>17</sup> 29 C.F.R. § 1910.1200(b)(6)(vii).

Use and reference of ACGIH occurs in another section of the HCS and not to the same effect. The HCS says:

The chemical manufacturer, importer or employer evaluating chemicals shall treat the following sources as establishing that the chemicals listed in them are hazardous [the particular hazard is not specified]...

Threshold Limit Values for Chemical Substances and Physical Agents in the Work Environment," American Conference of Governmental Industrial Hygienists (ACGIH) (latest edition). *The chemical manufacturer, importer, or employer is still responsible for evaluating the hazards associated with the chemicals in these source lists in accordance with the requirements of this standard.*<sup>18</sup>

Unlike targeted IARC, NTP and OSHA listed carcinogens, employers are not required by a mandatory direction to identify something as a carcinogen *or* as a reproductive toxin solely by virtue of it being listed by ACGIH - even if ACGIH classifies it as a carcinogen or reproductive toxicant. Section 1910.1200(d)(3)(ii) – ACGIH - is not another incorporated list, it is a direction that employers must use OTHER lists or other criteria in appendix A in a mandatory way when identifying carcinogens or reproductive toxicants that ACGIH also considers. It is those other lists that are referenced. None of them cite ACGIH for endpoints applicable to Proposition 65.

The HCS also states:

Chemical manufacturers, importers and employers evaluating chemicals shall *treat the following sources as establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purposes:*

National Toxicology Program (NTP), "Annual Report on Carcinogens" (latest edition);

International Agency for Research on Cancer (IARC) "Monographs" (latest editions); or

29 CFR part 1910, subpart Z, Toxic and Hazardous Substances, Occupational Safety and Health Administration.<sup>19</sup>

Clearly OSHA does not consider ACGIH as an identified source “establishing that a chemical is a carcinogen or potential carcinogen for hazard communication purpose” automatically. ACGIH chemicals must be assessed under the other means HCS provides to evaluate hazards.

Errors are likely to result if ACGIH is used as a source to automatically list reproductive toxicants as the possible regulatory language suggests. OEHHA and the public would not know if the underlying toxicological studies ACGIH panels use to identify a chemical relied solely on prenatal exposures to a chemical, the only exposure applicable to this

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<sup>18</sup> Emphasis added; 29 C.F.R. §1910.1200(d)(3)

<sup>19</sup> 29 C.F.R. §1910.1200(d)(4).

Proposition 65 endpoint. These distinctions are the kind that can only be determined through the mechanisms available under Health and Safety Code §25249.8(b)

**B. Case Law (And Applicable Legislative History) Does Not Support Using ACGIH as an Identified Reference.**

OEHHA and now, contrary to earlier views, some environmental groups, apparently conclude that the Duke case requires them to use ACGIH as a source for chemicals identified by reference. That conclusion is not supportable. Both in the lower superior court ruling and in briefs on appeal, all parties confirmed – and the court’s ruling confirms – that ACGIH chemicals were not recognized as those “identified by reference” for mandatory inclusion in an initial or later list. The original complaint filed by plaintiffs in the lower court specified the chemicals – carcinogens or reproductive toxins - and their source that proponents meant by the term “identified by reference.” The complaint attached a specific list of chemicals that had to be so listed. ACGIH chemicals are not part of that list.<sup>20</sup>

Papers filed in the appeal unequivocally show that no reproductive toxins that could be derived from ACGIH are within the scope of chemicals “identified by reference.” The lower court and appeals court allowed only chemicals specifically named as reproductive toxins by OSHA to be within that scope. Respondent/plaintiffs in their appeal brief stated:

Appellant makes much of the trial court's exclusion of 10 of the 12 reproductive toxins respondents had sought to have placed on the March 1st list. **Judge Warren ruled that these reproductive toxins were not required under Labor Code (6382(d) because, unlike, the two reproductive toxins that were required[to be listed] these were not mentioned by name in the HCS..This point is irrelevant, however, since the Court's ruling on these reproductive toxins was not appealed by respondents.**<sup>21</sup>

All parties agreed that only substances mentioned by name – not those generally described by the HCS casual use of ACGIH or any others plaintiffs had described in their original complaint - are “identified.”

The exclusion of ACGIH by proponents at this crucial point of Proposition 65’s defining legislative history and initial lawsuits is significant considering their high motivation to maximize the content of the list. The Voter Pamphlet also makes this clear. Voters only know that IARC and NTP chemicals were included because they are defined by the “most highly regarded...scientists.” It would have been simple for proponents to include ACGIH scientists in that group, especially since ACGIH was a part of the OSHA adopted HCS since 1983 before the Initiative came to the voters. Proponents did not do so either in the pamphlet or in the contemporary public materials or official documents to the Health and Welfare Agency distributed when Proposition 65 was enacted. They took

<sup>20</sup> A copy of the Superior Court’s ruling and list of chemicals which plaintiffs identified are attached.

<sup>21</sup> Emphasis added; Resp. Br. At 12, fn 15 – A copy of relevant pages in the brief is attached.

pains to spot other “highly regarded scientists” without adding ACGIH to that company. ACGIH was not meant by the drafters of the Proposition to be identified by reference in the Labor Code. Voters did not understand it to be.

**C. State Expert Opinion that Must Be Considered Does Not Support Using ACGIH Chemicals as “Identified by Reference.”**

On April 6, 1990, the state’s experts formally considered and denied naming ACGIH as an authoritative body.<sup>22</sup> Pursuant to Health and Safety Code §25249.8(d), those opinions must apply to and affect any determination of the references meant to be within the scope of the Labor Code. ACGIH is not to be included.

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**V Conclusion.**

Previous OEHHA actions listing pharmaceuticals highlight problems articulated here. As a public health agency, it behooves OEHHA to act from an excess of caution to neutralize or inhibit the misuse that we know occurs and which disreputable individuals are eager to exploit. Please reconsider the application of the Labor Code Concept to these situations affecting critical decisions of personal and public health and consider annotating the current lists as requested.

I would like the agency to be aware that these comments are not submitted on behalf of any regulated or for profit entity such as a pharmaceutical manufacturer or healthcare provider. These comments represent the interests of those I have spoken for previously, the patient community and public interest that requires responsible communications, public health policies and science based decisions to encourage the highest standard of care and treatment. That standard includes all ways to encourage patients to seek advice promptly from qualified physicians and to withstand misinformation that constantly assails them through various media. Please stand with patients to educate them accurately as to real level of risk and real importance of benefit when negotiating complex illnesses.

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<sup>22</sup> Transcript of the Science Advisory Panel meeting, April 6, 1990, pp. 67-70.

I would be happy to meet with OEHHA to discuss these issues in particular. Thank you for the chance to participate in these workshops. I can be reached at tel: 415-570-1010 or by email at [rjreinhard@gmail.com](mailto:rjreinhard@gmail.com)

Sincerely,

A handwritten signature in cursive script that reads "Robert Reinhard".

Robert Reinhard

Attachments

Cc:

Dr. Joan Denton

Dr. Lauren Zeise